### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM S-1

**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: Eric D. Kline, Esq. David I. Meyers, Esq. **Troutman Pepper Hamilton Sanders LLP** 1001 Haxall Point, 15<sup>th</sup> Floor Richmond, Virginia 23219 Telephone: (804) 697-1200

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

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 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.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) 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.  $\Box$ 

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  $\Box$ Non-accelerated filer ⊠

Accelerated filer  $\Box$ Smaller reporting company ⊠ Emerging growth company  $\boxtimes$ 

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.

#### CALCULATION OF REGISTRATION FEE

		Proposed	Proposed	
		Maximum	Maximum	
	Amount to be	Offering Price Per	Aggregate	Amount of
Title of each Class of Securities to be Registered	Registered (1)	Share	Offering Price	<b>Registration Fee</b>

Common stock, par value \$0.0001 per share	6,125,000(2)	\$ 4.43(3)	\$ 27,133,750	\$ 2,961(4)
Common stock, par value \$0.0001 per share	18,401,290(5)	\$ 11.50(6)	\$ 211,614,835	\$ 23,088(4)
Common stock, par value \$0.0001 per share	1,106,108(7)	\$ 10.01(6)	\$ 11,072,142	\$ 1,208(4)
Common stock, par value \$0.0001 per share	1,000,000(8)	\$ 6.28(6)	\$ 6,280,000	\$ 686(4)
Common stock, par value \$0.0001 per share	500,000(9)	10.00(6)	\$ 5,000,000	\$ 546(4)
Total			\$ 261,100,727	\$ 28,489

- (1) This registration statement also covers an indeterminate number of additional shares of common stock, par value \$0.0001 per share (the "common stock"), of Ensysce Biosciences, Inc. (the "Company") that may be offered or issued to prevent dilution resulting from share splits, share dividends or similar transactions in accordance with Rule 416 under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Represents (i) 125,000 shares of common stock issuable in satisfaction of \$2,000,000 in deferred underwriting fees payable to the underwriters of the initial public offering (the "LACQ IPO") of our predecessor company, Leisure Acquisition Corp., a Delaware Corporation ("LACQ"); (ii) 500,000 shares of common stock issuable to DelMorgan Group LLC ("DelMorgan") under the terms of the Email Agreement, dated January 31, 2021, among the Company and DelMorgan, as amended by the First Amendment to the Email Agreement, dated June 7, 2021 (the "Email Agreement"); (iii) up to 250,000 shares of common stock issuable to David J. Kovacs under the terms of a letter agreement dated July 22, 2021; (iv) up to 250,000 shares of common stock issuable to Mercury FundingCo, LLC (David Tanzer, Managing Member) (together with David J. Kovacs, the "Consultants") under the terms of a letter agreement dated July 22, 2021; and (v) 5,000,000 shares of common stock purchased by Hydra Management, LLC ("Hydra"), Matthews Lane Capital Partners LLC ("MLCP" and together with Hydra, the "Sponsors") and HG Vora Capital Management LLC on behalf of one or more funds or accounts managed by it (the "Strategic Investor"), in a private placement prior to the LACQ IPO and for which all 5,000,000 shares are subject to a lock-up arrangement further described under the Section entitled "Plan of Distribution" beginning on page 129 of the prospectus.
- (3) Pursuant to Rule 457(c) under the Securities Act, and solely for the purpose of calculating the registration fee, the proposed maximum offering price per share is \$4.43, which is the average of the high and low prices of shares of the Company's common stock on The Nasdaq Capital Market ("*Nasdaq*") on August 4, 2021 (such date being within five business days of the date that this registration statement was filed with the U.S. Securities and Exchange Commission (the "SEC")).
- (4) Calculated by multiplying the proposed maximum aggregate offering price of securities to be registered by .0001091.
- (5) Represents (i) approximately 10,000,000 shares of common stock that may be issued upon the exercise of approximately 10,000,000 warrants (the "Public Warrants") originally sold as part of the units in the LACQ IPO; (ii) 6,325,000 shares of common stock that may be issued upon the exercise of 6,325,000 warrants (the "Private Placement Warrants") sold in a private placement that closed simultaneously with the consummation of the LACQ IPO; (iii) 1,000,001 shares of common stock that are issuable upon the exercise of 1,000,001 warrants issued in exchange for outstanding loans under the Expense Advancement Agreement dated December 1, 2017 among LACQ, the Sponsors, and the Strategic Investor (the "Expense Advancement Agreement"); (iv) up to 566,288 shares of common stock that are issuable upon exercise of 566,288 warrants issued in exchange for previously outstanding loans under the Expense Advancement Agreement dated December 5, 2019 between LACQ and Gateway Holdings Limited, as amended (the "GTWY Expense Advancement Agreement") (collectively with the warrants described in (iii) herein, the "other private warrants"); and (v) up to 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants issued at the closing of the business combination between LACQ and the Company in exchange for outstanding loans under the Expense Advancement Agreement.
- (6) Calculated pursuant to Rule 457(g) under the Securities Act, based on the exercise price of the warrants.
- (7) Represents 1,106,108 shares of common stock that may be issued upon the exercise of 1,106,108 warrants (the "GEM Warrants") issued to GEM Yield Bahamas Limited ("GYBL") under the terms of the Share Purchase Agreement between us, GEM Global Yield LLC SCS ("GEM Global") and GYBL, dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the "GEM Agreement")
- (8) Represents (i) 500,000 shares of common stock that may be issued upon the exercise of 500,000 warrants issued to David J. Kovacs under the terms of a letter agreement dated July 22, 2021; and (ii) 500,000 shares of common stock that may be issued upon the exercise of 500,000 warrants issued to Mercury FundingCo, LLC (David Tanzer, Managing Member) under the terms of a letter agreement dated July 22, 2021.
- (9) Represents 500,000 shares of common stock that may be issued upon the exercise of 500,000 warrants issued to DelMorgan under the terms of the Email Agreement.

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 or until the registration statement shall become effective on such date as the SEC, 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 August 6, 2021.

PRELIMINARY PROSPECTUS



#### **ENSYSCE BIOSCIENCES, INC.**

Up to 6,125,000 Shares of Common Stock Up to 21,007,398 Shares of Common Stock Underlying 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 27,132,398 shares of our common stock, par value \$0.0001 per share ("common stock"), which consists of (i) up to 500,000 shares of common stock that are issuable upon the exercise of 500,000 warrants issued to DelMorgan Group LLC ("DelMorgan") under the terms of the Email Agreement, dated January 31, 2021, among Ensysce Biosciences, Inc. (the "Company") and DelMorgan, as amended by the First Amendment to the Email Agreement, dated June 7, 2021 (the "Email Agreement"), (ii) up to an aggregate of approximately 10,000,000 shares of common stock that are issuable upon the exercise of 10,000,000 warrants (the "Public Warrants") issued in connection with the initial public offering of our predecessor company, Leisure Acquisition Corp., a Delaware corporation ("LACQ"), (the "LACQ IPO"), (iii) up to an aggregate of 6,325,000 warrants issued in connection with a private placement that closed simultaneously with the consummation of the LACQ IPO (the "Private Placement Warrants"), (iv) up to an aggregate of 1,000,001 shares of common stock that are issuable upon the exercise of 1,000,001 shares of common stock that are issuable upon the exercise of 1,000,001 shares of common stock that are issuable upon the exercise of 6,325,000 warrants issued in connection with a private placement that closed simultaneously with the consummation of the LACQ IPO (the "Private Placement Warrants"), (iv) up to an aggregate of 1,000,001 shares of common stock that are issuable upon the exercise of 1,000,001 warrants issued in exchange for outstanding loans under the Expense Advancement Agreement dated December 1, 2017 among LACQ, Hydra Management, LLC ("Hydra"), Matthews Lane Capital Partners LLC ("MLCP" and together with Hydra, the "Sponsors"), and HG Vora Capital Management LLC on behalf of one or more funds or accounts managed by it (the "Strategic Investor") (the

Limited, as amended (the "*GTWY Expense Advancement Agreement*") (collectively with the warrants described in (iv) herein, the "*other private warrants*"), (vi) up to an aggregate of 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants issued at the closing of the business combination (as defined below) in exchange for outstanding loans under the Expense Advancement Agreement, (vii) up to 1,106,108 shares of common stock that are issuable upon exercise of 1,106,108 warrants issued at the closing of the business combination (as defined below) in connection with the GEM Agreement (as defined below) (the "*GEM Warrants*"), (viii) 125,000 shares of common stock issuable in satisfaction of \$2,000,000 of deferred underwriting fees payable to the underwriters, (ix) 500,000 shares of common stock issuable to DelMorgan under the terms of the Email Agreement, (x) 5,000,000 shares of common stock issuable to David J. Kovacs and Mercury FundingCo, LLC (David Tanzer, Managing Member) (together, the "*Consultants*"), and (xii) up to 1,000,000 shares of common stock that are issuable upon the exercise of 1,000,000 warrants issued to the Consultants.

On June 30, 2021, we consummated the transactions contemplated by that certain Agreement and Plan of Merger, dated as of January 31, 2021 (the *Merger Agreement*"), by and among the Company, LACQ and EB Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of LACQ ("*Merger Sub*"), with the Company surviving such merger as a wholly-owned subsidiary of LACQ (the "*Merger*"). The Merger, together with the other transactions contemplated by the Merger Agreement and the related agreements, are referred to herein as the "*Transactions*." In connection with the consummation of the Transactions, LACQ changed its name to "Ensysce Biosciences, Inc."

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 hereby registered. The Selling Securityholders may offer, sell, or distribute all or a portion of the securities hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any of the proceeds from such sales of our common stock or warrants by the Selling Securityholders pursuant to this prospectus, except with respect to amounts received by us upon exercise of the Warrants to the extent such Warrants are 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. Most of the Selling Securityholders are subject to lock-up arrangements. See "*Plan of Distribution*" beginning on page 129 of this prospectus.

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

Our common stock is listed on the Nasdaq under the symbol "ENSC" and our Public Warrants are listed on the OTC Pink Open Market under the symbol "ENSCW." On August 4, 2021, the closing sale price of our common stock as reported on Nasdaq was \$4.09 and the closing sale price for our Public Warrants as reported on the OTC Pink Open Market was \$0.69.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and, as such, have elected to comply with certain reduced disclosure and regulatory requirements.

Our business and investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus and in the other documents that are incorporated by reference in 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.

The date of this prospectus is

, 2021.

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#### FREQUENTLY USED TERMS

"additional private warrants" are to (i) warrants issued to DelMorgan to purchase 500,000 shares of common stock under the terms of the Email Agreement as described under "Description of Capital Stock—Warrants—Private Warrants" and (ii) warrants issued to the Sponsors and the Strategic Investor to purchase 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants issued at the closing in exchange for outstanding loans under the Expense Advancement Agreement as described under "Description of Capital Stock—Warrants—Private Warrants;"

"Board" are to the board of directors of Ensysce, or a committee thereof, as applicable;

"business combination" are to the combination of Ensysce and LACQ into a single business;

"closing" are to the consummation of the Merger;

"closing date" are to the date on which the Transactions were consummated;

"Company" are to Ensysce Biosciences, Inc., a Delaware corporation (f/k/a Leisure Acquisition Corp), and its subsidiaries;

"Consultants" are to David J. Kovacs and David Tanzer, Managing Member of Mercury FundingCo, LLC;

"DGCL" are to the Delaware General Corporation Law, as amended;

"Email Agreement" are to the Email Agreement, dated January 31, 2021, among Ensysce and DelMorgan, as amended by the First Amendment to the Email Agreement, dated June 7, 2021;

"Ensysce" are to the Company;

"Exchange Act" are to the Securities Exchange Act of 1934, as amended;

"Expense Advancement Agreement" are to the Expense Advancement Agreement dated December 1, 2017 among LACQ, the Sponsors and the Strategic Investor, as amended;

"Former Ensysce" are to Ensysce Biosciences, Inc., a Delaware corporation, prior to the consummation of the merger with and into Merger Sub;

"founder shares" are to the 7,187,500 shares of Ensysce common stock initially purchased by LACQ's initial stockholders in a private placement prior to the LACQ IPO (of which a total of 2,187,500 were previously forfeited);

"GEM Warrants" are to 1,106,108 shares of common stock that may be issued upon the exercise of 1,106,108 warrants issued to GEM Yield Bahamas Limited (GYBL") under the terms of the Share Purchase Agreement between us, GEM Global Yield LLC SCS ("GEM Global") and GYBL, dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the "GEM Agreement");

"GTWY Expense Advancement Agreement" are to the Expense Advancement Agreement dated December 5, 2019 between LACQ and Gateway Holdings Limited, as amended;

"LACQ" are to Leisure Acquisition Corp, a Delaware corporation, our predecessor company which was renamed Ensysce Biosciences, Inc. after the business combination;

"common stock" are to Ensysce's common stock, par value \$0.0001 per share;

"DelMorgan" are to DelMorgan Group LLC;

"LACQ IPO" are to the initial public offering by LACQ, which closed on December 5, 2017;

"Merger" are to 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 Transactions;

"Merger Agreement" are to that certain 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 Transactions;

"Merger Sub" are to EB Merger Sub, Inc., a Delaware corporation, a wholly-owned subsidiary of LACQ prior to the consummation of the Merger;

"Net Tangible Assets" are to the net tangible assets (as determined in accordance with Rule 3a51-1(g)(1) of the Exchange Act) of Ensysce;

"other private warrants" are to the (i) warrants issued to the Sponsors and the Strategic Investor to purchase 1,000,001 shares of common stock in exchange for previously outstanding loans under the Expense Advancement Agreement and the warrants exchanged for such private warrants as described under "Description of Capital Stock— Warrants—Private Warrants," and (ii) warrants issued to Gateway Casinos & Entertainment Limited to purchase 566,288 shares of common stock issued in exchange for previously outstanding loans under the GTWY Expense Advancement Agreement and the warrants exchanged for such private warrants as described under "Description of Capital Stock— Capital Stock—Warrants—Private Warrants;"

"Other Stockholders" are to (i) the underwriter of the LACQ IPO, to which, pursuant to an agreement entered into on January 31, 2021, Ensysce is entitled, in certain circumstances, to pay a portion of the deferred underwriting commission in shares of common stock (at \$10.00 per share) instead of cash and which is assumed to be settled in common stock for purposes of this proxy statement/prospectus, and (ii) DelMorgan that previously had entered into an engagement letter with Ensysce and received 500,000 shares of common stock on closing in connection with the modification of a brokerage fee and release of certain claims by DelMorgan;

"Private Placement Warrants" are to the warrants issued by LACQ to the Sponsors and the Strategic Investor in a private placement simultaneously with the closing of the LACQ IPO and the warrants exchanged for the Private Placement Warrants as described under "Description of Capital Stock—Warrants—Private Placement Warrants,"

"Private Warrants" are to the Private Placement Warrants, the other private warrants and the additional private warrants;

"public shares" are to the 20,000,000 shares of common stock sold as part of the units in the LACQ IPO (whether they were purchased in the LACQ IPO or thereafter in the open market), of which 18,780,732 shares had been previously redeemed;

"*public stockholders*" are to the holders of LACQ's public shares, including LACQ's directors, officers and other initial stockholders and their respective affiliates (including Sponsors and Strategic Investor) to the extent they purchase public shares, provided that each of their status as a "public stockholder" shall only exist with respect to such public shares;

"Public Warrants" are to 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 10,000,000 shares of common stock at a purchase price of \$11.50 per share;

"SEC" are to the U.S. Securities and Exchange Commission;

"Selling Securityholders" are to the selling security holders named in this prospectus under the heading "Selling Securityholders;"

"Sponsors" are to (i) Hydra Management, LLC, a Delaware limited liability company and an affiliate of A. Lorne Weil, the Executive Chairman of LACQ until his resignation upon consummation of the Transactions and (ii) Matthews Lane Capital Partners LLC, a Delaware limited liability company and an affiliate of Daniel B. Silvers, the Chief Executive Officer of LACQ until his resignation upon the consummation of the Transactions;

"Strategic Investor" is to HG Vora Capital Management LLC on behalf of one or more funds or accounts managed by it;

"Transactions" are to the Merger, together with the other transactions contemplated by the Merger Agreement and the related agreements;

"units" are to the 20,000,000 units sold in the LACQ IPO on December 5, 2017, with each unit consisting of one public share and one-half (1/2) of one Public Warrant, each whole Public Warrant entitling the holder thereof to purchase one share of common stock for \$11.50 per share; and

"Warrants" are to the Public Warrants, Private Placement Warrants, the Private Warrants and the GEM Warrants.

II

#### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC using the "shelf" registration process. Under this shelf registration process, the Selling Securityholders may, from time to time, sell the securities offered by them described in this prospectus. We will not receive any proceeds from the sale by such Selling Securityholders of the securities offered by them described in this prospectus also relates to the issuance by us of the shares of common stock issuable upon the exercise of the Warrants. We will not receive any proceeds from the sale of shares of common stock underlying the Warrants pursuant to this prospectus, except with respect to amounts received by us upon the exercise of the Warrants for cash.

We may also file a prospectus supplement or post-effective amendment to the registration statement of which this prospectus forms a part that may contain material information relating to these offerings. The prospectus supplement or post-effective amendment may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement or post-effective amendment, as applicable. Before purchasing any securities, you should carefully read this prospectus, any post-effective amendment, and any applicable prospectus supplement, together with the additional information described under the heading "Where You Can Find More Information."

Neither we, nor the Selling Securityholders, have 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. We and the Selling Securityholders will not 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 of the date on its respective cover. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus contains, and any post-effective amendment or any prospectus supplement may contain, market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. In addition, the market and industry data and forecasts that may be included in this prospectus, any post-effective amendment or any prospectus contained. In addition, the market and industry data and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" contained in this prospectus, any post-effective amendment and the applicable prospectus supplement. Accordingly, investors should not place undue reliance on this information.

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 of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference 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  $\mathbb{R}$ ,  $\mathbb{M}$  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, LACQ, Former Ensysce and Merger Sub, consummated the closing of the transactions contemplated by the Merger Agreement, following the approval at a special meeting held on June 28, 2021. Pursuant to the terms of the Merger Agreement, a business combination of LACQ and Former Ensysce was effected through the merger of Merger Sub with and into Former Ensysce, with Former Ensysce surviving as a wholly owned subsidiary of LACQ. On the Closing Date, LACQ changed its name to Ensysce Biosciences, Inc.

Unless the context indicates otherwise, references in this prospectus to the "Company," "Ensysce," "we," "us," "our," and similar terms refer to Ensysce Biosciences, Inc. (f/k/a Leisure Acquisition Corp.) and its consolidated subsidiaries.

III

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This registration statement/prospectus includes statements that express Ensysce's 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 a

number of 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 Ensysce operates. Such forward-looking statements are based on available current market material and management's expectations, beliefs and forecasts concerning future events impacting Ensysce. Factors that may impact such forward-looking statements include:

- the risk that Ensysce's lead product candidate PF614 and PF614-MPAR<sup>™</sup> may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- reliance by Ensysce on third-party contract research organizations, or CROs, for its research and development activities and clinical trials;
- the need for substantial additional funding to complete the development and commercialization of Ensysce's product candidates;
- the risk that Ensysce's clinical trials may fail to replicate positive results from earlier preclinical studies or clinical trials conducted by Ensysce or third parties;
- the risk that the potential product candidates that Ensysce develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all;
- the risk that clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this registration statement/prospectus;
- the risk that Ensysce will be unable to successfully market or gain market acceptance of its product candidates;
- the risk that Ensysce's product candidates may not be beneficial to patients or successfully commercialized;
- the risk that Ensysce has 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 Ensysce depends for laboratory, clinical development, manufacturing, and other critical services will fail to perform satisfactorily;
- the risk that Ensysce's business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic;
- the risk that Ensysce 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 Ensysce's management team;
- changes in Ensysce's regulatory environment;
- Ensysce's need for additional financing to fund its operations and research and development;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in Ensysce's industry;
- Ensysce's ability to remediate any material weaknesses or maintain effective internal controls over financial reporting;
- the risk that our common stock will be suspended from trading on Nasdaq;

IV

- the ability to meet and maintain applicable listing standards of the Nasdaq;
- the ability to recognize the anticipated benefits of the Transactions, which may be affected by, among other things, the factors described above;
- potential litigation associated with the Transactions;
- · other factors disclosed in this registration statement/prospectus; and
- other factors beyond Ensysce's control.

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

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#### PROSPECTUS SUMMARY

The following summary highlights selected information included in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider or that may be important to you in making an investment decision. You should carefully read the entire prospectus before making an investment in our common stock. You should carefully read this entire prospectus, including the information under, "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements included elsewhere in this prospectus.

#### The Company

We are a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the fear of and the potential for addiction, opioid misuse, abuse and overdose. Prescription opioid abuse and addiction present major burdens to society, resulting in significant costs, illnesses and deaths, many of which we believe could be prevented through the use of our proprietary technologies. We believe the intertwined issues of (1) the widespread abuse of prescription opioids and (2) the resultant reluctance of many prescribers to write prescriptions for opioid analgesics, have resulted in the persistent under-treatment of patients with moderate-to-severe pain. Our platforms utilize a novel molecular delivery technology designed to deter prescription opioid abuse at the molecular level. We own numerous patents and applications in the United States and significant commercial markets, such as Europe, China and Japan, relating to our product candidates currently in development, as well as other product candidates that may be developed in the future.

Our current development pipeline includes two new drug platforms: (1) an abuse-resistant opioid prodrug technology – the Trypsin Activated Abuse Protection, or the TAAP platform; and (2) an over-dose protection opioid prodrug technology – the Multi-Pill Abuse Resistant, or the MPAR<sup>TM</sup> platform. The TAAP platform is designed to seek to improve the care of patients with chronic pain while reducing the human and economic costs associated with prescription opioid drug abuse. The MPAR<sup>TM</sup> platform when combined with our TAAP prodrugs is designed not only to seek to prevent abuse of prescription drugs but also to reduce overdose occurrences. Each prodrug is intended to be able to be combined with our MPAR<sup>TM</sup> technology for overdose protection.

While our principal focus and lead product candidates are geared towards combating abuse and overdose of opioid drugs, we have, over the years of research and development, discovered and recognized qualities and unique features of certain product candidates that may be useful in addressing other treatments. For example, we discovered the ability of nafamostat di-mesylate (*"nafamostat"*) in inhibiting the action of enzymes associated with the COVID-19 infection, and, as such, have devoted efforts to develop an oral and inhalation drug product of nafamostat, for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis.

#### **Corporate Information**

We were originally incorporated in the State of Delaware in April 2003 as PharmacoFore, Inc. and, in January 2012, we changed our name from PharmacoFore, Inc. to Signature Therapeutics Inc. ("Signature"). On December 28, 2015, Signature, Signature Acquisition Corp., a wholly-owned subsidiary of Signature (SAQ"), and Ensysce Biosciences, Inc. ("EB") entered into an Agreement and Plan of Merger ("EB-ST Agreement"). Pursuant to the EB-ST Agreement, SAQ merged with and into EB with EB surviving the merger as a wholly-owned subsidiary of Signature. As part of the transaction, Signature changed its name to "Ensysce Biosciences, Inc." ("Former Ensysce") and changed EB's name to EBI Operating Inc. On January 31, 2021, LACQ, Former Ensysce, and Merger Sub entered into the Merger Agreement. On June 30, 2021, pursuant to the Merger Agreement, Merger Sub merged with and into Former Ensysce, with Former Ensysce surviving the transaction as a wholly-owned subsidiary of LACQ. As part of the transaction, LACQ changed its name to "Ensysce Biosciences, Inc." and Former Ensysce changed its name to EBI OpCo, Inc.

The mailing address of our principal executive office is 7946 Ivanhoe Avenue, Suite 201, La Jolla, California. Our corporate telephone number is (858) 263-4196. Our website address is www.ensysce.com. Information contained on our website, or connected thereto, does not constitute part of, and is not incorporated by reference into, this prospectus or the registration statement of which it forms a part.

#### **Channels for Disclosure of Information**

Investors, the media, and others should note that we announce material information to the public through filings with the SEC, the investor relations page on our website, blog posts on our website, press releases, public conference calls, webcasts, and our twitter feed (@EnsysceBio).

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The information disclosed by the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels.

Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

#### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenues during our last completed fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable generally to public companies. These reduced reporting requirements include:

- an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal control over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding a supplement to the auditor's
  report providing additional information about the audit and the financial statements;
- reduced disclosure about our executive compensation arrangements; and
- an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or a stockholder approval of any golden parachute arrangements.

We have elected to take advantage of some, but not all, of the available benefits under the JOBS Act. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Further, pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

We will remain an emerging growth company until the earliest to occur of: (i) the end of the first fiscal year in which our annual gross revenues are \$1.07 billion or more; (ii) the end of the first fiscal year in which we are deemed to be a "large accelerated filer," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities; and (iv) December 31, 2025.

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#### **Issuance of Common Stock**

Shares of common stock issued by us

### 21,007,398 shares, consisting of:

Ensysce Biosciences, Inc.

- 10,000,000 shares of common stock to be issued upon the exercise of all the Public Warrants;
- 8,901,290 shares of common stock to be issued upon the exercise of all the Private Warrants (including the DelMorgan warrants);
- 1,106,108 shares of common stock to be issued upon the exercise of the GEM Warrants; and • 1,000,000 shares of common stock to be issued upon the exercise of the consultant warrants.

Shares of common stock outstanding prior to exercise of the24,275,541 shares (as of August 4, 2021) Public Warrants, Private Warrants, GEM Warrants, consultant warrants and share issuances

Exercise price of Public Warrants and Private Warrants	\$11.50 per share
Exercise price of GEM Warrants	\$10.01 per share
Exercise price of consultant warrants	\$6.28 per share
Exercise price of DelMorgan warrants	\$10.00 per share
Use of proceeds	We will receive up to an aggregate of approximately \$234.0 million from the exercise of the Warrants, assuming the exercise in full of all of the Warrants for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. See "Use of Proceeds."
Resale of Common Stock and Warrants	
Shares of common stock offered by the Selling Securityholders	<ul> <li>27,132,398 shares consisting of:</li> <li>10,000,000 shares of common stock to be issued upon the exercise of all the Public Warrants;</li> <li>8,901,290 shares of common stock to be issued upon the exercise of all the Private Warrants (including the DelMorgan warrants);</li> <li>1,106,108 shares of common stock to be issued upon the exercise of the GEM Warrant;</li> <li>5,000,000 founder shares;</li> <li>125,000 shares of common stock to be issued in satisfaction of \$2,000,000 of deferred underwriting fees payable under the agreement with the underwriters dated January 31, 2021;</li> <li>500,000 shares of common stock issuable to DelMorgan under the terms of the Email Agreement; and</li> <li>1,500,000 shares of common stock issuable to the Consultants under the terms of the letter agreements dated July 22, 2021.</li> </ul>
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Terms of the offering	The Selling Securityholders will determine when and how they will dispose of the shares of common stock registered under this prospectus for resale.
Use of proceeds	We will not receive any proceeds from the sale of shares of common stock by the Selling Securityholders.
Risk factors	See " <i>Risk Factors</i> " and other information included in this prospectus for a discussion of factors you should consider before investing in our securities.
Ticker symbols	Our common stock listed on the Nasdaq under the symbol "ENSC" and our Public Warrants are listed on the OTC Pink Open Market under the symbol "ENSCW."

#### **Risk Factor Summary**

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the section titled "Risk Factors" beginning on page 9 of this prospectus. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed. You should consider carefully the risks and uncertainties described under the section titled "Risk Factors" as part of your evaluation of an investment in our securities:

- We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We must obtain regulatory approval and fulfill numerous other requirements to be successful.
- We require substantial additional funding.
- The price of our common stock on the Nasdaq and Public Warrants on the OTC Pink Open Market may be volatile.
- The proceeds under the GEM Agreement may be less than anticipated and issuances of common stock pursuant thereto would result in dilution of existing . stockholders.
- We depend heavily on the success of PF614 and PF614-MPAR<sup>TM</sup> product candidates, which are currently in clinical trials, and which may not be successful.

- Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others.
- If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business.
- If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed.
- Competitive products may reduce or eliminate potential commercial opportunity for our product candidates.
- Our business could be harmed if we lose the services of our key personnel or if we are unable to hire additional highly qualified employees.
- Our employees or others on which our business depends may engage in misconduct or other improper activities.
- We are subject to business interruptions resulting from the COVID-19 pandemic or similar public health crises.
- Government grant awards may not be available to us in the future.
- Social issues around the abuse of opioids could decrease the potential market for our product candidates.
- We currently rely on, and expect to rely on in the future, third parties to conduct our clinical trials.
- We expect to be completely dependent on third parties to manufacture our product candidates.
- We must develop our sales, marketing and distribution capability on our own or through collaborations.
- The regulatory approval processes is lengthy, time-consuming and inherently unpredictable.
- Our clinical trials my not succeed.
- Regulatory authorities may disagree with our regulatory plan for our product candidates.
- Interim topline and preliminary data from our clinical trials may change.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the preclinical and clinical studies necessary.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain.
- Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies.
   We may an equivalent differentiate arealized and the subject is an eliminated with the subject is an eliminated with the subject is a subject to ongoing enforcement of post-marketing requirements by regulatory agencies.
- We may encounter difficulties enrolling patients in our clinical trials.
- Fast track designation by the FDA for PF614 may not lead to a faster development or regulatory review or approval process and does not assure FDA approval.
- If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if such requirements are not as we expect, the approval pathway will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

- We are subject to risks if we submit a 505(b)(2) application that references a third-party product.
- Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile
  of an approved label, or result in significant negative consequences following regulatory approval, if obtained.
- Even if any of our product candidates receives regulatory approval, we may fail to achieve the degree of market acceptance necessary for commercial success.
- We are subject to potential product liability lawsuits against us or any of our future collaborators.
- Oxycodone is a Schedule II controlled substance under the federal CSA, and we must comply with the CSA or its state equivalents.
- Manufacturing of oxycodone is subject to annual quotas that limit the amount of API and dosage forms that can be produced in any given year.
- Prescription drug abuse, especially involving opioids, has been declared a national epidemic causing limits in prescribing and adverse publicity for the entire class of drugs.
- If we are unable to obtain and maintain patent protection for our products candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates that are similar or identical to our product candidates.
- We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property.
- The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.
- We may not be able to obtain protection under the Hatch-Waxman Amendments by extending the patent term.
- We may not be able to protect our intellectual property rights throughout the world.
- Changes in United States' patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability
  to protect our products.
- We may be subject to claims that we infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- · We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent.
- Our intellectual property agreements with third parties may be subject to disagreements.
- Intellectual property rights do not necessarily address all potential threats to our business.
- The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties.
- If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.
- Cyber-attacks or other failures in our telecommunications or information technology systems, or those of third parties could result in information theft, data corruption and significant disruption of our business.
- We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.
- Raising additional capital in the public or private equity markets at prices per share below the current market price of our common stock could cause dilution to our stockholders, adversely affect the market price of our common stock, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of Sarbanes-Oxley Act, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business.

- We identified material weaknesses in our internal control over financial reporting as of December 31, 2020 and 2019.
- LACQ identified material weaknesses in its internal control over financial reporting as of December 31, 2020.
- We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act.

- The Nasdaq may delist our common stock and/or our Public Warrants may not continue to trade on the OTC Pink Open Market.
- Certain of our warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results.
- Due to the uncertainty with respect to classification of warrants issued by SPACs as equity or indebtedness, there can be no assurance that future guidance might not
  require us to restate our financial statements and have other adverse consequences.

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#### MARKET AND INDUSTRY DATA AND FORECASTS

We obtained the industry and market data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in the section entitled "*Risk Factors.*" These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

#### **RISK FACTORS**

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Stockholders should carefully consider the following risk factors, together with all of the other information included in this registration statement/prospectus, 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. The following discussion should be read in conjunction with the financial statements and notes to the financial statements of both LACQ and Ensysce included herein.

#### Risks Related to Our Business, Financial Condition and Capital Requirements

### We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage pharmaceutical company with a limited operating history. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, engage in clinical development beyond Phase 1 trials, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or enter into licensing arrangements to commercialize a product, or conduct sales and marketing activities necessary for successful product commercialization.

We have no products approved for commercial sale and we have not generated any revenue from product sales to date, nor do we expect to generate any significant revenue from product sales for the next few years. We will continue to incur significant research and development and other expenses related to our product development, preclinical and clinical activities and ongoing operations. As a result, we are not profitable and have incurred losses in each period 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. Our net loss was \$10.1 million for the year ended December 31, 2019, and \$160,875 for the year ended December 31, 2020 and \$1.0 million for the three months ended March 31, 2021. As of December 31, 2020 and March 31, 2021, we had an accumulated deficit of \$56.0 million and \$56.9 million, respectively. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continues our research and development of, and seek regulatory approvals for, our product candidates.

If we continue to suffer losses as we have since inception, investors may not receive any return on their investment and may lose their entire investment.

In addition, as a public company, we incur significant additional legal, accounting and other expenses that we did not incur as a private company as we:

- meet the requirements and demands of being a public company;
- expand our operational, financial and management systems and increases personnel to support our operations;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- advance our clinical-stage product candidate PF614 through clinical development;
- advance our preclinical stage product candidates into clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory
  approval in regions where we choose to commercialize our products on our own or jointly with third parties;
- · maintain, expand and protect our intellectual property portfolio; and
- make milestone, royalty or other payments due under any future in-license or collaboration agreements.

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Pharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable. Therefore any investment in us would be highly speculative. Our prospects are subject to the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We will likely encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the United States Food and Drug Administration, or FDA, or other regulatory

authorities to perform clinical trials in addition to those that we currently expect to conduct, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

### Our ability to generate revenue from any of our potential products is subject to our ability to obtain regulatory approval and fulfill numerous other requirements and we may never be successful in generating revenues or becoming profitable.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize the product candidates we are developing or may develop. Successful commercialization, to the extent it occurs, will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling, or entering into other agreements to commercialize, those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we cannot accurately and precisely predict the timing and amount, if any, of revenues, the extent of any further losses or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are sufficient enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability or a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

### We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.

We are a clinical stage pharmaceutical company that will need to raise additional capital to continue to operate as a going concern. Our quarterly operating results are likely to show continued losses in the future. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our planned Phase 2 program for nafamostat and planned clinical trials for PF614 and PF614-MPAR<sup>TM</sup>. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to obtain marketing approval for product candidates that we develop, we would require significant additional amounts of funding in order to launch and commercialize such product candidates. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop and we may require substantial additional funding to complete the development and commercialization of our product candidates.

Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and
  pursue in the future, including the costs related to preclinical and clinical development of the product;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;

- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any
  future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, the amount of revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- · our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and establishes a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate, and many of these factors are outside of our control. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory and marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. We cannot be certain that additional funding will be available on acceptable terms, or at all. Please see the risk factors under "*Risks Related to the Ownership of Common Stock and Financial Reporting*."

We believe that the net proceeds from the Merger, together with our existing cash and cash equivalents, including subsequent draw downs, if, to the extent, available, under the Share Purchase Agreement between us, GEM Global Yield LLC SCS ("*GEM Global*") and GEM Yield Bahamas Limited ("*GYBL*"), dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the "*GEM Agreement*") (as described in the following risk factor), will enable us to fund our operating expenses and capital expenditure requirements through the end of 2021, while advancing our main product candidates such as, PF614 and PF614 MPAR<sup>TM</sup> and nafamostat through their respective next phases of clinical development. Our estimate may prove to be wrong, and we could use our available capital resources, if any, sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly funds sooner than planned. To the extent this occurs, it could impose significant dilution on our stockholders.

We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our platforms, programs, planned clinical trials or future commercialization efforts.

#### The price of our Common Stock on the Nasdaq and Public Warrants on the OTC Pink Open Market may be volatile.

The price of our common stock on the Nasdaq and our Public Warrants on the OTC Pink Open Market may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;

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- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- news about, among other things, the results of our clinical trials or other developments, or the use or abuse of opioids,
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- sales, or anticipated sales, of large blocks of our common stock;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

These and other factors, many of which are beyond our control, may cause the market price and demand for our shares of common stock to fluctuate substantially. Low trading volume could increase the volatility of our share price in response to news in the market, could prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

# The proceeds under the GEM Agreement may be less than anticipated. The issuances of common stock pursuant to the GEM Agreement would result in dilution of existing stockholders and could have a negative impact on the market price of our common stock. Additionally, the negative covenants under the GEM Agreement are onerous and any breach by us thereunder may entitle GEM Global and GYBL to indemnification payments, reimbursements of legal and other expenses and other compensation thereby diverting our time and resources.

We are entitled to draw down up to \$60 million of gross proceeds from GEM Global in exchange for shares of our common stock at a price equal to 90% of the average closing bid price of the shares of our common stock on Nasdaq for a 30 day period, subject to meeting the terms and conditions of the GEM Agreement. This equity line facility is available for a period of 36 months from the closing date of the Merger. Please see the section entitled "*Business*" for additional information. The limitations on the amount and frequency of the draws that we can make under the GEM facility, which include the requirement that (i) there be an effective registration statement and (ii) size restrictions relating to our trading volume, may affect the ability to draw under the GEM Agreement and result in proceeds that are less than anticipated.

In addition, the occurrence of the Merger triggered (i) payment of a commitment fee of \$1.2 million to GEM Global payable in either our common stock or cash and (ii) the issuance of a warrant granting GYBL the right to purchase 1,106,108 shares of our common stock, at a strike price per share of \$10.01, the closing bid price for such common shares on the closing date of the Merger. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits and certain issuances of additional shares of our common stock.

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The issuances of shares at discount under the GEM Agreement and the anti-dilution protection granted to GEM Global in connection with issuances of additional shares of our common stock, would result in dilution of existing stockholders and have a negative impact on the market price of our common stock and our ability to obtain equity financing.

In addition, the negative covenants under the GEM Agreement are onerous and any breach thereof may trigger indemnification, reimbursement of losses and other liability for us thereby diverting our time and resources.

### Raising additional capital could cause dilution to our stockholders, adversely affect the market price of our common stock, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

In addition, we may sell securities in the public or private equity markets if and when conditions are favorable, or at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of shares of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital.

Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

Our future success and ability to generate significant revenue from our product candidates, which we do not expect will occur for several years, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. We completed our Phase 1 clinical study for our most advanced product candidate, PF614, in February 2018. A Phase 1 study for nafamostat was completed in December 2020. A Phase 1 study for PF614-MPAR<sup>™</sup> is expected to be initiated during 2021. All of our other product candidates are in earlier stages of development and will require substantial additional investment for manufacturing, preclinical testing, clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates. Even if clinical trials are completed, we may experience other issues that may delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;

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- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates that are similar to ours, leading to a
  decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from
  regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of manufacturing facilities or inability of those facilities to maintain a compliance status acceptable to the FDA, EMA or comparable regulatory authorities;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

Our product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that such product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure stockholders that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

### We depend heavily on the success of our lead product candidate PF614, which is currently in clinical trials. Our clinical trials of PF614 may not be successful. If we are unable to commercialize PF614 or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the research and development of our lead product candidate, PF614 and we expect to continue to do so. Our ability to generate revenues from the sale of abuse-deterrent opioid products, which may not occur at a significant level for several years, will depend heavily on the successful development, regulatory approval and eventual commercialization of PF614.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from similar regulatory authorities outside of the United States. Even if PF614 or another product candidate were to successfully obtain approval from the FDA and non-U.S. regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for PF614 in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing and/or commercialization of PF614 or any other product candidate that we may discover, in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for P614, we will still need to develop a commercialization of PF614, establish commercially viable pricing and obtain approval for adequate reimbursement from a third-party and government payors. If we or our commercialization collaborators are unable to successfully commercialize PF614, we may not be able to generate sufficient revenues to continue our business.

## Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We currently have three clinical-stage product candidates as well as certain other product candidates that are at various stages of preclinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidates, such as nafamostat, PF614 and PF614-MPAR<sup>TM</sup>, and ensuring the development of additional potential product candidates.

Due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misinterpret trends in the pharmaceutical industry, in particular for opioid abuse and drug overdose, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may (i) fail to capitalize on viable commercial products or profitable market opportunities, (ii) be required to forego or delay pursuit of opportunities with other product candidates or other diseases pathways that may later prove to have greater commercial potential than those we choose to pursue, or (iii) relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

### Our PF614 and PF614-MPAR<sup>TM</sup> product candidates may not be successful in limiting or impeding abuse, overdose or misuse or providing additional safety upon commercialization.

We are committing a substantial majority of our resources to the development of products utilizing our TAAP and MPAR<sup>TM</sup>. There can be no assurance that our products will perform as tested and limit or impede the actual abuse, overdose or misuse of such products or provide other benefits in commercial settings. Moreover, there can be no assurance that if our products are approved by the FDA, the post-approval epidemiological studies required by the FDA as a condition of any such approvals of the products will show a reduction in the consequences of abuse and misuse by patients for whom the applicable product is prescribed. The failure of our products to limit or impede actual abuse, overdose or misuse or provide other safety benefits in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

#### If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. In addition, we may also seek to commercialize certain treatments that may not be proprietary to us.

Although the development and commercialization of our current product candidates are our initial focus, as part of our long-term growth strategy, we plan to develop other product candidates. We may also seek to commercialize treatments that may not be proprietary to us. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates. While our technology platforms have potential applicability to other uses, we have not conducted any clinical trials on these other uses and we may not be successful in developing product candidates for other uses.

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In addition, we intend to devote capital and resources for basic research to discover and identify additional product candidates. These research programs require technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not
  meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including many with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we finds acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

### If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we seek to estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The potential achievement of many of these milestones may be outside of our control. Each of these milestones is based on a variety of assumptions which, if not realized as expected, may cause the timing of such potential achievement of the respective milestones to vary considerably from our estimates, including:

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- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- clinical outcomes;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve any announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed and it could negatively impact our share price performance. Please see "Business" for more information.

## Competitive products may reduce or eliminate commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than any such technologies or product candidate of ours, our ability to develop and successfully commercialize our own technologies or product candidates may be adversely affected.

The clinical and commercial landscapes for the solution of opioid abuse and drug overdose are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. These companies include, but are not limited to, Purdue Pharma, LP, and Collegium Pharmaceutical, Inc. Potential competitors include not only pharmaceutical companies but also academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for the same indications that we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled "*Business — Competition*" for examples of the competition that our product candidates face.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than us. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates, including PF614, is approved, these product candidates could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective or less costly than PF614, our or other product candidates or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop.

Competitive products may make any products we develop obsolete or noncompetitive before we are able to recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, if we are successful at all, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of PF614 or any other product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect any such competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

#### Our business could be harmed if we lose the services of our key personnel or if we are unable to hire additional highly qualified employees.

Our business depends upon our ability to attract and retain highly qualified personnel, including managerial, sales and technical personnel. We compete for key personnel with other companies, healthcare institutions, academic institutions, government entities and other organizations. We do not have written employment agreements with our Chief Executive Officer. Our ability to maintain and expand our business may be impaired if we are unable to retain our current key personnel or hire or retain other qualified personnel in the future.

We currently only have four full-time employees and five consultants and we expect to add additional employees. Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel.

Competition for such individuals, particularly in the United States, is intense, and we may not be able to hire sufficient personnel to support our efforts. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, our cost base with respect to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on our financial results, including the potential for additional dilution to our stockholders. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

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### Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that we and our contract research organizations' ('*CROs*'') employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operati

### Business interruptions resulting from the COVID-19 pandemic or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business and our results of operations.

Public health crises such as pandemics or similar outbreaks could adversely impact Ensysce's business. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease (COVID-19), was reported to have surfaced in Wuhan, China and has since reached multiple other regions and countries worldwide. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

The continued spread of COVID-19 or other global health matters, such as pandemics, could adversely impact our clinical trials or preclinical studies. For instance, the COVID-19 pandemic could impair our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if a pandemic occurs in their geography or due to prioritization of hospital resources toward the pandemic and restrictions on travel. Furthermore, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if guarantines or travel restrictions impede patient movement or interrupt healthcare services. COVID-19 may also negatively affect the operations of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. For instance, while we have taken measures to revise clinical trial protocols in our Phase 2 program of nafamostat, including home delivery of study medication, home health care visits to collect safety data and telemedicine visits to collect clinician-based trial assessments, such measures may not be sufficient to prevent missing data from impacting trial outcomes or delays in enrollment and trial completion caused by COVID-19. If patients are reluctant to participate in these trials due to fears of COVID-19 infection resulting from regular visits to a healthcare facility, we may not be able to meet our current trial completion timelines. Any negative impact COVID-19 has to patient enrollment or treatment or the timing and execution of our clinical trials could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for the commercialization of our product candidates, increase our operating expenses, and have a material adverse effect on our business and results of operations. We may also take temporary precautionary measures intended to help minimize the risk of COVID-19 to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings. These measures could negatively affect our business. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which the ongoing COVID-19 pandemic impacts our business, results of operation and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, new information that may emerge concerning the severity of COVID-19, or the effectiveness of actions to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if any. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operation and financial condition.

We have received funding under grant award programs funded by governmental agencies, such as the NIH and NIDA. To fund a portion of our future research and development programs, we may apply for additional grant funding from these or similar governmental agencies in the future. However, funding by these, and other, governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Also, the continued spread of COVID-19 could affect governmental priorities in the future or prospective funding for our product candidates. Therefore, we cannot provide any assurance that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products.

### Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioid and regulatory efforts to combat abuse, could decrease the potential market for our product candidates.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances have become commonplace. Law enforcement and regulatory agencies may apply additional policies that further seek to limit the availability of opioids. Such efforts may inhibit our ability to commercialize our product candidates. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our drug products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and decrease the revenues and royalties, if any, we are able to generate from their sale. Similarly, to the extent opioid abuse becomes less prevalent or a less urgent public health issue, regulators and third-party payers may not be willing to pay a premium for abuse deterrent formulations of opioids.

In addition, efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product candidates. For example, in February 2016, as part of a broader initiative led by United States Department of Health and Human Services (the "*HHS*") to address opioid-related overdose, death and dependence, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the Risk Evaluation and Mitigation Strategy ("*REMS*") requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic abuse-deterrent opioid formulations, and seeking input from the FDA's Scientific Board to broaden the understanding of the public risks of opioid abuse. Many of these changes could require us to expend additional resources in developing and commercializing our product candidates to meet additional requirements. In October 2017, the acting director of HHS under the directive of former President Trump, declared the opioid crisis a national health emergency and initiated a five point plan including (i) improving access to prevention, treatment, and recovery support services; (ii) targeting the availability and distribution of overdose-reversing drugs; (iii) strengthening public health data reporting and collection; (iv) supporting cutting-edge research on addiction and pain; and (v) advancing the practice of pain management. The impact that this five-point plan will have on us is unclear at this time, especially after the change in administrations following the 2020 presidential elections.

#### We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of their attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

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#### **Risks Related to Our Dependence on Third-Party Providers**

### We currently rely on, and expect to rely on in the future, third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials, failing to satisfy legal or regulatory requirements or terminating the relationship.

We currently rely on, and expect to rely on in the future, third-party CROs to conduct research and development activities and our clinical trials for our product candidates. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities.

Our reliance on these CROs for research and development activities and clinical trials will reduce our control over these activities but will not relieve us of any of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or our stated protocols, it could adversely affect the development of our product candidates and it could result in us not being able to obtain, or being delayed in obtaining, marketing approvals for our product candidates and it could adversely affect our efforts to successfully commercialize our product candidates.

#### We expect to be completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities, fail to provide to us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the ingredients in our product candidates for use in our clinical trials or for commercial product, if any. We have entered into a Manufacturing Agreement (the "*Recro Agreement*") with Recro Gainesville LLC ("*Recro*") for the production of PF614 capsules and other materials and services with respect to our clinical studies. In addition, we do not have the capability to encapsulate any of our product candidates as a finished product for commercial distribution. As a result, we expect to be obligated to rely on contract manufacturers, like Recro, if and when any of our product candidates are approved for commercialization. In the event that Recro is unable to perform its obligations under the Recro Agreement, we may be unable to replace the Recro Agreement on terms as favorable to us. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our product candidates on favorable terms to us, or at all.

The processes used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities and the facilities at which the product candidates are manufactured must maintain a compliance status acceptable to the FDA and foreign regulatory authorities. FDA and foreign regulatory authorities will conduct inspections after we submit a new drug application, or NDA, to the FDA or its equivalent to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, its contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates.

If our contract manufacturers, including Recro, do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, our product candidates may not be approved. If these facilities do not maintain a compliance status acceptable to the FDA, Drug Enforcement Agency, or DEA, or comparable regulatory authorities, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our contract manufacturers, including Recro, will be subject to ongoing periodic unannounced inspections by the FDA, DEA and corresponding state and foreign agencies for compliance with cGMPs, security, recordkeeping and similar regulatory requirements. Although we will not have control over our contract manufacturers' compliance with these regulations and standards, we are nonetheless responsible for assuring such compliance. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and results of operations. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties, including Recro, are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our ingredients or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product candidates if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decide to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer, including Recro, could be disruptive to our operations and delay development of our investigational products. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our investigational products and, if approved, product candidates.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our product candidates over time. If the commercial-scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities.

We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

### If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize PF614 or one or more of our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of PF614, our other product candidates and other future product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

#### Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

### The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for our most advanced product candidate, PF614, or any other product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate are toxic or not well tolerated when that is not in fact the case. Serious adverse events, or SAEs, or other adverse effects, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our
  proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

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- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain
  regulatory approval in the United States, the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with the manufacturing processes of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in us failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The FDA may recommend scheduling with respect to any of our current or future product candidates. In such event, prior to a product launch, the DEA will need to determine the controlled substance schedule of the product, taking into account the recommendation of the FDA. The timing of the scheduling process is uncertain and may delay our ability to market any product candidate that we successfully developed and approved.

The FDA has the authority to grant an Emergency Use Authorization ("*EUA*") to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. Based on the outcomes of our clinical testing for nafamostat, Ensysce expects to apply for an EUA for use against coronaviral infections, which would permit us to commercialize nafamostat prior to FDA approval of an NDA. However, commercialization under an EUA is permitted only during the period of time that FDA determines that the statutory criteria for EUA are met, meaning that we would be required to obtain NDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA—for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict how long, if at all, an EUA for nafamostat or any other product candidates may remain in place. Any termination or revocation of an EUA (if any) for nafamostat or any other product candidates could adversely impact our business in a variety of ways, including if nafamostat is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide nafamostat under an EUA.

### If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for, or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For example, preclinical studies showed that PF614 does not readily convert into oxycodone in the blood stream and the Phase 1 trial we have conducted with TAAP prodrug (a medication or compound that, after administration, is metabolized (i.e., converted within the body) into a pharmacologically active drug, or "prodrug") PF614, demonstrated that, after oral administration of the TAAP prodrug, the corresponding opioid was measured in the subjects' blood. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval.

#### The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

We have submitted IND applications for PF614 and nafamostat and completed a Phase 1 trial for each product candidate. We have applied for and received fast track designation for PF614. However, fast track designation does not guaranty a faster development or regulatory review or approval process and does not assure FDA approval. We have received feedback from the FDA on requirements to achieve abuse deterrent labeling claims for PF614. We have submitted an IND for PF614-MPAR<sup>TM</sup> and have received feedback on required pre-clinical, manufacturing and clinical studies that will be required for an NDA.

Our clinical trial results may not support approval of our product candidates. The general approach for FDA approval of a new drug is dispositive data from two or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs, and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our Phase 2 clinical trials of nafamostat for coronaviral infections after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA, the FDA will not require us to modify our trials, these trials will enable us to conduct the required Phase 3 studies or other testing or that completing these trials will result in regulatory approval.

### Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

### Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with such development and commercialization, including our design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. Ensysce has no experience in submitting and supporting the applications necessary to gain marketing approvals and we expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and requires additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. For example, during the product approval process, the FDA will determine whether a REMS plan is necessary to assure the safe use of the product. All opioid analgesic products currently on the market in the United States are subject to a REMS. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS plan must include a timetable to assess the strategy at eighteen months, three years and seven years after approval. We may be required to develop a REMS for the product, or participate in a REMS with other manufacturers, or to develop a si

Even if approved, our contract manufacturers will need to obtain quota from DEA to manufacture sufficient quantities and maintain inventories of product to be commercially distributed.

If we experience delays in obtaining manufacturing approval or if we fail to obtain manufacturing approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

## Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, as well as the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA also may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act and other federal and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients using our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal or recall of the product from the market;
- refusal to approve pending applications or supplements to approved applications that Ensysce submits;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of our products can also result in significant financial penalties.

### Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the preclinical and clinical studies necessary for development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval that we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary
  significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipates;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and

 the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm its business. The development costs of our product candidates will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure stockholders that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

#### If we encounters difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with our protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

We may experience difficulties in patient enrollment in our clinical trials for a variety of factors, including:

- the effects of COVID-19 on our ability to recruit and retain patients, including as a result of potential heightened exposure to COVID-19, prioritization of hospital
  resources toward the pandemic and unwillingness by patients to enroll or comply with clinical trial protocols if quarantines or travel restrictions impede patient
  movement or interrupt healthcare services;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, negatively affect the timing or outcome of the planned clinical trials, delay the product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could cause our value to decline and limit our ability to obtain additional financing if needed.

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

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

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We may seek FDA approval through the Section 505(b)(2) regulatory pathway for our product candidate PF614. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDC Act, permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDC Act, would allow an NDA we submit to FDA to rely in part on data in the public domain or on the FDA's prior conclusions regarding the safety and effectiveness of an approved product, or listed drug, which could expedite the development program for our product candidates by potentially decreasing the amount of data that we would need to generate in order to obtain FDA approval. If the FDA

does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for PF614, we may need to conduct additional preclinical and clinical trials, provide additional data and information, and meet additional standards for regulatory approval. For example, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain financing in terms acceptable to us, if at all. Moreover, the inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact of our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure our stockholders that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

#### If we submit a 505(b)(2) application that references a third-party product, we may be subject to a patent infringement suit and the approval of our product may be delayed.

If we submit a 505(b)(2) application that relies in whole or in FDA's findings for a listed drug, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our product. A certification that our new drug will not infringe the Orange Book-listed patents for the applicable listed drug, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our 505(b)(2) application is filed by the FDA. The third party may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit within the required 45-day period, our 505(b)(2) application will not be subject to the 30-month stay of FDA approval.

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#### Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or repeating one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

### Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in restrictive warnings or contraindication or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a less favorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of PF614, opioid side effects were observed. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which its trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trials subjects or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

### Even if any of our product candidates receives regulatory approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues, if any, or become profitable.

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and 31

We have not commercialized any products and therefore we are not known in the medical community or to third-party payors. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

### Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;

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- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- · diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

Oxycodone is a Schedule II controlled substance under the federal CSA, and any failure to comply with the CSA or its state equivalents would have a negative impact on

#### our business.

Oxycodone, the ingredient in PF614, is classified as a Schedule II controlled substance under the Controlled Substances Act, or CSA and regulations promulgated by the DEA. The law and regulations classify substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, shipment, sale, use, distribution and physician prescription procedures. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. In addition to federal scheduling, oxycodone is subject to state-controlled substance laws and regulations, and in some cases, with additional requirements than those imposed by federal law and regulations. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may schedule products separately.

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain complete and accurate records and file reports, including reports related to thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances. Registered entities also must follow specific labeling and packaging requirements. Facilities must maintain appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations.

Our contract manufacturing organizations, or CMOs, who manufacture and distribute PF614 are required to be registered with DEA and relevant state authorities and comply with all security, recordkeeping and reporting requirements. Manufacturers and distributors are subject to routine inspections and audits by the DEA related to compliance with security, recordkeeping and reporting requirements. Failure to maintain the required registrations or to comply and follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration to manufacture or distribute such products.

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### Manufacturing of oxycodone is subject to annual quotas that limit the amount of API and dosage forms that can be produced in any given year; the failure of our CMOs to obtain the necessary manufacturing and/or procurement quota would have a negative impact on our business.

The CSA and DEA regulations establish an annual aggregate production quota for Schedule I and II controlled substances, including oxycodone and other narcotic drugs. In addition, each manufacturer of active pharmaceutical ingredient, or API or dosage forms must obtain an individual manufacturing or production quota that limits the amount of product that a company can produce and/or distribute in a given year. The DEA allocates manufacturing quota issued to companies so as to not exceed the aggregate quota established for a given year. Moreover, companies must demonstrate the need for procurement quota based on expected demand and sales of the controlled substance the DEA requires the submission of substantial evidence of expected legitimate medical and scientific need for the drug product before assigning its aggregate production quotas, or manufacturing and procurement quotas to manufacturers. The DEA has decreased the aggregate quota diversion in establishing quotas for narcotic drugs which could lead to continued decreases in quota available to API manufacturers and dosage form manufacturers of these substances.

In future years, we may need greater amounts of controlled substances that are subject to the DEA's quota system to sustain our development program. We may also need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. If any of our manufacturers of API or dosage forms are unable to obtain the necessary annual quota to meet the research and development or commercial demand for PF614, our business would be negatively impacted. Any delay or refusal by the DEA in establishing a quota, a reduction in quota, or a failure to increase quota over time could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

### Prescription drug abuse, especially involving opioids, has been declared a national epidemic causing limits in prescribing and adverse publicity for the entire class of drugs.

Federal and state authorities, including the HHS, the Centers of Disease Control and Prevention and the DEA have identified opioid and narcotic prescription drug abuse as a national epidemic. Products containing narcotic controlled substances may generate public controversy. As a result, these products may have their marketing approvals withdrawn. Also, federal and state authorities have recommended limitations on prescribing and dispensing of such products. Regulatory action, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of our product candidates.

#### **Risks Related to our Intellectual Property**

## If we are unable to obtain and maintain patent protection for our products candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates that are similar or identical to our product candidates, and our ability to successfully commercialize our product candidates may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with significant commercial markets with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business, as appropriate. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we may apply for in the future with respect to one or more of our product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we may enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We currently owns patents in the United States and other countries that are directed to PF614, PF614-MPAR<sup>IM</sup> and uses thereof that would expire between 2030 and 2032, subject to any potential patent term extension that may be available in a jurisdiction. We also own a pending provisional application directed to oral formulations of PF614-MPAR<sup>IM</sup>, which if pursued and issued, would expire in 2042, subject to any potential patent term adjustment or extension that may be available in a jurisdiction.

We currently own a patent in Europe that is directed to the use of nafamostat for treating respiratory diseases, which will expire in 2028, subject to any potential patent term extension that might be available. We do not own or license any pending patent applications or issued patents outside of Europe for this use. We also owns pending provisional applications directed to methods of treating COVID-19 with orally-administered nafamostat and oral formulations of nafamostat, which if pursued and issued, would expire in 2041 and 2042, respectively, subject to any potential patent term adjustment or extension that may be available in a jurisdiction. Currently, we do not have any issued patent or pending application directed to methods of treating infections caused by coronaviruses, including COVID-19, with inhaled nafamostat, but intends to file patent applications upon development of a suitable inhalation formulation of nafamostat.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Even if the patent applications that we own or licenses issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Even if the patent, competitors who obtain the requisite regulatory approval can offer product candidates for which we do not hold or do not obtain composition of matter patents, competitors who obtain the requisite regulatory approval can offer product when used or sold for the specified method. However, this type of patent protection can be more difficult to enforce and does not limit a competitor from making and marketing a product that is identical to our product candidate that is either labeled or marketed for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Changes in either the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions.

We cannot be certain that our patents and patent rights will be effective in protecting our product candidates and technologies. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

### We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents.

Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development, and on our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties.

We may be exposed to, or be threatened with, adversarial proceedings or additional future litigation by third parties regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the United States Patent and Trademark Office, or USPTO, or similar adversarial proceedings or litigation in other jurisdictions seeking to challenge the validity of our intellectual property rights, claiming that we have misappropriated the trade secrets of others, or claiming that our technologies, products or activities infringe the intellectual property rights.

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There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, post grant review, inter partes review and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We are aware of patents owned by third parties, including potential competitors, that are directed to compositions comprising a chemically modified opioid, such as oxycodone, which decreases the potential of the opioid to be abused or cause overdose and related methods of use. Third parties, including potential competitors, may assert infringement claims against us based on existing patents or patents that may be granted in the future including, perhaps, the aforementioned patents, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us.

Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable potents, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or to enable the commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business and financial condition significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than us or our licensors or collaborators can. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, ability to compete in the marketplace, financial condition, results of operations and growth prospects.

#### We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

a material impact on our business, results of operations and financial condition in the future.

We may not be able to prevent, alone or with any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

#### The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable.

Certain of our patents relating to PF614 will expire in the next nine years. In addition, certain of our patents relating to the use of nafamostat for treating respiratory diseases will expire in the next seven years. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions.

#### If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

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Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case

#### We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and our patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of us or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, We and our licensees or any future licensors may have limited remedies if patents are infringed or if we or our licensees or any

future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, we and our licensees' or any future licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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### Changes in United States' patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation, and that legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patent applications.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, the Federal Circuit has recently expanded its doctrine of obviousness-type double patenting by holding that a later-granted patent (which may expire earlier) can, in some circumstances, render an earlier-granted patent invalid under the doctrine unless a terminal disclaimer is timely filed in the earlier granted patent over the later-granted patent. While issued patents are generally granted a term of 20 years from the earliest claimed non-provisional filing date, in certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment). The expansion of this doctrine could result in the loss of patent term adjustment and ultimately result in the loss of patent term. In addition to increasing uncertainty with regard to our ability to obtain patents, the federal courts has regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent application and our ability to obtain new patents or to enforce patents that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent applications and our ability to obtain new patents or to enforce patents that we may obtain in the future. We cannot p

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Having a mandatory non-exclusive license grant may diminish the value of our patents as well as making it more difficult to protect our product candidates.

### We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

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In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. For example, we have not obtained assignments for certain patent applications relating to abuse-resistant amphetamines. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property rights could be forced to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

### Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our future collaborators fail to maintain the patents and patent applications covering our products, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

#### Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed and if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we expect to rely on third parties to manufacture our product candidates and we expect to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seeks to preserve the integrity and confidentiality of our data, trade secrets and know-how by

maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations and products. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may have resulted and may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights.

We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. For example, we are aware that certain of our former employees founded Elysium Therapeutics, which appears to be developing orally administered abuse deterrent opioids. Additionally, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

#### We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or that we may own or license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own; our licensors may face similar obstacles. In addition, we have not updated the records in the patent offices to reflect our ownership of our patent filings relating to PF614 and other technologies. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Furthermore, as noted above, we have not obtained assignments for certain patent applications relating to abuse-resistant ampletamines. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

### We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

### Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;

- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates.

We have acquired all intellectual property rights from Signature and Mucokinetica, Ltd. ("*Mucokinetica*"), with the exception of our pending application directed to the use of orally administered nafamostat to treat coronaviruses. Any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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#### Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent
  application that we own;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a
  proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party submits an application under Section 505(b)(2) or an abbreviated new drug application, or ANDA, for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month s

all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

#### If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and market exclusivity in the United States and other countries with respect to our product candidates. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, certain of our product candidates may be eligible for marketing exclusivity.

The FDC Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA or Section 505(b) (2) NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with the FDA by the innovator NDA holder.

The FDC Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a Section 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Three-year exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our approval to obtain approval of competing products and launch their product earlier than might otherwise be the case.

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### Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of us, our collaborators', CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber-attacks. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable United States and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

#### Risks Related to the Ownership of Common Stock and Financial Reporting

### We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the stockholders' sole source of gain for the foreseeable future.

#### Raising additional capital could cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our stockholders' ownership interest may be diluted. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional capital through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to grant to third parties rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

In addition, any issuances of common stock pursuant to the GEM Agreement would result in dilution of the ownership interest of our stockholders. Any such issuances may also have a negative impact on the market price of our common stock because of the discount at issuance. See "*We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts*" for description of risks related to additional funding.

#### Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of Sarbanes-Oxley Act, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business.

We previously operated as a private company. In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2019, we concluded that there were material weaknesses in our internal controls over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified are insufficient internal controls because of inadequate technical accounting expertise and inappropriate level of supervision and review due to the limited number of accounting personnel. While we are taking steps to remediate the material weaknesses in our internal controls over financial reporting, including hiring a Chief Financial Officer in February 2021, we may not be successful in remediating such weaknesses.

Following the business combination, our management has significant requirements for enhanced financial reporting and internal controls as a public company. The process of designing and implementing effective internal controls is a continuous effort that will require us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis or result in material misstatements in our consolidated financial statements, which could harm our operating results. In addition, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management's attention from other matters that are important to our business. Our independent registered public accounting firm is required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are not able to complete an initial assessment of our internal controls and otherwise implement the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or with adequate complex of the cart of the sarbanes-Oxley Act in a timely manner or with adequate compliance, our independent registered publ

Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the Securities and Exchange Commission, or SEC, or violations of applicable stock exchange listing rules, which may result in a breach of the covenants under existing or future financing arrangements. There also could be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements. Confidence in the reliability of our financial statements also could suffer if we or our independent registered public accounting firm continue to report a material weakness in our internal controls over financial reporting. This could materially adversely affect us and lead to a decline in the market price of our common stock.

#### **Risks Related to Tax Matters**

#### Prospective tax legislation could adversely affect our business and financial condition.

The United States government in the future may enact additional legislation that affects the taxation of business entities, including with respect to the treatment of net operating losses. This registration statement/prospectus does not discuss any such tax legislation or the manner in which it might affect holders of our common stock. Holders of our common stock are urged to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of holding our common stock.

### Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our financial condition and results of operations.

We are subject to income taxes in the United States, and our tax liabilities will be subject to the allocation of expenses in differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including:

- tax effects of stock-based compensation;
- costs related to intercompany restructurings;

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- changes in tax laws, regulations or interpretations thereof; or
- lower than anticipated future earnings in jurisdictions where we have lower statutory tax rates and higher than anticipated future earnings in jurisdictions where we have higher statutory tax rates.

#### Risks Related to Our Securities and to Being a Public Company

We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to "emerging growth companies" or "smaller reporting companies," this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of the end of any second quarter of a fiscal year, in which case we will rely on these exemptions. If some investors find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out

of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is not an emerging growth company or is an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates is greater than or equal to \$250 million as of the end of that fiscal year's second fiscal quarter, and (ii) our annual revenues are greater than or equal to \$100 million during the last completed fiscal year and the market value of our common stock held by non-affiliates exceeds \$700 million as of the end of that fiscal year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

### The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

• the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry,

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- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of COVID-19;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete
  with our product candidates;
- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide, if any.

### If the Nasdaq delists our Common Stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, this could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

If Nasdaq delists our common stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, as applicable, from trading on their exchanges for failure to meet the listing standards, our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that the our common stock is a "penny stock" which will require brokers trading in such securities to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future, including our inability to obtain financing under the GEM Agreement.

### Warrants for shares of our common stock, if exercised, will increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

There are Public Warrants exercisable for an aggregate of approximately 10,000,000 shares of our common stock currently exercisable. In addition, there are Private Warrants exercisable for an aggregate of 9,351,289 shares of our common stock, of which Private Placement Warrants to purchase an aggregate of 6,325,000 shares of our common stock became exercisable on July 30, 2021, in accordance with the terms of the warrant agreements governing those securities. The exercise price of these Warrants is \$11.50 per share. To the extent such Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares of common stock eligible for resale in the public market. Sales of substantial numbers of such shares of common stock in the public market or the fact that such Warrants may be exercised could adversely affect the market price of our common stock.

Substantial blocks of our total outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of shares of our common stock by our directors, executive officers, or significant stockholders, if there is a large number of shares of our common stock available for sale, or if there is the perception that these sales could occur. Immediately after the Merger, a significant portion of our shares of common stock or Warrants exercisable for our shares of common stock were held by persons who had been affiliated with LACQ prior to the Merger but did not remain so with respect to us after the Merger. In addition, we may soon register shares of common stock that we may issue under our 2021 Omnibus Incentive Plan. Shares held by our directors, executive officers and other affiliates are subject to restrictions on resale under the Securities Act and may be subject to various vesting agreements.

Certain of our initial stockholders have agreed, subject to certain exceptions, not to transfer, pledge, assign, sell or otherwise dispose of any of our common stock held by them immediately after the Merger until the earlier to occur of (a) one year after the Merger and (b) the date on which we complete a liquidation, merger, share exchange or other similar transaction after closing that results in all of our stockholders having the right to exchange their common shares for cash, securities or other property. However, if the closing price of our common shares equals or exceeds \$12.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Merger, the shares of those initial stockholders will be released from the lock-up.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of such shares intend to sell their shares.

### Our issuance of additional capital stock in connection with financings, acquisitions, investments, our 2021 Omnibus Incentive Plan or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our 2021 Omnibus Incentive Plan. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

### Trading on the OTC Pink Open Market is volatile and sporadic, which could depress the market price of the Public Warrants and make it difficult for the Public Warrant holders to resell their Public Warrants.

The Public Warrants are quoted on the OTC Pink Open Market. Trading in securities quoted on the OTC Pink Open Market is often thin and characterized by wide fluctuations in trading prices, due to many factors, some of which may have little to do with our operations or business prospects. This volatility could depress the market price of the Public Warrants for reasons unrelated to operating performance. Moreover, the OTC Pink Open Market is not a stock exchange, and trading of securities on the OTC Pink Open Market is often more sporadic than the trading of securities listed on Nasdaq. These factors may result in investors having difficulty reselling any Public Warrants.

#### Certain of our warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results.

On April 12, 2021, the Acting Director of the Division of Corporation Finance and Acting Chief Accountant of the SEC together issued a statement regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("*SPACs*")" (the "*SEC Statement*"). Specifically, the SEC Statement focused on certain settlement terms and provisions related to certain tender offers following a business combination, which terms are similar to those contained in the warrant agreement governing our warrants. As a result of the SEC Statement, LACQ reevaluated the accounting treatment of its 10,000,000 public warrants and 7,825,001 private warrants, and determined to classify the private warrants as derivative liabilities measured at fair value, with changes in fair value for each period reported in earnings.

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As a result, included on its consolidated balance sheet as of December 31, 2020 are derivative liabilities related to embedded features contained within its private warrants. Accounting Standards Codification 815, Derivatives and Hedging ("*ASC 815*"), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our consolidated financial statements and results of operations would fluctuate quarterly, based on factors which are outside of our control. Due to the recurring fair value measurement, this would require us to recognize non-cash gains or losses on our warrants each reporting period and that the amount of such gains or losses could be material. See "*—While LACQ has determined that its public warrants should be classified as equity and its private warrants will be treated as equity on a pro forma basis, due to the uncertainty with respect to classification of warrants issued by SPACs as equity or indebtedness, there can be no assurance that future guidance might not require us to change its position and restate our financial statements and have other adverse consequences."* 

### Our predecessor identified material weakness in its internal control over financial reporting as of December 31, 2020. We may face litigation and other risks as a result of the material weakness in our internal control over financial reporting.

Following this issuance of the SEC Statement, on May 13, 2021, after consultation with its independent registered public accounting firm, LACQ's management and audit committee concluded that, in light of the SEC Statement, it was appropriate to restate its previously issued audited financial statements as of and for the period ended December 31, 2020 (the "Restatement"). See "—Certain of our warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results." As part of such process, it identified a material weakness in its internal controls over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

As a result of such material weakness, the Restatement, the change in accounting for the warrants, and other matters raised or that may in the future be raised by the SEC, we face the potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the Restatement and material weaknesses in our internal control over financial reporting and the preparation of our financial statements. As of the date of this registration statement/prospectus, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition.

## While LACQ determined that its Public Warrants should be classified as equity and its private warrants will be treated as equity on a pro forma basis, due to the uncertainty with respect to classification of warrants issued by SPACs as equity or indebtedness, there can be no assurance that future guidance might not require us to change its position and restate our financial statements and have other adverse consequences.

While LACQ's financial statements have been restated to classify its private warrants as liabilities, we have determined that it is appropriate to continue to classify its Public Warrants as equity. LACQ reviewed the terms of the warrant agreement related to its Public Warrants and concluded that they do not include any provision requiring the Public Warrants to be classified as liabilities. In this respect, it should be noted that the warrant agreement included a provision that in the event of a tender or exchange offer made to and accepted by holders of more than 50% of the outstanding shares of a single class of common shares, all holders of the warrants could be entitled to receive cash for their warrants (the "*tender offer provision*"). This tender offer provision was similar to one of the examples referred to in the SEC Statement as a basis for concluding that warrants issued by a SPAC should be classified as liabilities and not equity. LACQ concluded that, while the SEC Statement did not expressly refer to a multi-class structure (such as a Class A and Class B structure) and not a single class structure like LACQ's. Certain other SPACs, including those with single class structures, have taken different approaches in their recent public filings with the SEC and have classified similar warrants as liabilities.

LACQ classified its private warrants as liabilities because they provided for potential changes to the settlement amounts dependent upon the characteristics of the holder of the warrant (i.e., certain rights differ if the warrants are held by the original holder and its permitted transferees or by a subsequent transferee). LACQ entered into agreements with the holders of its private warrants under which each holder will exchange its private warrants for warrants on the same terms as the private warrants, except that they are non-transferable except to certain permitted transferees. LACQ believed that as a result of the exchange, the private warrants would be appropriately classified as equity and not liabilities subsequent to the date of such agreements.

The accounting treatment of warrants issued by SPACs is subject to substantial uncertainty and there can be no assurance that future guidance might not require us to change LACQ's position and restate our financial statements or treat private warrants as liabilities, which could have a material adverse effect us.

### Our Common Stock could be delisted from Nasdaq and may become subject to "penny stock" rules, which could damage our reputation and the ability of investors to sell their shares.

There can be no assurance that our common stock will maintain our listing on Nasdaq which could have a material adverse effect on us. 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.

### Our directors and executive officers own a significant percentage of our Common Stock and will be able to exert significant control over matters subject to stockholder approval.

As of August 4, 2021, our executive officers and directors beneficially owned approximately 52.7% of our common stock. These stockholders, acting together, may be able to control matters requiring stockholder approval. For example, they may be able to control elections of directors, changes to equity incentive plans, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transactions. This concentration of ownership control may delay, discourage or prevent a change of control, including unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, entrench our management and board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

#### Delaware law and provisions in our certificate of incorporation and bylaws could make a takeover proposal more difficult.

Our organizational documents are governed by Delaware law. Certain provisions of Delaware law and of our charter and bylaws could discourage, delay, defer or prevent a merger, tender offer, proxy contest or other change of control transaction that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of our common stock held by our stockholders. These provisions provide for, among other things:

- the ability of our Board to issue one or more series of preferred stock;
- no stockholder action by written consent;
- inability of stockholders to call a special stockholder meetings;
- a classified board of directors; and
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered before any meeting.

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These anti-takeover provisions as well as certain provisions of Delaware law could make it more difficult for a third party to acquire the Company, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. If prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our common stock. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and to cause the Company to take other corporate actions that our stockholders desire.

#### Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings and the federal district courts as the sole and exclusive forum for other types of actions and proceedings, in each case, that may be initiated by our stockholders, which could limit our stockholders' ability to obtain what such stockholders believe to be a favorable judicial forum for disputes with the Company or our directors, officers or other employees.

Our charters provides that, unless we consent in writing to the selection of an alternative forum, subject to certain limitation, 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 District of Delaware) for:

- any derivative action or proceeding brought on behalf of us;
- any action asserting a claim of breach of a fiduciary duty owed by any of our director, officer or other employee to us or our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the DGCL, our charter or the 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 the 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 the 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 the 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.

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#### USE OF PROCEEDS

All of the shares of common stock and warrants offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any of the proceeds from these sales, except with respect to amounts received by us upon exercise of the warrants to the extent such warrants are exercised for cash.

We will receive up to an aggregate of approximately \$234.0 million from the exercise of the Warrants, assuming the exercise in full of all of the Warrants for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. We will have broad discretion over the use of proceeds from the exercise of the Warrants. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. To the extent that the Warrants are exercised on a "cashless basis," the amount of cash we would receive from the exercise of the Warrants will decrease.

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#### DETERMINATION OF OFFERING PRICE

The offering price of the shares of common stock underlying the Private Placement Warrants and the Private Warrants offered hereby is determined by reference to their exercise price of \$11.50 per share. The offering price of the shares of common stock underlying the GEM Warrants offered hereby is determined by reference to their exercise price of \$10.01 per share. The Public Warrants are listed on the OTC Pink Open Market under the symbol "ENSCW."

We cannot currently determine the price or prices at which shares of common stock, the Private Placement Warrants, the Private Warrants or the GEM Warrants may be sold by the Selling Securityholders under this prospectus.

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#### MARKET PRICE, TICKER SYMBOL AND DIVIDEND INFORMATION

#### **Market Price and Ticker Symbol**

Our common stock are currently listed on the Nasdaq Stock Market under the symbol "ENSC." Our Public Warrants are currently listed on the OTC Pink Open Market under the symbol "ENSCW."

The closing price of our common stock and Public Warrants on August 4, 2021, was \$4.09 and \$0.69, respectively.

#### Holders

As of August 4, 2021, there were approximately 196 holders of record of our common stock, one holder of record of the Public Warrants, six holders of record of the Private Placement Warrants, one holder of the GEM Warrants, four holders of record of the other private warrants, four holders of record of the additional private warrants, and two holders of record of the consultant warrants.

Such numbers do not include beneficial owners holding our securities through nominee names.

#### **Dividend Policy**

We have not paid any cash dividends on our common stock to date. We may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future.

#### Securities Authorized for Issuance under Equity Compensation Plans

As of August 4, 2021, we had a total of 5,444,068 shares of common stock is reserved for issuance under the Incentive Plan, consisting of (i) 4,444,068 shares of common stock underlying awards under the Incentive Plan and (ii) 1,000,000 additional shares of common stock reserved for issuance under the Incentive Plan. We intend to file one or more registration statements on Form S-8 under the Securities Act to register the shares of common stock issued or issuable under the Incentive Plan.

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#### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

#### Introduction

The unaudited pro forma combined balance sheet as of March 31, 2021 gives pro forma effect to the business combination as if it had been consummated as of that date. The unaudited pro forma combined statements of operations for the three months ended March 31, 2021 give pro forma effect to the business combination as if it had occurred as of January 1, 2020. The unaudited pro forma combined statements of operations for the year ended December 31, 2020 give pro forma effect to the business combination as if it had occurred as of January 1, 2020. This information should be read together with Ensysce's and LACQ's respective audited financial statements and related notes, *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* and other financial information included elsewhere in this registration statement/prospectus.

The unaudited pro forma combined financial information is for illustrative purposes only. The financial results may have been different had the companies always been combined. The unaudited pro forma condensed combined financial information is not indicative of the historical financial position and results that would have been achieved had the companies always been combined or the future financial position and results that Ensysce will experience. Ensysce and LACQ had no historical relationship prior to the business combination. Accordingly, no pro forma adjustments were required to eliminate activities between the companies.

The following pro forma condensed combined financial statements presented herein reflect the actual redemption of 5,000 shares of common stock of LACQ's stockholders in conjunction with the shareholder vote on the business combination contemplated by the Merger Agreement and meeting held on June 28, 2021.

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# PRO FORMA COMBINED BALANCE SHEET AS OF MARCH 31, 2021 (UNAUDITED)

		Ensysce Historical)	(	LACQ Historical)	A	ransaction Accounting djustments	Note 3		Pro Forma Combined	
Assets						ajasententes	110000		, on one of the second s	
Current assets:										
Cash and cash equivalents	\$	289,927	\$	18,034	\$	12,690,899	Α	\$	7,719,926	
						(405,444)	С			
						(4,821,558)	Е			
						(51,932)	F			
Right of use asset		16,476		-		-			16,476	
Prepaid expenses and other current assets		78,880		210,179		-			289,059	
Deferred transaction costs		797,902		-	_	(797,902)	Е		-	
Total Current Assets		1,183,185		228,213		6,614,063			8,025,461	
Marketable securities held in Trust Account		-		12,690,899		(12,690,899)	Α		-	
Property and equipment, net		100		-		-			100	
Other assets		3,780		61,278					65,058	
Total Assets	\$	1,187,065	\$	12,980,390	\$	(6,076,836)		\$	8,090,619	
Liabilities and Shareholders' Equity										
Current liabilities:										
Accounts payable and accrued expenses	\$	2,883,931	\$	319,180	\$	(1,117,082)	Е	\$	2,086,029	
Lease liability	Ŷ	17,848	Ψ	-	Ŷ	-	-	Ψ	17,848	
Note payable, current portion		4,526,552		-		(405,444)	С			
····· p, ····· p ······		.,				(4,121,108)	G			
Derivative liabilities, current portion		709,583		-		(709,583)	G		-	
Total Current Liabilities		8,137,914	-	319,180		(6,353,217)		_	2,103,877	
Note payable, net of current portion		349,272				(349,272)	G		2,105,077	
Convertible promissory note				460,000		(460,000)	B		-	
Derivative liabilities, net of current portion		3,316		8,307,375		(8,307,375)	D		-	
F		-,		.,,		(3,316)	G			
Deferred underwriting fees		-		2,000,000		(2,000,000)	E		-	
Total Liabilities		8,490,502		11,086,555		(17,473,180)		_	2,103,877	
Commitments and Contingencies										
Stockholders' (Deficit) Equity										
Preferred stock		-		-		-			-	
Common stock		6,095		622		75	Е		2,439	
		.,.,.				(1)	F		_,,	
						(4,352)	G			
Additional paid-in capital		49,818,501		4,812,500		460,000	В		81,172,629	
						8,307,375	D			
						8,199,925	Е			
						(51,931)	F			
						1,555,445	G			
						8,070,814	Н			
(Accumulated deficit) Retained earnings		(56,906,447)		(2,919,287)		(10,702,378)	Е		(74,966,740	
						3,632,186	G			
						(8,070,814)	н			
Stockholders' (Deficit) Equity		(7,081,851)		1,893,835		11,396,344			6,208,328	
Noncontrolling interest		(221,586)		_		-			(221,586	
Total Stockholders' (Deficit) Equity		(7,303,437)		1,893,835		11,396,344			5,986,742	
Total Liabilities and Stockholders' Equity	\$	1,187,065	\$	12,980,390	\$	(6,076,836)		\$	8,090,619	
					_					

# PRO FORMA COMBINED STATEMENT OF OPERATIONS THREE MONTHS ENDED MARCH 31, 2021 (UNAUDITED)

	sysce orical)	LACQ (Historic		Transa Accour Adjustr	nting	Note 3	o Forma ombined
Federal grants	\$ 250,576	\$	-	\$	-		\$ 250,576

Research and development	324,378		-		-			324,378
Stock-based compensation	-		-		8,070,814	AA		8,070,814
General and administrative	490,471		292,027		-			782,498
Operating expenses	 814,849		292,027		8,070,814			9,177,690
	 	_						
Loss from operations	(564,273)		(292,027)		(8,070,814)			(8,927,114)
				_				
Other income (expense):								
Change in fair value of derivative liabilities	(39,585)		(1,481,087)		1,520,672	BB		-
Interest income	-		229		(229)	CC		-
Interest expense	 (347,834)				347,834	DD		_
(Loss) income before income taxes	(951,692)		(1,772,885)		(6,202,537)		_	(8,927,114)
Provision (Benefit) for income taxes	 -		(61,278)		61,278	EE		_
Net (loss) income	\$ (951,692)	\$	(1,711,607)	\$	(6,263,815)		\$	(8,927,114)
	 		<u> </u>		<u> </u>			<u> </u>
Basic and diluted weighted average shares outstanding			6,224,268		18,051,273	FF		24,275,541
Basic and diluted net loss per share		\$	(0.27)				\$	(0.37)
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## PRO FORMA COMBINED STATEMENT OF OPERATIONS YEAR ENDED DECEMBER 31, 2020 (UNAUDITED)

	Ensysce Historical)	(1	LACQ Historical)	Acco	action unting tments	Note 3	Pro Forma Combined
Federal grants	\$ 3,931,209	\$	-	\$	-		\$ 3,931,209
Research and development	4,389,579		-		-		4,389,579
Stock-based compensation	-		-	8	,070,814	AA	8,070,814
General and administrative	 1,154,917		1,368,841		-		 2,523,758
Operating expenses	5,544,496		1,368,841	8	3,070,814		14,984,151
Loss from operations	 (1,613,287)		(1,368,841)	(8	3,070,814)		(11,052,942)
Other income (expense):							
Change in fair value of derivative liabilities	2,447,908		2,126,250	(4	1,574,158)	BB	-
Forgiveness of debt	-		3,298,207		-		3,298,207
Interest income	-		719,646		(719,646)	CC	-
Interest expense	 (995,496)		(220,000)	1	,215,496	DD	 -
(Loss) income before income taxes	(160,875)		4,555,262	(12	2,149,122)		(7,754,735)
Provision for income taxes	 -		244,493		(244,493)	EE	 
Net (loss) income	\$ (160,875)	\$	4,310,769	\$ (11	,904,629)		\$ (7,754,735)
Basic and diluted weighted average shares outstanding			6,642,759	17	,632,782	FF	24,275,541
Basic and diluted net income (loss) per share		\$	0.65				\$ (0.32)
	59						

# NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

# Note 1 - Description of the Transactions

On January 31, 2021, LACQ entered into an Agreement and Plan of Merger (the 'Merger Agreement') by and among LACQ, EB Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of LACQ ('Merger Sub'), and Former Ensysce, providing for, among other things, and subject to the 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 surviving as a wholly-owned subsidiary of LACQ (the 'Merger'). On June 30, 2021 (the 'Closing Date'), the Merger was consummated. The Merger, together with the other transactions contemplated by the Merger Agreement and the related agreements, are referred to herein as the 'Transactions.''

Pursuant to the Merger Agreement, at the effective time of the Merger:

- each outstanding share of Former Ensysce's common stock, including shares issuable upon conversion of certain convertible notes of Former Ensysce convert into
  Former Ensysce common stock immediately prior to the effective time of the Merger, was cancelled and automatically converted into the right to receive a number of
  shares of LACQ common stock calculated pursuant to the Merger Agreement; and
- each option to acquire Former Ensysce's common stock that was outstanding immediately prior to the effective time of the Merger, was assumed and automatically
  converted into an option to purchase a number of shares of LACQ common stock at the exercise price calculated pursuant to the Merger Agreement and each warrant to
  acquire Former Ensysce's common stock that was outstanding immediately prior to the effective time of the Merger, was assumed and automatically converted into a
  warrant to purchase a number of shares of LACQ common stock at the exercise price calculated pursuant to the Merger Agreement.

The following summarizes the number of outstanding shares of the combined company after giving effect to the Transactions, excluding the potential dilutive effect of the exercise of 20,007,398 warrants and 4,444,068 stock options:

Shares

%

Former Ensysce investors		
	17,431,273	71.8
LACQ Initial Stockholder shares (Sponsors and Strategic Investor)	6,000,000	24.7
LACQ shares issued to Other Stockholders	625,000	2.6
LACQ public shares (excluding the Strategic Investor)	219,268	0.9
	24,275,541	100.0

# Note 2 - Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses." Release No. 33-10786 replaced the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction (*"Transaction Accounting Adjustments"*) and present the reasonably estimable synergies and other transaction effects that have occurred or are reasonably expected to occur (*"Management's Adjustments"*). The unaudited pro forma condensed combined financial information does not present Management's Adjustments and only present Transaction Accounting Adjustments.

The unaudited pro forma combined balance sheet as of March 31, 2021 has been prepared using the following:

- Ensysce's unaudited historical condensed consolidated balance sheet as of March 31, 2021, as included elsewhere in this registration statement/prospectus; and
- LACQ's unaudited historical condensed consolidated balance sheet as of March 31, 2021, as included elsewhere in this registration statement/prospectus.

The unaudited pro forma combined statement of operations for the three months ended March 31, 2021 has been prepared using the following:

- Ensysce's unaudited historical condensed consolidated statement of operations for the three months ended March 31, 2021, as included elsewhere in this registration statement/prospectus; and
- LACQ's unaudited historical condensed consolidated statement of operations for the three months ended March 31, 2021, as included elsewhere in this registration statement/prospectus.

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The unaudited pro forma combined statement of operations for the year ended December 31, 2020 has been prepared using the following:

- Ensysce's audited historical consolidated statement of operations for the year ended December 31, 2020, as included elsewhere in this registration statement/prospectus; and
- LACQ's audited historical statement of operations for the year ended December 31, 2020, as included elsewhere in this registration statement/prospectus.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, LACQ will be treated as the acquired company for financial reporting purposes. Accordingly, the Merger will be treated as the equivalent of Ensysce issuing stock for the net assets of LACQ accompanied by a recapitalization. The net assets of LACQ will be stated at historical cost with no goodwill or other intangible assets recorded. Operations prior to the Merger are those of Ensysce.

Ensysce was determined to be the accounting acquirer based on evaluation of the following facts and circumstances:

- Ensysce has the largest portion of voting rights in the combined company;
- Ensysce has the right to appoint the majority of the directors of the combined company;
- Ensysce's existing senior management comprises the senior management of the combined company;
- The operations of Ensysce primarily represent the operations of the combined company; and
- The combined company assumed Ensysce's name and headquarters.

Upon its initial analysis, management did not identify differences in accounting policies that would have a material impact on the pro forma combined financial information. Accordingly, the unaudited pro forma combined financial information does not assume any differences in accounting policies. Upon a comprehensive review of such policies, management may identify differences between the accounting policies of the two entities which, when conformed, could have a material impact on the financial statements of the combined company.

There was no historical activity with respect to Merger Sub, and accordingly, no adjustments were required with respect to this entity in the pro forma combined financial statements.

# Note 3 - Transaction Accounting Adjustments

#### Pro Forma Adjustments to the Unaudited Condensed Combined Balance Sheet as of March 31, 2021

- A Reflects the release of cash from marketable securities held in the trust account.
- **B** Reflects the conversion of convertible promissory notes due to the Sponsors into warrants of the combined company. The warrants issued in connection with such conversion were on the terms set forth in the note D below and, accordingly, meet the criteria to be classified as equity instruments, in accordance with Accounting Standards Codification ("ASC") No. 815, "Derivatives and Hedging" ("ASC 815") and ASC No. 480 "Distinguishing Liabilities from Equity" ("ASC 480").
- C Reflects the repayment of promissory notes.
- D Reflects the reclassification of 6,325,000 Private Placement Warrants, 1,000,001 warrants issued to the Sponsors and HG Vora and 566,288 warrants issued to GTWY Holdings for an aggregate amount of \$8,307,375 to equity. The reclassification is the result of the exchange of the original warrants for new warrants that are non-transferable except to permitted transferees, such that the warrants will be classified as equity instruments, in accordance with ASC 815 and ASC 480.
- E Reflects fees and expenses related to the business combination consisting of (a) the sum of (i) \$1,117,082 of accounts payable and accrued expenses directly attributable to business combination related to legal, financial advisory, accounting and other professional fees, (ii) an additional \$4,502,378 of legal, financial advisory, accounting and other professional fees, (iii) a commitment fee of \$1.2 million payable under Ensysce's GEM Agreement after the closing, plus (iv) \$5.0 million payable to DelMorgan; net of (b) \$319,180 which is accrued on LACQ's balance sheet and (c) \$797,902 which is accrued on Ensysce's balance sheet.

LACQ paid \$4,821,558 of cash in satisfaction of \$319,180 of accounts payable and \$4,502,378 of additional legal, financial advisory, accounting and other professional fees. In payment of the payables in clause (iii) and (iv) in the preceding paragraph, LACQ will issue an estimated 120,000 shares of LACQ common stock on account of a commitment fee of \$1.2 million payable under Ensysce's GEM Agreement after the closing, valued at \$10.00 per share, for services rendered, and issued to DelMorgan 500,000 shares of LACQ common stock, valued at \$10.00 per share, and private warrants to purchase 500,000 shares of LACQ common stock (which will be on the terms set forth in note D above and, accordingly, will meet the criteria to be classified as equity instruments, in accordance with ASC 815 and ASC 480). These amounts are payable in LACQ common stock in accordance with rights provided under existing agreements. No value has been given to the private warrants to be lissued to DelMorgan in clause (iv), because there was a corresponding reduction in the private warrants to be issued by LACQ to the Sponsors pursuant to the Warrant Surrender Agreement. The total value of these shares, amounting to \$6,200,000, will be recorded as legal, financial advisory, accounting and other professional fees. The direct, incremental costs of the business combination related to the legal, financial advisory, accounting and other professional fees of approximately \$10,702,378 is reflected as an adjustment to accumulated deficit. In addition to the amounts above, LACQ will also issue 125,000 shares of common stock to the underwriter in satisfaction of \$2,000,000 of deferred underwriting fees payable (reduced from the \$6,750,000 referenced above through agreement with the underwriters dated January 31, 2021).

- F Reflects 5,000 shares redeemed for \$51,392 cash by LACQ stockholders prior to closing of the Merger.
- **G** Reflects the recapitalization of LACQ through (a) the contribution of all the share capital in Ensysce to LACQ in the amount of \$49,824,596, (b) the conversion of promissory notes into common stock in the amount of \$4,470,380, (c) the elimination of the derivative liability associated with the promissory notes in the amount of \$712,899, (d) the issuance of 17,431,273 newly issued shares of common stock in connection with the business combination and (e) the elimination of the historical accumulated deficit of LACQ, the legal acquiree, in the amount of \$2,919,287.
- H Reflects the issuance of 1,106,108 warrants under the GEM Agreement, representing the right to purchase an estimated 1,106,108 shares of common stock (which amount is equal to 4% of the total number of common shares outstanding as of the closing date, calculated on a fully diluted basis), at a strike price of \$10.01 per share. The warrants were valued at \$7.30 per share, or \$8,070,814, utilizing the Black-Scholes option pricing model using the following assumptions: (i) a risk-free interest rate of 0.45%, (ii) an expected term of 3.00 years, (iii) an assumed volatility of 126.6% and (iv) no dividends.

# Pro forma adjustments to the Unaudited Combined Statements of Operations for the Three Months Ended March 31, 2021 and Year Ended December 31, 2020

- AA Reflects an adjustment to record the issuance of 1,106,108 warrants under the GEM agreement, representing the right to purchase an estimated 1,106,108 shares of common stock at a strike price of \$10.01 per share.
- BB Reflects an adjustment to eliminate the change in fair value of derivative liabilities as of the beginning of the period.
- CC Reflects an adjustment to eliminate interest income on marketable securities held in the trust account as of the beginning of the period.
- DD Reflects an adjustment to eliminate interest expense on notes payable as of the beginning of the period.
- EE Reflects an adjustment to record normalized blended statutory income tax benefit rate of 21% for pro forma financial presentation purposes resulting in the recognition of an income tax benefit, which however, has been offset by a full valuation allowance as the combined company expects to incur continuing losses.
- FF The calculation of weighted average shares outstanding for basic and diluted net income (loss) per share assumes that LACQ's initial public offering occurred as of the earliest period presented. In addition, as the business combination is being reflected as if it had occurred as of the beginning of the earliest period presented, the calculation of weighted average shares outstanding for basic and diluted net income (loss) per share assumes that the shares have been outstanding for the entire period presented. This calculation is retroactively adjusted to eliminate the number of shares redeemed in the business combination for the entire period. The computation of diluted loss per share excludes the effect of 4,444,068 options and 20,007,398 warrants because the inclusion of these securities would be anti-dilutive.

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# BUSINESS

References in this section to "we," "our," "us," the "Company" or "Ensysce" generally refer to Ensysce and its consolidated subsidiaries.

# **Business Overview**

Ensysce Biosciences, Inc. is a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the fear of and the potential for addiction, opioid misuse, abuse, and overdose. We have also incorporated a 79.2%-owned subsidiary, Covistat, a clinical stage pharmaceutical company that is developing a compound utilized in our overdose protection program for the treatment of COVID-19. Certain of our affiliates own the remaining portions of Covistat. See *"Certain Relationships and Related Person Transactions"* for additional information.

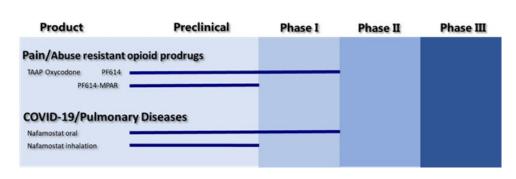
We were originally incorporated in the State of Delaware in April 2003 as PharmacoFore, Inc. and, in January 2012, we changed our name from PharmacoFore, Inc. to Signature Therapeutics Inc. ("Signature"). On December 28, 2015, Signature, Signature Acquisition Corp., a wholly-owned subsidiary of Signature (SAQ"), and Ensysce Biosciences, Inc. ("EB") entered into an Agreement and Plan of Merger ("EB-ST Agreement"). Pursuant to the EB-ST Agreement, SAQ merged with and into EB with EB surviving the merger as a wholly-owned subsidiary of Signature. As part of the transaction, Signature changed its name to "Ensysce Biosciences, Inc." ("Former Ensysce") and the Merger Agreement, on Merger Sub merged with and into Former Ensysce, with Former Ensysce surviving the transaction as a wholly-owned subsidiary of LACQ. As part of the transaction, LACQ changed its name to "Ensysce Biosciences, Inc." and Former Ensysce changed its name to EBI OpCo, Inc.

In August 2020, Covistat entered into a Technology Transfer Agreement with Mucokinetica to acquire its intellectual property and all assets associated with the inhaled nafamostat program. Specifically, Covistat acquired Patent EP2124926B1 and all data and assets associated with the development and expansion of the inhaled nafamostat program. These assets included COVID-19 and cystic fibrosis drug targets in development.

In consideration for this intellectual property, Mucokinetica received a 1% equity ownership in Covistat, and its founders, Roderick Hall and Peter Cole, entered into Consulting Agreements with Covistat. Pursuant to these agreements, Messrs. Hall and Cole are each paid hourly consulting fees not to exceed a monthly maximum of \$20,000 and will receive success fees up to \$150,000 each if a drug target covered by the inhaled nafamostat program is out-licensed. The amount of the success fee depends upon revenues realized by Covistat from the out-licensing of the drug target.

We are currently developing product candidates designed to improve the safety of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Prescription opioid abuse and addiction present major burdens to society, resulting in significant costs, illnesses, and deaths, many of which we believe could be prevented through the use of our proprietary technologies. We believe the intertwined issues of (1) the widespread abuse of prescription opioids and (2) the resultant reluctance of many prescribers to write prescriptions for opioid analgesics, have resulted in the persistent under-treatment of patients with moderate-to-severe pain. Our platforms utilize a novel molecular delivery technology designed to deter prescription opioid abuse at the molecular level.

Our current development pipeline includes two new drug platforms - an abuse-resistant opioid prodrug technology – theTrypsin Activated Abuse Protection, or the TAAP platform, and an over-dose protection opioid prodrug technology - the Multi-Pill Abuse Resistant, or the MPAR<sup>TM</sup> platform. The TAAP platform is designed to seek to improve the care of patients with chronic pain while reducing the human and economic costs associated with prescription opioid drug abuse. Our development pipeline of TAAP prodrugs is summarized in the table below. The MPAR<sup>TM</sup> platform when combined with our TAAP prodrugs is designed not only to seek to prevent abuse of prescription drugs but also to reduce overdose occurrences. Each prodrug is intended to be able to be combined with our MPAR<sup>TM</sup> technology for overdose protection. Additionally, nafamostat di-mesylate ("*inafamostat*"), which is an ingredient in our overdose protection combination products, is also being developed for the intended purpose of treating infection and pulmonary lung diseases.



The technology under the TAAP platform when applied to opioid drugs is designed to release clinically effective opioid drugs only when exposed to specific physiological conditions (i.e., when the drug is ingested and exposed to the digestive enzyme trypsin). Our lead product candidate, PF614, is a TAAP oxycodone prodrug that is a biologically inactive compound which can be metabolized in the body to produce a drug with demonstrable features aimed at resisting both oral and non-oral modes of prescription drug abuse. This approach differs from current formulation-based strategies such as OxyContin OP which uses Intac® Technology (crush-resistant polymers) and Extampza®ER which uses DETERx<sup>TM</sup> (insoluble fatty acid salts in polymers), in a number of ways. First, the TAAP technology seeks to remove the ability of a user to abuse PF614 intravenously or intranasally based on preclinical studies that show PF614 does not readily convert into oxycodone in the blood stream and trypsin is not present in the nasal passage, and, accordingly, PF614 would not convert to oxycodone in the nose. Furthermore, the chemically modified and abuse-resistance TAAP opioid drug is unaffected by simple physical manipulations designed to extract abusable amounts of opioid, such as through kitchen chemistry. Our portfolio of TAAP product candidates is based on a differentiated understanding of chemical reactivity and metabolism, as well as the key pillars of our unique approach which focuses on: (1) enzyme mediated metabolic activation localized in the gastrointestinal track; (2) rearrangement chemistry to achieve ideal pharmacokinetic release of active drug products; and (3) robust packages of preclinical data that set forth the metabolic and chemical activation profile for each of our clinical candidates. This approach has led to the filing of an Investigational New Drug application, or IND (116794), and a Phase 1 clinical trial for PF614, which was completed in February 2018. In addition, the clinical data from the Phase 1 trial has demo

The MPAR<sup>TM</sup> technology is designed to enable the bioavailability of active opioid following co-ingestion of multiple doses, whether inadvertent or intentional, to be limited through a combination of a TAAP prodrug with nafamostat. Nafamostat is a small molecule with a steep dose response curve and is a highly potent trypsin inhibitor. When combined with our TAAP prodrugs in an appropriate ratio, it is designed to not affect metabolism and the release of the active pharmaceutical ingredient. However, if the TAAP prodrug nafamostat combination is taken in larger quantities than intended, the excess nafamostat is designed to inhibit trypsin, thereby preventing metabolic activation and averting a drug overdose. We believe the potential benefits to society of an opioid that resists both oral and parenteral abuse are considerable.

Our pipeline has been developed over the course of 15 years of research and investment and includes three clinical-stage product candidates. While our principal focus and lead product candidates are geared towards combating abuse and overdose of opioid drugs, we have, over the years of research and development, discovered and recognized qualities and unique features of certain product candidates that may be useful in addressing other treatments. For example, we discovered the ability of nafamostat in inhibiting the action of enzymes associated with the COVID-19 infection, and, as such, have devoted efforts to develop an oral and inhalation drug product of nafamostat, for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis.

### PF614

PF614 is our lead TAAP prodrug candidate that is being developed, for the treatment of chronic pain. PF614 is an extended release TAAP prodrug of oxycodone designed to release oxycodone on an extended basis under certain specific physiological circumstances when taken orally. PF164 was evaluated for safety and pharmacokinetic release of oxycodone in a Phase 1 single ascending dose clinical trial in 64 healthy subjects. The trial showed that PF614 was well tolerated with no serious adverse events. The study also showed pharmacokinetics had a maximum blood concentration of oxycodone at 4 to 6 hours after swallowing PF614, demonstrating its extended release profile. We believe PF614 has the potential to provide a safer alternative to the abuse deterrent formulated opioid products that are currently commercially available.

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#### **РF614-МРА***R*™

PF614-MPAR<sup>TM</sup>, a combination product of PF614 and nafamostat has been designed to limit abuse potential by providing resistance to use through injection or inhalation and to provide overdose protection against excessive oral ingestion. Our IND application (150966) for PF614-MPAR<sup>TM</sup> has received the FDA allowance and we currently plan to proceed to a Phase 1 clinical trial with an authorized IND in 2021.

#### Nafamostat

Nafamostat is an enzyme inhibitor (protease inhibitor) used in our combination overdose protection technology, MPAR<sup>TM</sup>. Due to its ability to inhibit the action of enzymes associated with the COVID-19 infection, we are also developing an oral and inhalation drug product of nafamostat, for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis. An IND was submitted (149877) for the evaluation of oral nafamostat in coronaviral infections.

# Next Steps

We intend to undertake additional clinical studies in 2021. We have initiated a Phase 1b multidose and Phase 2 bioequivalence clinical trials to evaluate the release of

oxycodone from PF614, and a Phase 1 safety clinical trial to evaluate safety and pharmacokinetics for PF614-MPAR<sup>TM</sup>, a combination of our lead product candidate, PF614, with our MPAR<sup>TM</sup> technology. Additionally, two human abuse liability studies will be initiated to understand the tendency for drug abusers to like the effects achieved from taking PF614 either orally or nasally as compared to that of a comparator product such as crushed OxyContin. We are also planning to evaluate nafamostat in COVID-19 subjects when delivered as an oral drug product. The ability to undertake these studies will depend on additional financing. We have funded our operations to date primarily with proceeds from the sale of equity and borrowings under convertible promissory notes and federal grants. See "*—Promissory Notes*" and "*—Federal Grants*" for additional information. On December 29, 2020, we entered into the GEM Agreement, which gives us the ability to draw down up to \$60 million of gross proceeds in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. See "*—GEM Facility*" for additional information.

# **Our Strategy**

We seek to become a leading specialty pharmaceutical company focused on addressing the safe use of pharmaceuticals by developing a broad portfolio of TAAP and  $MPAR^{TM}$  products with enhanced safety features and benefits. Specifically, we intend to:

- Capitalize on our management team's collective experience and expertise in the development and approval process of innovative drug delivery technologies that address
  medication safety. We have received fast track designation for PF614, our lead drug candidate, from the FDA. However, fast track designation does not guaranty a faster
  development or regulatory review or approval process and does not assure FDA approval. We are currently devoting our efforts to develop PF614 for the chronic pain
  market, while bringing other TAAP and MPAR<sup>TM</sup> products through regulatory approval with the expertise of team members who have launched a number of products in
  the central nervous system, or CNS, space.
- Leverage our proprietary technologies to develop a full line of pharmaceutical products. Medication abuse and misuse is not limited to single drugs but often pervades entire drug categories. We have initiated programs to apply our TAAP and MPAR<sup>™</sup> technology to other categories of prescription drugs such as amphetamine and methadone.
- Commercialize our products through focus on the United States market to commercialize our lead products while licensing our technology internationally and through patent life extension. We intend to bring PF614 and PF614-MPAR<sup>™</sup> through regulatory approval to commercialization in the United States. We expect to seek licensing partners in jurisdictions outside the United States for our product candidates. We also expect to seek partners who wish to license our TAAP and MPAR<sup>™</sup> technologies for patent life extension of their portfolio products, or to improve delivery or pharmacokinetic properties of certain of their drug candidates.

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• Maintain an efficient internal cost structure. Our internal cost structure has been designed to enable us to focus on our lead drug products, PF614, PF614-MPAR<sup>™</sup>, and nafamostat oral and inhalation drug products clinically through to commercialization. We outsource many high-cost elements of development such as clinical trials. Outsourcing these functions minimizes our fixed overhead without reliance or dependence on individual third parties, and capital investment and thereby reduce our business risk in our view.

# **Our Strengths**

We seek to achieve our strategic goals through the utilization of our key competitive strengths, including:

- Our worldwide patent portfolio has extensive coverage in major markets and coverage in select secondary markets. These patents provide protection to the underlying molecules of both our immediate and extended release drug candidates. We expect our patent portfolio will continue to expand and deepen as new products are developed and new markets are identified. Our lead product candidates are new chemical entities and not simply re-formulations. Our TAAP prodrugs have a unique technology that has been demonstrated in our Phase 1 clinical trials for PF614.
- Pedigree of our leadership team in all stages of discovery, development, marketing, and business development. Our team has successfully developed and launched many successful products with multi-billion dollar selling market leaders in the CNS area.
- Fast track designation Food and Drug Administration ("FDA"). Our lead clinical candidate, PF614, has received fast track designation from the FDA.
- Received Federal grants from Federal agencies including the National Institute of Drug Abuse ("NIDA"), the National Institutes of Health ("NIH"). We have received two large Federal government grants to support our MPAR<sup>™</sup> overdose protection program and our opioid use disorder program from NIH/NIDA.
- Clinical proof of concept. We have conducted a Phase 1 trial with TAAP prodrug PF614. The trial demonstrated that, after oral administration of the TAAP prodrug, the corresponding opioid was measured in the subjects' blood.

#### **Market Opportunity**

### Drug Abuse and Drug Overdose

Pain medications are essential for improving the care and outcomes for the 100 million adults living with chronic pain in the United States. Prescription opioids drugs, such as morphine, hydromorphone, hydrocodone, and oxycodone, have a long history of use for the management of patient pain. Because these drugs are highly effective in treating pain, they are one of the largest prescribed drug categories in the United States, with 191 million prescriptions dispensed in the United States in 2017 and over \$11 billion in market size in the United States over that same period. Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches, and other formats. Oxycodone is one of the most effective pain killers available in the market today. This drug helps the patient to overcome the pain and focus on his or her work and other chores. Opioids have an increased risk of dependence and, when used improperly, a common side effect of high doses of opioids like oxycodone can be euphoria, or a "high." As a result of these side effects, opioids have become amongst the most misused or abused prescription drugs in the United States. Opioid abuse has been declared a public-health emergency; more than 130 people die every day from opioid-related overdoses. Based on information from the Cent for Disease Control, or the CDC, the most common drugs involved in prescription opioid overdose deaths include: Methadone, Oxycodone (such as OxyContin®), and Hydrocodone (such as Vicodin®). The CDC indicates that improving opioid prescripting, treatment of opioid use disorder, and prevention of opioid use disorder would help improve this opioid crisis. From 2017 to 2018 the prescription opioid-involved death rates decreased by 13.5% showing attention to the problem had beneficial effect. Misuse or abuse of opioids is often done in one of the following manners:

- Oral Excessive Tablet Abuse. Generally recognized as the most prevalent route of administration by abusers, an abuser orally ingests more tablets (or capsules) than is recommended for pain relief.
- Nasal snorting. Crushed tablets are insufflated for absorption of the drug through the nasal tissues.
- Injection. The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.

- Oral Manipulated Tablet Abuse. Extended-release tablets or patches are crushed, chewed, or otherwise physically or chemically manipulated to defeat an extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.
- Poly-pharmacy. Opioids are sometimes used in conjunction with alcohol, methamphetamine, or other drugs to accentuate the euphoria.
- Overdose. Users may accidentally introduce excessive quantities of drugs in their systems or combine drugs that may heighten the chance of adverse effects of drugs. Some patients may over-ingest drugs accidentally or with the express intent of suicide.
- Chronic or prolonged use. Chronic or prolonged use of opioids resulting in dependence is another form of misuse or abuse.

Amphetamines like Adderall are manufactured in pill form and are intended for oral ingestion. Fifty-three percent of Adderall prescriptions are prescribed to the 10.5 million adults that are diagnosed with attention deficit hyperactivity disorder, or ADHD. ADHD is the most common neurodevelopment disorder in children. Five million adults misuse stimulant medication annually, by using alternative consumption methods to achieve a more intense high faster; snorting or injecting are most-common methods of abuse. Both of these methods involve crushing pills.

We believe that having prescription drug products available that have a reduced potential for abuse by crushing and injecting, snorting, and chewing could provide an even greater reduction of prescription opioid related deaths in the abuse of opioids or amphetamines.

### Nafamostat

Nafamostat's market opportunity is multifaceted. The oral form could be used alone or in combination with other antiviral drugs that target separate processes needed for virus product, such as RNA replication or viral protein processing. An inhaled form of nafamostat could be applied to patients that have a more severe stage of the disease.

Our lead clinical program is an oral drug product of nafamostat for use against COVID-19 and other coronaviral infections. The dosing and positioning of oral nafamostat will be similar to antiviral drug oseltamivir phosphate, Tamiflu®. Tamiflu® is a seasonal influenza treatment that is taken in oral form within two days of influenza symptoms starting and applying a two-dosage daily schedule. During the H5N1 outbreaks and the H1N1 and other coronavirus outbreaks, Tamiflu® had annual U.S. sales above \$1 billion and has had cumulative sales of \$15.9 billion since its launch in 1999.

The World Health Organization estimates influenza epidemics result in approximately three to five million cases of severe illness and 250,000 to 500,000 deaths each year. Nafamostat will be well positioned to generate revenue from several changing market conditions:

- As new virus strains of influenza and coronavirus create new outbreaks, there is a window of opportunity to grow or boost sales before production of the appropriate vaccine is increased.
- Applying our antiviral in situations of waning immunity to vaccines, particularly in the elderly, and in immunocompromised patients; seasonal influenza vaccines are approximately 45% effective since the 2010 influenza season.
- Universal influenza and coronavirus vaccines remain several years from market launch, making nafamostat a potential first line of defense against infections.
- There are only four antiviral treatments for early symptoms of influenza for hospitalized patients that have severe, complicated, or progressive illness, or who are at high
  risk for complications.
- The reality of unexpected and rapidly spreading influenza or coronavirus outbreaks causes healthcare systems to stockpile and replenish first response antivirals.
- Utilizing a drug repurposing model and the Hatch Waxman Act, we believe that we will be able to receive eight to ten years of market exclusivity in North America, European Union, and Japan. See "—Intellectual Property" for further detail.

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# **Our Technology Platform Solution**

# TAAP Prescription Drugs

The technology under the TAAP platform utilizes a novel technology designed to deter prescription drug abuse at the molecular level. The molecular delivery system is designed to release clinically effective drugs only when exposed to specific physiological conditions (i.e., when the drug isingested and exposed to the digestive enzyme trypsin). Our TAAP prodrugs delivery system demonstrates a number of features aimed at resisting both oral and non-oral modes of abuse. This platform's approach differs from current formulation-based strategies (abuse deterrent formulations, or ADFs) in a number of ways. First, the abuse-resistance provided by TAAP is designed to be unaffected by simple physical manipulations (e.g. crushing and extraction and/or chewing of the dose form provided to patients). We believe the potential benefits to society of applying TAAP to opioids and amphetamines providing medication that resists both oral and parenteral abuse are considerable.

# MPAR<sup>™</sup> Prescription Drugs

MPAR<sup>TM</sup> combination therapy, involves co-formulating TAAP prodrugs with a trypsin inhibitor, nafamostat, which, when administered at prescribed dose levels, are intended to have no effect on the conversion of the prodrug to the active ingredient thus allowing normal drug plasma exposure levels. However, if the drug were taken in greater than prescribed quantities, the trypsin inhibitor would also be present at higher levels, inhibiting the first step in the activation process, preventing the conversion of the prodrug to the active ingredient thus limiting the potential to an overdose from the medication.

### **Our Development Programs**

We are currently developing product candidates designed to improve the safety of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Our development pipeline of TAAP prodrugs is summarized in the table below. Each prodrug is intended to be able to be combined with our MPAR<sup>TM</sup> technology for overdose protection. Additionally, nafamostat, which is an ingredient in our overdose protection combination products, is also being developed for infection and pulmonary lung diseases.

Product	Preclinical	Phase I	Phase II	Phase III
Pain/Abuse resistant o	pioid prodrugs			
TAAP Oxycodone PF614 PF614 PF614-MPAR				
COVID-19/Pulmonar	y Diseases			
Nafamostat oral				
Nafamostat inhalation				

Besides our clinical candidates, we have a product portfolio of other TAAP and MPAR<sup>TM</sup> opioids and amphetamines that could potentially be developed to build on this pipeline.

#### **Clinical agents**

# PF614

PF614 is a chemically modified, extended-release oxycodone-derivative which releases clinically effective oxycodone only when exposed trypsin in the gut (i.e., when the drug is ingested). This approach differs from formulation-based strategies which are currently commercially available, in a number of ways. First, the abuse-resistance provided by PF614 is designed to be unaffected by simple physical manipulations (e.g., extraction, chewing, and/or crushing). It also limits the bioavailability of active medication following co-ingestion of multiple doses.

Following ingestion, the release of oxycodone from PF614 proceeds via a two-step process comprised of (1) trypsin activation in the small intestine and (2) a subsequent intramolecular cyclization release reaction. This reaction releases oxycodone with concomitant formation of a cyclic urea metabolite. The time-course of oxycodone release from PF614 is a function of the kinetics of (i) the trypsin hydrolysis and (ii) the cyclization-release reaction. In the Phase 1 study of PF614, the time to maximal blood concentration of oxycodone ( $T_{max}$ ) was five to six hours for the release of oxycodone and this time cannot be modified by crushing, chewing, or physically manipulating the drug product. Oxycodone safety, metabolism, and pharmacokinetics have been well studied.

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### PF614-101 Phase 1 Clinical Trial

PF614 (IND 116796) has been evaluated in a Phase 1 clinical study for safety and pharmacokinetics of oxycodone release in 64 healthy subjects in seven different closing cohorts from November 2016 to January 2018. This study was conducted for us by PRA Health Sciences – Early Development Services Lenexa, Kansas, principal investigator, Daniel Dickerson, M.D., Ph.D. to evaluate the safety and pharmacokinetics of PF614, as well as the pharmacokinetics of oxycodone at doses sufficient to characterize the extent to which plasma oxycodone is produced and maintained following oral ingestion of PF614 and was compared to the oxycodone released from extended release oxycodone from OxyContin OP. Subjects were randomized to receive a single dose of PF614 (dose of 15, 25, 50, 100, and 200 mg with 6 subjects per dosing group) or OxyContin OP (dose of 10, 20, 50, and 80 mg with 2 subjects per dosing group). New subjects were recruited for each cohort. Cohort 1 compared subjects receiving PF614 and OxyContin OP with and without naltrexone blockade. Naltrexone is an opioid blocker to prevent opioids from attaching to the opioid receptors, preventing the effect of the opioid medication such as pain relief, feeling of euphoria or respiratory depression. The single ascending dose study also compared the release of oxycodone from PF614 under both fasted and fed conditions at the highest does of PF614 evaluated, 200 mg. The pharmacokinetics of the prodrug fragments was also evaluated. In addition, this study instructed as to the "conversion efficiency" of the PF614 prodrug to oxycodone, with respect to OxyContin.

#### Pharmacokinetic Analyses

The shape of the plasma concentration versus time curve of oxycodone was similar following administration of OxyContin OP (oxycodone extended release) and PF614. The efficiency of conversion for PF614 to oxycodone was determined to be approximately 86%. A PF614 dose of 50 mg yields oxycodone exposure comparable to a 20.01 mg dose of OxyContin, indicating a potency ratio of 0.40. This data has allowed us to match doses of PF614 to those of commercially available OxyContin OP.

### Safety

A total of 64 subjects were included in this study, of which 23 (35.9%) experienced 47 treatment-emergent adverse events, or TEAEs. The majority of TEAEs were either gastrointestinal disorders or nervous system disorders with no deaths, serious adverse events, or severe TEAEs. Additionally, there were no discontinuations due to study drug-related adverse events. Over half of TEAEs were study drug related, but they were mostly mild in severity. The three TEAEs that were moderate in severity were nephrolithiasis, or kidney stones, nausea, and vomiting, with the nausea and vomiting being study drug related. Comparing safety data across cohorts, the data indicated that dose, naltrexone, and fed/fasted state had no clinically relevant effect on the safety profile of PF614. PF614 was generally well tolerated at doses up to 200 mg in healthy subjects.

### Next Steps

We intend to undertake additional clinical studies with PF614 in 2021. We anticipate that a multidose and bioequivalence clinical trials to evaluate the release of oxycodone from PF614 and compare it to the release of oxycodone from OxyContin will be initiated. Additionally, two human abuse liability studies will be initiated to understand the tendency for drug abusers to like the effects achieved from taking PF614 either orally or nasally as compared to that of a comparator product such as crushed OxyContin.

# PF614-MPAR<sup>TM</sup>

Our IND application (IND 150966) has received the FDA allowance and a Phase 1 study is planned to evaluate PF614-MPAR<sup>™</sup> in study entitled "A Single Dose, 2 Part Study to Evaluate the Pharmacokinetics of Oxycodone, PF614, PFR06082, and nafamostat, when PF614 Solution is Co-Administered with nafamostat, as an Immediate Release Solution and/or Extended Release (ER) Capsule Formulations in Healthy Subjects":

# PF614-MPAR<sup>™</sup>-101 Phase 1 Clinical Trial

The primary objectives of the Phase 1 study are to assess the pharmacokinetics of oxycodone, when PF614 solution is administered alone and with nafamostat as an immediate release solution and/or extended release capsule prototypes. The study is designed to aid in the selection of the optimal nafamostat formulation and dose to combine with PF614 in order to provide oxycodone when a prescribed dose is taken yet attenuate the maximum plasma concentration ( $C_{max}$ ) and the area under the concentration time curve (AUC) of oxycodone when more than the prescribed PF614-MPAR<sup>TM</sup> dose is taken. Extended release prototype capsule formulations will be selected from a two-dimensional design space describing formulation variables for release rate and dose.

# NAFAMOSTAT

### NAF-101 Phase 1 Clinical Trial

We believe nafamostat has the potential to be effective in the treatment of patients with COVID-19 as it is an inhibitor of transmembrane protease Serine 2 (TMPRSS2) the protease responsible for cleaving the spike protein of SARS-CoV-2. While patients with COVID-19 typically present with fever and a respiratory illness, some patients also report gastrointestinal symptoms, such as diarrhea, vomiting, and abdominal pain. Studies have identified the most recent strain of COVID-19 virus, SARS-CoV-2 RNA, in stool specimens of infected patients, and its viral receptor angiotensin converting enzyme 2 was found to be highly expressed in gastrointestinal epithelial cells. These suggest that SARS-CoV-2 can actively infect and replicate in the gastrointestinal tract, and oral nafamostat which acts locally in the gut will reduce the ability of the virus to replicate. The purpose of our study was to evaluate the safety of oral nafamostat in healthy volunteers. This was a three-part single ascending dose study (Part 1) examining safety and pharmacokinetics of single doses of 50, 100, and 200 mg nafamostat daministered sequentially on three separate days to a single cohort of eight subjects. The multiple ascending dose study (Part 2) administered 100 mg nafamostat twice daily to four healthy subjects and evaluated safety and pharmacokinetic for five days. A second cohort of four subjects received 200 mg nafamostat twice daily for five days and evaluated safety and pharmacokinetic. A final group of six healthy subjects received 200 mg nafamostat twice daily for oral nafamostat solution administered three times daily.

### Pharmacokinetic Analyses

Nafamostat was shown to have limited bioavailability at any dose level evaluated up to 200 mg.

# Safety

There were no drug-related adverse events reported for nafamostat delivered at 200 mg three times daily, therefore additional dose levels are currently being examined for safety. We concluded that 200 mg can be delivered three times daily which may provide local effects in the gastrointestinal tract.

## Next Steps

We are also planning to evaluate nafamostat in a Phase 2 clinical trial in COVID-19 subjects when delivered as an oral drug product.

## Competition

Our industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We expect to face competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies, and academic and research institutions. Most of these existing and potential competitors have significantly greater financial and other resources than we do.

The key competitive factors that are expected to affect the development and commercial success of our product candidates include their respective degree to limit human abuse potential, bioavailability, therapeutic efficacy, and convenience of dosing and distribution. In addition, other factors include their respective safety, cost and tolerability profiles are likely to be factors. Our lead product candidate, PF614, may also face competition from commercially available generic and branded extended-release and long-acting opioid drugs other than oxycodone, including, but not limited to, fentanyl, hydromorphone, oxymorphone, and methadone, as well as opioids that are currently in clinical development.

Obtaining an abuse-deterrent label through the FDA involves a lengthy and complicated process. We believe abuse-deterrent opioids represent a therapeutic option to maximize pain relief in patients for whom opioid analgesia is indicated, while reducing the risks of abuse and diversion. Before approval, the FDA evaluates the results from in vitro manipulation and extraction, pharmacokinetics, and clinical human abuse potential studies to determine whether the accumulated evidence is sufficient to warrant claims of abuse deterrence. Post-marketing studies may also be required to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting.

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There are only four commercially available (in the United States) opioid drugs for chronic pain relief that have an abuse-deterrent label. These drugs are MorphaBond<sup>™</sup> ER, marketed by Daiichi Sankyo, OxyContin<sup>®</sup> ER and Hysingla<sup>®</sup> ER, both of which are marketed by Purdue Pharma, LP, and Collegium Pharmaceutical, Inc.'s XTampza<sup>®</sup>ER. Hysingla<sup>®</sup> ER is a once-a-day hydrocodone extended-release product. Xtampza<sup>®</sup> ER is a twice daily, extended-release opioid formulation that contains microspheres that combine oxycodone with inactive ingredients to increase the difficulty of tampering. Xtampza<sup>®</sup>ER has abuse-deterrent properties in the FDA approved product label, and post-marketing data has shown Xtampza<sup>®</sup>ER abuse, misuse, and diversion and tampering are low relative to other prescription opioid analgesics.

Purdue Pharma LP is expected to have tighter marketing and management controls than it has exhibited in the past which may impact its overall market share. While Oxycontin OP is an abuse-deterrent formula that has impacted the ability to snort or inject, the drug has been documented to be abused through other means.

A number of other companies including, but not limited to, Pfizer Inc., Daiichi Sankyo, Endo Health Solutions, Nektar Therapeutics, Teva Pharmaceutical, Inc., Egalet Ltd., KemPharm Inc., Elysium Therapeutics Inc., and Acura Pharmaceutical, offer either extended-release or abuse-deterrent products in various stages of development. Other companies offer products indicated for chronic, severe, long-term pain with various delivery technologies, but these products do not have abuse-deterrent claims on their labels.

We do not believe there are other companies developing products that have an overdose mechanism to compete with our MPAR<sup>TM</sup> technology.

# **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for product candidates and any of our future product candidates, novel discoveries, product development technologies, and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing United States and foreign patents and patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position.

# **Patents and Patent Applications**

We own numerous patents and applications in the United States and significant commercial markets, such as Europe, China, and Japan, relating to our product candidates currently in development, as well as other product candidates that may be developed in the future. These patents and applications are projected to expire between 2028 and 2041, subject to any patent term adjustment or extension that might be available in a particular jurisdiction. A table of the key patent families and their natural or projected expiry dates is presented below.

Natural or Projected Expiry Date

Countries of Filings

TAAP and MPAR <sup>TM</sup> Patents and Applications for Opioids		
Compositions Comprising Enzyme-Cleavable Ketone-Modified Opioid Prodrugs and	U.S., Australia, Brazil, Canada, China, Europe,	2030
Optional Inhibitors Thereof	Hong Kong, Israel, India, Japan, Mexico, Russia	
Compositions Comprising Enzyme-Cleavable Opioid Prodrugs and Inhibitors Thereof	U.S.	2030
Compositions Comprising Enzyme-Cleavable Oxycodone Prodrugs	U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Russia	2032
Compositions Comprising Enzyme-Cleavable Prodrugs and Controlled Release Nafamostat and Methods of Use Thereof	U.S.	2042
Active Agent Prodrugs with Heterocyclic Linkers	U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Russia	2032
Nafamostat Patents and Applications		
Methods of Treating coronavirus infections and COVID-19	PCT	2041
Oral formulations of Nafamostat	U.S.	2042
Methods of Treating Respiratory Diseases with mucostasis	Germany, France, Italy, United Kingdom	2038
TAAP and MPAR <sup>TM</sup> Patents and Applications for Amphetamines		
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	U.S., Europe	2031
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	РСТ	2040
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While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our product candidates.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a period due to delay by the United States Patent and Trademark Office ("USPTO") in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed fourteen years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our products or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see "*Risk Factors—Risks Related to Our Intellectual Property*."

# TAAP and MPAR<sup>TM</sup> Patents and Applications for Opioids

Following our merger with Signature, we became the owner of patent families that include several granted U.S. patents, as well as granted patents and pending patent applications in numerous foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, and Russia, relating to chemically modified opioids, such as oxycodone, methadone, and hydromorphone, covalently linked using specific linkers to a gastrointestinal enzyme-cleavable moiety and pharmaceutical compositions containing these modified opioids, pharmaceutical compositions containing these modified opioids and a gastrointestinal enzyme inhibitor, and methods of using the same to treat pain. Three of these patent families are directed to ketone containing opioids and cover PF614 and PF614-MPAR<sup>TM</sup> and certain methadone TAAP product candidates that are still in the discovery phase. These three families contain issued patents in the United States and certain foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, and Russia and expire between 2030 and 2032, subject to any applicable patent term extension that might be available in a jurisdiction. We also own a pending provisional application directed to oral formulations of PF614-MPAR<sup>TM</sup>, which if pursued and issued would expire in 2042, subject to any potential patent term adjustment or extension that may be available in a jurisdiction. We also own one patent family that includes granted patents in the United States, as well as granted patents and pending patent applications in numerous foreign jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, and Russia, relating to chemically modified ketone-containing agents, such as oxycodone, methadone, and hydromorphone, covalently linked using specific linkers to a gastrointestinal enzyme-cleavable moiety, pharmaceutical compositions containing these modified ketone-containing agents, pharmaceutical compositions containing these modified ketone-containing agents and a gastrointestinal enzyme inhibitor, and methods of using the same to treat pain, would cover certain methadone TAAP product candidates that are still in discovery phase and expire in 2032. While we own these patent families, we have not updated records in the various patent offices to reflect our ownership of these patent families. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Furthermore, as noted above, we have not obtained assignments for certain patent applications relating to abuse-resistant amphetamines.

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We believe that one patent covering PF614 will be eligible for up to five years of patent term extension in the United States and intend to pursue such extension. In addition to patent exclusivity until at least 2032, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that PF614 will be eligible for five-year New Chemical Entity, or NCE, regulatory exclusivity, during which time no 505(b)(2) New Drug Application, or NDA, or Abbreviated New Drug Application, or ANDA, can be approved that contains the same active moiety as the chemical entity in the PF614 NDA. In addition, if an ANDA or 505(b)(2) applicant were to file its application referencing the NDA for PF614 before expiration of our formulation patent and the applicant asserted that the patent is invalid or would not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory thirty-month stay, starting at the end of the five-year NCE regulatory exclusivity period, if we sue for infringement, or a shorter period if the patent expires of there are certain settlements or judicial decisions in the patent litigation) and may ultimately be required to wait until the natural expiration of our compositions patents if the patents are found to be valid and infringed by the challenging applicant. For more information please see "*—Patents and Patent Applications*."

#### Nafamostat Patents Applications

We own one pending Patent Cooperation Treaty, or PCT, application directed to the use of orally administered nafamostat for the treatment of infections caused by coronaviruses, including COVID-19, and one pending provisional application directed to oral formulations of nafamostat. We intend to pursue these applications in the United

States and other significant commercial markets and any patents that may be issued would expire in 2041 and 2042, respectively, subject to any applicable patent term adjustment or extension in a particular jurisdiction. Additionally, we acquired one European patent from Mucokinetica Ltd. that is directed to the use of certain compounds, including nafamostat, for the manufacture of a medicament for the treatment of respiratory diseases with mucostasis or poor mucus clearance. This patent was validated in Germany, France, Italy, and the United Kingdom and expires in 2038, subject to any applicable patent term extension that might be available in Europe Union or United Kingdom. Currently, we do not have any issued patent or pending application directed to methods of treating infections caused by coronaviruses, including COVID-19, with inhald nafamostat, but intends to file pending applications upon development of a suitable inhalation formulation of nafamostat. We believe that one patent ecclusivity, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that nafamostat will be eligible for five-year NCE regulatory exclusivity, during which time no 505(b)(2) NDA or ANDA can be approved that contains the same active moiety as the chemical entity in the nafamostat NDA. In addition, if an ANDA or 505(b)(2) applicant were to file its application asperted that contains the same active moiety as the chemical entity in the applicant asserted that the patent is invalid or would not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory thirty-month stay, starting at the end of the five-year NCE regulatory exclusivity period, if we sue for infringement, or a shorter period if the patent expires of there are certain settlements or judicial decisions in the patent litigation) and may ultimately be required to wait until the natural expiration of our compositions patents if the patents are found to be valid and infringed by the

# TAAP and MPAR<sup>TM</sup> Patents and Applications for Amphetamines

Following the merger with Signature, we became the owner of one patent family that includes pending applications in the United States and numerous European foreign jurisdictions relating to chemically modified amphetamines covalently linked to a gastrointestinal enzyme-cleavable moiety, pharmaceutical compositions containing the modified amphetamines and a gastrointestinal enzyme inhibitor and methods of using the same to treat a subject. While we own this patent family, we have not updated the records in the various patent offices to reflect our ownership of this patent family. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. In addition, we own one pending Patent Cooperation Treaty, or PCT, application directed to pharmaceutical compositions containing chemically modified amphetamines covalently linked to a gastrointestinal enzyme-cleavable moiety and a trypsin inhibitor and methods of using the same to treat a subject, which we intend to pursue in the United States and in certain significant commercial markets. We have not obtained assignments from all of the inventors of this PCT application to date, which could negatively impact our ability to pursue or enforce this application. If issued, these patent applications would expire between 2031 and 2040, subject to any applicable patent term adjustment or extension that might be available in a jurisdiction.

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#### Trademarks and Trade Secrets

We intend to pursue trademark registrations in the United States and other significant commercial markets for our product candidates as they progress through clinical development.

Furthermore, we rely upon trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting knowhow and inventions.

# Manufacturing and Supply

Our drug substance and drug products are manufactured by contract manufacturing organizations. We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. See "*Risk Factors*" for more information. Although we intend to rely on third-party contract manufacturers to produce our product candidates, we have personnel with experience managing the third-party contract manufacturers who are expected to produce our product candidates and other product candidates or products that we may develop in the future.

Our lead product candidate, PF614, is small molecule opioid prodrug. As such, it is a controlled substance, regulated by the Drug Enforcement Administration ("DEA") and state-controlled substance authorities. Our third-party manufacturers will be required to be registered with DEA and will be responsible for obtaining adequate quota to manufacture and otherwise handle controlled substances.

We currently engage third parties to provide clinical supplies of PF614 and nafamostat. We also currently engage a third-party manufacturer to provide drug product manufacture of PF614, PF614-MPAR<sup>TM</sup>, and nafamostat. We currently have sufficient supplies of PF614 and nafamostat on hand for our current clinical trial needs. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. See "*Risk Factors*" for more information.

### **Recro Manufacturing Agreement**

Pursuant to the Recro Agreement, we engaged Recro to manufacture PF614 and other clinical trial materials under cGMP conditions and provide stability studies with respect to our PF614 clinical trials. Pursuant to the agreement, Recro will create placebo capsules, PF614 powder-filled capsules and provide us with master batch records and a GMP manufacturing report upon completion of manufacturing and analytical activities. Under the Recro Agreement, Recro also generated stability data according to ICH program for two formulations to provide stability data for shelf-life assessment with respect to our Phase II clinical trial. We have agreed to pay Recro \$173,000 and pass-through costs, estimated at \$14,000 at the time of the agreement, for the manufacturing and services provided under the Recro Agreement. The term of the Recro Agreement began on September 19, 2019 and continues until the completion of the manufacturing and services described in therein. However, we paused the Recro Agreement in early 2020 in connection with the timing of our PF614 clinical studies and resumed in the first quarter of 2021. We expect to enter into additional related agreements with Recro. In the event that Recro is unable to perform the services promised under the Recro Agreement, we may be subject to unforeseen costs and delays with respect to our clinical trials and be unable to replace the Recro Agreement on terms as favorable to us. See "*Risk Factors—We expect to be completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities, fail to provide to us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices" for more information.* 

#### **Government Grants**

We have received funding under federal grant award programs funded by governmental agencies, such as the NIH and NIDA. Specifically, for fiscal year 2020, we received an aggregate of approximately \$4.0 million in federal grant funds, approximately \$3.0 million from the NIH related to preclinical development and Phase 1 clinical trial for PF614 MPAR<sup>TM</sup> and approximately \$1.0 million from NIDA under our five year award to undertake the preclinical development of our opioid use disorder- MPAR<sup>TM</sup>

technology, including to cover the costs of a Phase 1 trial. For the three months ended March 31, 2021, we received federal grants totaling \$0.3 million, \$73,726 from NIH related to preclinical development and Phase 1 clinical trial for PF614 MPAR<sup>TM</sup> and \$176,850 from NIDA under our five year award to undertake the preclinical development of our opioid use disorder- MPAR<sup>TM</sup> technology. We received a Notice of Award from NIDA that will provide \$2.8 million beginning July 1, 2021 to undertake the Phase 1 clinical trial of PF614-MPAR<sup>TM</sup>. We may apply for additional grant funding from these or similar governmental agencies in the future. See *Risks Related to Our Business, Financial Condition and Capital Requirements*" for additional information.

# Promissory and Convertible Notes

We have entered into promissory notes and convertible notes with certain of our affiliates. See 'Certain Relationships and Related Person Transactions'' for additional information.

# **GEM Facility**

Pursuant to the GEM Agreement, we are entitled to draw down up to \$60 million of gross proceeds ('*Aggregate Limit*') from GEM Global in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. This equity line facility is available for a period of 36 months from the closing date of the Merger. A draw down is subject to limitations on the amount that is drawn under the facility and must comply with certain conditions precedent including the listing of our shares on a principal market (which includes Nasdaq), having the necessary number of shares that are issuable pursuant to the draw down registered under an effective registration statement, and other notice and timing requirements. Upon our valid exercise of a draw down, pursuant to delivery of a notice and in accordance with other conditions, GEM Global is required to pay, in cash, a per-share amount equal to 90% of the average closing bid price of the shares of our common stock recorded by Nasdaq (*'Draw Down Limit*') of the average daily trading volume for the 30 trading days immediately preceding the date we deliver the draw down notice. We are entitled to request a draw down of up to \$10 million in the first month following the closing of the Merger subject to Draw Down Limit and other conditions provided in the GEM Agreement.

Further, upon the closing of the Merger, GEM Global became entitled to a commitment fee in the form of cash or freely tradeable shares of our common stock in an amount equal to 2% of the Aggregate Limit or \$1.2 million to be paid in two tranches. The commitment fee for the first tranche, which is equal to 67% of the commitment fee, or \$800,000, becomes payable on the first anniversary of the closing of the Merger and the commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or \$400,000, becomes payable on the eighteen-month anniversary of the closing of the Merger.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GYBL the right to purchase 1,106,108 shares of our common stock (an amount equal to 4% of the total number of our common stock outstanding as of the closing date of the Merger (subject to adjustments described below), calculated on a fully diluted basis), at a strike price per share equal to \$10.01, which was the closing bid price for such common stock on the first day of trading on Nasdaq. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GYBL's exercise will entitle GYBL to compensation in addition to other remedies. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits, and issuances of additional common shares at a price per share less than the exercise price.

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

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

#### **Government Regulation**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, and those pharmaceutical products that are controlled substance are also subject to extensive regulation by the DEA. The Federal Food, Drug, and Cosmetic Act (the "*FDC Act*"), the Controlled Substances Act ("*CSA*"), and other federal, state, and local statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, prescribing, dispensing, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Pharmaceutical products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs, revocation of licensing authority, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

#### The FDA Drug Approval Process

FDA approval is required before any new drug can be marketed. A new drug is one not generally recognized, by experts qualified by scientific training and experience, as safe and effective for its intended use. The process of drug development is complex and lengthy. The activities undertaken before a new pharmaceutical product may be marketed in the United States generally include, but are not limited to, preclinical studies; submission to the FDA of an IND, which must become active before human clinical trials may commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; submission to the FDA of an NDA; filing of the NDA by FDA; satisfactory completion of an FDA pre-approval inspection of the clinical trial sites and manufacturing facility or facilities at which both the active ingredients and finished drug product are produced to assess compliance with, among other things, patient informed consent requirements, the clinical trial protocols, current Good Clinical Practices, or GCP, and GMPs; and FDA review and approval of the NDA prior to any commercial sale and distribution of the product in the United States.

Preclinical studies include laboratory evaluation of product chemistry and formulation, and in some cases, animal studies and other studies to preliminarily assess the potential safety and efficacy of the product candidate. The results of preclinical studies together with manufacturing information, analytical data, and detailed information including protocols for proposed human clinical trials are then submitted to the FDA as a part of an IND. An IND must become effective, and approval must be obtained from an Institutional Review Board ("*IRB*") prior to the commencement of human clinical trials. The IND becomes effective 30 days following its receipt by the FDA unless the FDA objects to, or otherwise raises concerns or questions and imposes a clinical hold. We, the FDA, or the IRB may suspend or terminate a clinical trial at any time after it has commenced due to safety or efficacy concerns or for commercial reasons. In the event the FDA imposes a clinical hold, the IND sponsor must address any outstanding FDA concerns or questions to the satisfaction of the FDA before clinical trials can proceed or resume.

Human clinical trials are typically conducted in three sequential phases that may sometimes overlap or be combined:

In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical

effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefitrisk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding \$2.8 million for Fiscal Year 2021. Under an approved NDA, the applicant is also subject to an annual program fee, currently exceeding \$330,000. These fees typically increase annually. Under limited circumstances, an applicant may be exempt from or seek a waiver of the application fee requirement.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. For a standard review, the goal for review of a new molecular entity ("*NME*") is ten months from the date the FDA files the NDA, while the goal for review of a non-NME is six months from the date the FDA files the NDA, while the goal for review of a non-NME is six months from the fate the FDA files the NDA, while the goal for review of a non-NME is six months from the FDA files the NDA, while the goal for review of a non-NME is six months from the FDA files the NDA, while the goal for review of a non-NME is six months from the fate the FDA files the NDA, while the goal for review of a non-NME is six months from the fate the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel drug products, as well as drug products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee—typically a panel that includes clinicians, statisticians, and other experts—for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facilities at which the drug product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the claimed indication.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("*REMS*") to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product safe use ("*ETASU*"). An ETASU REMS can include, but is not limited to, special training or certification for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, manufacturing processes, or facilities, require submission and FDA approval of a new NDA, or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

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# Section 505(b)(2) NDAs

An alternative to the NDA pathway described above is an NDA submitted under Section 505(b)(2) of the FDC Act, which enables the applicant to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for modified formulations, new routes of administration, or new uses of previously approved products. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety or effectiveness is scientifically appropriate, it may eliminate the need to conduct eratin preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

## Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

# Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on the website

www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

## **Pediatric Information**

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any exclusivity-patent or non-patent-for a drug product if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

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#### The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "*Orange Book*") and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA's acceptance or approval of certain competitor applications.

#### Patent Term Extension

Patent Term Extension ("*PTE*") in the United States can compensate for lost patent grant time during product development and the regulatory review process for a patent that covers a new product or its use. This PTE period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. PTEs that can be obtained are for up to five years beyond the expiration of the patent or fourteen years from the date of product approval, whichever is earlier. Only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a nonprovisional patent application related to the patent. A U.S. patent also may be accorded patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for a patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. PTE cannot extend the remaining term of a patent beyond a total of fourteen years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug may be extended. Similar provisions are available in applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also believe that (1) PF614 and nafamostat will be eligible for a five-year NCE regulatory exclusivity, and (2) PF614-MPAR<sup>TM</sup> will be eligible for a three-year clinical investigation, or CI, regulatory exclusivity, under the Hatch-Waxman Act, during which time no ANDA can be approved.

Under the Hatch-Waxman Act, patents covering the product such as patents claiming the approved composition of matter, approved methods of use, approved formulations, and approved dosing and administration shall be listed in the Orange Book, which identifies drug products approved by FDA under the FDC Act. Applicable regulatory exclusivities, such as the five-year NCE exclusivity and the three-year CI exclusivity, are also listed in the Orange Book. If an ANDA or 505(b)(2) applicant were to file its application before expiration of all patents listed in the Orange Book, it must certify whether it will either honor or challenge all the patents listed in the Orange Book. If an Orange Book listed patent is challenged and we sue the ANDA or 505(b)(2) applicant for infringement, a statutory 30-month stay of approval, started at the end of the NCE exclusivity period, will be put in place that will prohibit the FDA from finally approving the ANDA or 505(b)(2) application until the 30-months have expired or after a court has held in favor of the ANDA or 505(b)(2) applicant. The 30-month stay begins at the end of the five-year NCE exclusivity period. If the Orange Book listed patent(s) is ultimately held valid and infringed, the ANDA or 505(b)(2) applicant will not be finally approved until the Orange Book listed patent(s) expires. If a pediatric study is requested by the FDA in a Pediatric Written Request, or PWR, and we complete the pediatric study according to the terms of the PWR, all unexpired Orange Book listed exclusivities (patent or regulatory) will be extended by six months.

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Similar provisions are available in Europe, Japan, and certain other jurisdictions to extend the exclusivity of a patent that covers an approved drug. In Europe, we believe PF614 and nafamostat will be eligible for 10 years of regulatory exclusivity from European Marketing Application, or EMA, approval. In Japan, we believe PF614 will be eligible for eight years of regulatory exclusivity from a Japanese new drug application, or J-NDA, approval.

# Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents identified in the application for the drug are then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must

certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been filed with and accepted by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDC Act, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

# Market Exclusivity

Market exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of nonpatent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity ("*NCE*"). A drug is entitled to NCE exclusivity if it contains a drug substance with no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. For a drug that has been previously approved by the FDA, the FDC Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the new conditions of use and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and wellcontrolled clinical trials necessary to demonstrate safety and effectiveness.

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## Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-toconsumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("*PDMA*"), a part of the FDC Act. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. Unless the products were packaged prior to November 27, 2018, the DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

#### The CSA and DEA Regulation

Our products are regulated as "controlled substances" as defined under the CSA and regulations promulgated by DEA. The law and regulations establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, and other requirements administered by DEA.

Controlled substances are classified into five schedules: Schedule I, II, III, IV, or V, depending on the abuse potential. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

PF614 will be classified as a Schedule II controlled substance under the CSA and regulations because it contains oxycodone which is already regulated as a Schedule II controlled substance. Consequently, the manufacturing, shipping, storing, selling, prescribing, and dispensing of our products is subject to a high degree of regulation. Schedule

II drugs are subject to the strictest requirements for registration, security, recordkeeping, and reporting. Facilities must maintain complete and accurate inventories and records of all controlled substances received, manufactured, stored, and distributed. These facilities must comply with strict security requirements to prevent diversion of drugs in their possession. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, presented to a pharmacist and, generally limited to a 30-day supply, and may not be refilled, that is, a new prescription is required.

Annual registration is required for any facility that manufactures, distributes, imports, or exports any controlled substance. Also, practitioners and pharmacies are required to register every three years. The registration is specific to the particular location, activity, and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances the facility is authorized to handle. Our contract manufacturers must be registered with DEA.

In addition, the CSA establishes an annual quota system that limits the manufacturing of API and dosage forms in the United States of Schedule I and II controlled substances. First, the DEA establishes an annual aggregate quota for how much active opioid ingredients, such as oxycodone and tapentadol, may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production quotas. Also, dosage form manufacturers must also request a procurement quota to acquire opioid API to manufacture dosage forms for distribution. We and our contract manufacturing PF614. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year. DEA has substantial discretion in whether or not to make such adjustments. Our contract manufacturers must apply for and obtain the necessary quotas on an annual basis.

In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in calendar year 2018 by 20%. In October 2018, the SUPPORT Act was enacted, which included amendments to the CSA to require that appropriate quota reductions be made after estimating potential for diversion. DEA announced that the estimate is based on rates of overdose deaths and abuse, the overall public health impact related to specific controlled substances and may include other factors as appropriate. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. In October 2019, consistent with the SUPPORT Act, DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone), by an average of 28%. For 2021, the DEA decreased the aggregate quota for oxycodone by about 13% and for hydrocodone by about 10% from the final established 2020 quotas. Because PF614 is regulated as a Schedule II controlled substance, it is subject to the DEA's aggregate, individual production, and procurement quota scheme.

Ordering and distribution of any Schedule I or II controlled substance are also subject to special ordering requirements under either the electronic Controlled Substance Ordering System ("*CSOS*") or use of DEA Form 222s. Information regarding specific transactions are reported to DEA, and cumulative reports of such transactions are required monthly/quarterly.

The DEA also requires drug manufacturers to design and implement a system that identifies and reports suspicious orders of controlled substances. Such orders include those of unusual size, those that deviate substantially from a normal pattern, and those of unusual frequency. Manufacturers must refuse to complete any sale and report to DEA any orders for which it is unable to resolve any potential "red flags." A compliant suspicious order monitoring system includes well-defined due diligence, "know your customer" process as well as systems to identify and monitor ordering and sales of controlled substances.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, especially security and recordkeeping and as manifested in loss or diversion or inability to account for all controlled substances, can result in administrative, civil, or criminal enforcement action that could have a material adverse effect on our business, results of operations, and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. The DEA may also reduce or deny quota to manufacturing facilities based on non-compliance with these requirements. In certain circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances.

# Legislative and Regulatory Initiatives for Opioids

In response to widespread prescription opioid abuse, the United States government and a number of state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. The number and scope of legislative and regulatory actions, particularly in the last three years, emphasize the severity of the opioid epidemic and its impact on our society. The FDA has stated that addressing prescription drug abuse is a priority and has reaffirmed that the development of abuse-deterrent opioids is a key part of that strategy.

Recent actions to address the opioid abuse epidemic include:

- FDA guidance: In April 2015, the FDA adopted final guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The guidance describes four categories of abuse-deterrent properties under controlled conditions, while Category 4, post-marketing clinical trials and studies, assesses the real-world impact of abuse-deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.
- FDA Opioids Action Plan: In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid
  medications. The FDA's plan is part of a broader initiative led by the U.S. Department of Health and Human Services ("HHS"), to address opioid-related overdose,
  death, and dependence.
- CDC Prescribing Guidelines: In March 2016, the CDC released a new Guideline for Prescribing Opioids for Chronic Pain intended to assist primary care providers
  treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks
  and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy.
- Enhanced Warnings and Safety Labeling: In March 2016, the FDA announced required enhanced warnings for immediate-release opioid pain medications related to risks
  of misuse, abuse, addiction, overdose, and death. Subsequently, there have been several class-wide labeling changes, including the addition of boxed warnings relating to
  serious risks of using certain opioids medications along with benzodiazepines and other central nervous system depressants, including alcohol (Decembers 2016); and
  additional information relating to the new class-wide REMS (Septembers 2018).

- Enactment of the Comprehensive Addiction and Recovery Act ("CARA"): In 2016, the CARA was enacted to address the national epidemics of prescription opioid abuse
  and heroin use. Consistent with the initiatives of HHS, this legislation sought to, among other things, expand the availability of naloxone for law enforcement and other
  first responders; form an interagency task force to develop best practices for pain management with opioid medications; and provide resources to improve state
  monitoring of controlled substances, including opioids. In 2018, CARA 2.0 was introduced as follow-up legislation to limit initial prescriptions for opioids to 3 days,
  while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care.
- Enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"): In November 2018, the SUPPORT Act was enacted as a comprehensive legislative response to the continuing opioid epidemic. It includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries. It also includes a number of requirements directed at reducing the potential for oversupply of opioids to reduce the potential for misuse and diversion.

#### Properties

Our principal executive office is located at 7946 Ivanhoe Ave., Suite 201 in La Jolla, California, where we lease a total of 850 square feet of office space that we use for our administrative activities. The lease expires in October 2021. All other development activities are undertaken at contract research organizations.

We believe that all of our facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

## Employees

As of August 4, 2021 we had four full-time employees and five consultants. Of these, four have a Ph.D. and two have an M.B.A. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good. We intend to add additional full-time employees along with additional clinical support staff in 2021, and to expand our commercial sales force beginning 2023.

#### Legal Proceedings

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

### DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al., Los Angeles County Superior Court, Case Number 21 STCV25585

In July 2021, following the Company's business combination with Leisure Acquisition Corporation, the Company's former financial advisor, Del Morgan Group, LLC and Globalist Capital, LLC (together, "*Plaintiffs*") filed an action against the Company and its Chief Executive Officer (together, "*Defendants*") alleging that the Common Stock and Common Stock Warrants (together, "*Securities*") issued to Plaintiffs in satisfaction of its advisory fee should have been registered and the Securities immediately tradeable. The Plaintiffs asserted various causes of action in furtherance of their claims. The Plaintiffs are seeking registered and freely tradeable Securities and damages arising from their inability to trade the Securities, which Plaintiffs assert are in the millions of dollars. The Defendants believe there are meritorious defenses to the Plaintiffs claims, and possible counterclaims.

On August 3, 2021, the Plaintiffs and Defendants entered into a Settlement Agreement and Mutual General Release whereby Plaintiffs would have their Common Stock, and the Common Stock underlying their Warrants registered on the Company's Form S-1 Registration Statement. In addition, the Warrants would be modified to allow for cashless exercise and to reduce the exercise price from \$11.50/share to \$10.00/share. In consideration for this, both Parties agreed to release the other from any past, present or future claims. In addition, the Plaintiffs agreed to immediately stay the proceedings and inform the Superior Court of a conditional settlement and to dismiss the lawsuit with prejudice five days following the effectiveness of the Form S-1 Registration Statement.

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# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that management believes is relevant to an assessment and understanding of our financial condition and results of operations. This discussion should be read in conjunction with the consolidated financial statements and related notes thereto that appear elsewhere in this registration statement/prospectus. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere particularly in the sections titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" include elsewhere in this registration statement/prospectus. Unless the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "we," "us," "our" and the "Company" are intended to mean the business and operations of Ensysce and its consolidated subsidiaries.

#### Overview

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

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

Our lead product candidate, PF614, is in Phase 1b clinical development, PF614-MPAR™ is in Phase 1 clinical development and nafamostat is proceeding towards Phase 2 clinical development, and our other product candidates and our research initiatives are in preclinical or earlier stages of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We have not yet successfully completed any pivotal clinical trials, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities. Through March 31, 2021, we have received aggregate gross proceeds of \$42.7 million from the sale of equity, \$6.2 million from funding under federal

research grants and \$5.5 million from borrowings under promissory notes.

We expect to continue to incur net losses for the foreseeable future, and we expect our clinical development expenses, and general and administrative expenses to continue to increase. We have incurred significant operating losses since inception. Our net losses were \$0.2 million and \$10.1 million for the years ended December 31, 2020 and 2019, respectively, and \$1.0 million for the three months ended March 31, 2021. As of December 31, 2020 and March 31, 2021, we have an accumulated deficit of \$56.0 million and \$56.9 million, respectively. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

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

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- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future
  commercialization efforts and our transition to operating as a public company following the closing of the Merger.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. We may never become profitable.

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

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

We have generated limited revenues and have incurred significant operating losses since our inception, and as of March 31, 2021, have an accumulated deficit of \$56.9 million. In addition, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. We believe that the net proceeds from the Merger, proceeds raised under the GEM Agreement, subject to meeting certain conditions, together with our available resources and existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the 12 months following the completion of the Merger. We based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "— *Liquidity and Capital Resources.*" Our future viability beyond the twelve months is dependent on our ability to raise additional capital to finance our operations.

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

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#### COVID-19 pandemic Business Update

In March 2020, the World Health Organization declared COVID-19 a global pandemic. To date, our financial condition and operations have not been significantly impacted by the ongoing COVID-19 pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials and other operations required to support those clinical trials and research and development activities to advance our pipeline. The impact of the ongoing COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the ongoing COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected.

We are continuing to evaluate the impact of the ongoing COVID-19 pandemic on our business and continue to take proactive measures to protect the health and safety of our employees, as well as to maintain business continuity. We believe that the current measures we have implemented with respect to the ongoing COVID-19 pandemic are appropriate, reflecting both regulatory and public health guidance, to maintain business continuity. We will continue to closely monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate.

In 2015, Signature Therapeutics (prior to its merger with EB) entered into a purchase agreement with an existing investor to issue a convertible promissory note of \$100,000 (the "*Note*"). The original terms of the Note called for it to accrue simple interest at 5% per annum and matured in two years. The Note served as a bridge loan prior to a possible financing transaction. The Note was intended to automatically convert into common stock shares issued in a transaction at a 20% discount to the per share conversion price. Pursuant to the Merger Agreement, the Note has been amended to allow for the principal and interest to be converted into shares of our common stock at the per share conversion price of \$0.57 prior at the time of the closing of the Merger.

Between 2018 and 2020, we entered into a number of purchase agreements with existing investors to issue convertible promissory notes (the 2018 Notes") for \$3,500,000. The original terms of the 2018 Notes called for the 2018 Notes to accrue simple interest at 10% per annum and mature in two years. The maturity date for the 2018 Notes was extended in May 2020 by 12 months to May 2021. The 2018 Notes served as a bridge loan prior to a possible financing transaction. The 2018 Notes were intended to automatically convert into shares of common stock issued in a transaction at a price per share of \$0.25 or to convert with a cap of a \$55 million enterprise value. Pursuant to the Merger Agreement, the 2018 Notes have been amended to allow for the principal and interest to be converted into shares of our common stock at the per share conversion price of \$0.23 prior at the time of the closing of the Merger.

In January 2021, we entered into a purchase agreement with an existing stockholder to issue a convertible promissory note (the *2021 Note*") for \$50,000. The 2021 Note accrues simple interest at 10% per annum and matures in two years. The 2021 Note served as a bridge loan prior to a financing transaction. The 2021 Note was intended to automatically convert into shares of common stock issued in a transaction at a per share conversion price equal to 80% of the price of securities sold in such transaction. Pursuant to the Merger Agreement, the 2021 Note has been amended to allow for the principal and interest to be converted into shares of our common stock at the per share conversion price of \$0.57 prior at the time of the closing of the Merger.

### **Business Combination Transaction**

On January 31, 2021, LACQ executed a definitive merger agreement among it, Merger Sub and Former Ensysce, providing for, among other things, and subject to the 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. On June 30, 2021, the Merger was consummated. Former Ensysce's existing equity incentive plan was terminated; awards issued under our existing equity incentive plans were exchanged for awards issued under a new equity incentive plan that we adopted in connection with the Merger. We received net proceeds of approximately \$7.8 million at the closing and we continue to operate under our management team, led by our Chief Executive Officer Lynn Kirkpatrick. As of March 31, 2021, we recorded \$0.8 million of deferred transaction costs related to the Merger, consisting of legal and accounting fees. The deferred costs were offset against additional paid-in capital upon completion of the Merger.

# **Components of Our Operating Results**

## Revenue

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

## **Operating Expenses**

### Research and Development Expenses

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

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

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we continue our existing, and commences additional, planned clinical trials for PF614, PF614-MPAR<sup>TM</sup> and nafamostat, as well as conduct other preclinical and clinical development, including submitting regulatory filings for our other product candidates. We also expect

our discovery research efforts and our related personnel costs to increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, to increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

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

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

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

# General and Administrative Expenses

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

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

#### Other income (expense)

## Interest Expense

Interest expense consists of interest accrued on our convertible and other promissory notes and the amortization of debt discounts due to embedded derivative instruments in our convertible promissory notes.

## Change in Fair Value of Derivative Liability

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

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

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

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2020 and 2019, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

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

# **Results of Operations**

# LACQ

LACQ's only activities from inception through December 31, 2020 were organizational activities and those necessary to prepare for the Initial Public Offering, identifying a target for a business combination and seeking to complete an initial business combination, including activities in connection with the proposed acquisition of us and the announced and subsequently terminated acquisition of GTWY Holdings. LACQ generated non-operating income in the form of interest income on marketable securities. LACQ incurred expenses as a result of being a public company (for legal, financial reporting, accounting and auditing compliance), as well as for due diligence and transaction expenses in connection with completing a business combination.

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For the three months ended March 31, 2021, LACQ had a net loss of \$1,711,607, which consists of a change in the fair value of the warrant liability of \$1,481,087 and operating costs of \$292,027, offset by interest income on marketable securities held in the trust account of \$229 and a benefit for income taxes of \$61,278.

For the three months ended March 31, 2020, LACQ had a net income of \$1,792,718, which consists of a change in the fair value of the warrant liability of \$2,184,000 and interest income on marketable securities held in the trust account of \$639,954, offset by operating costs of \$915,813, a provision for income taxes of \$74,625, amortization of the debt discount on convertible promissory note of \$31,428 and a change in the fair value of conversion option liability of \$10,000.

For year ended December 31, 2020, LACQ had a net income of \$4,310,769, which consists of interest income on marketable securities held in the trust account of \$719,646, a non-cash change in the fair value of warrant liability of \$1,906,250, change in value of conversion option liability of \$220,000 and the forgiveness of accounts payable of \$3,298,207, offset by operating costs of \$1,368,841 and a provision for income taxes of \$244,493 and the amortization of debt discount on convertible promissory note of \$220,000.

For the year ended December 31, 2019, LACQ had net loss of \$1,067,296, which consists of interest income on marketable securities held in the trust account of \$4,249,828 offset by a non-cash change in fair value of warrant liability of \$1,433,250, operating costs of \$3,328,674 and a provision for income taxes of \$555,200.

As a result of the restatement described in Note 2 of the notes to the consolidated financial statements included herein, we classify the warrants issued in connection with the LACQ IPO as liabilities at their fair value and adjust the warrant instrument to fair value at each reporting period. These liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our statement of operations.

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## Comparison of the three months ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

	 Three Months Ended March 31,				
	2021		2020		Change
Federal grants	\$ 250,576	\$	862,400	\$	(611,824)
Operating expenses:					, í í
Research and development	284,378		838,970		(554,592)
General and administrative	490,471		277,693		212,778
Total operating expenses	774,849		1,116,663		(341,814)
Loss from operations	(524,273)		(254,263)		(270,010)
Other income (expense):					
Change in fair value of derivative liability	(39,585)		(439,334)		399,749
Interest expense	(347,834)		(329,650)		(18,184)
Total other income (expense), net	(387,419)		(768,984)		381,565
Net loss	\$ (911,692)	\$	(1,023,247)	\$	111,555

### Federal grants

Revenue from federal grants totaled \$0.3 million for the three months ended March 31, 2021, compared to \$0.9 million for the three months ended March 31, 2020. The decrease related to two grants from the NIH through the National Institute on Drug Abuse ("*NIDA*"). Revenue decreased by \$0.6 million during the three months ended March 31, 2021 under the MPAR<sup>TM</sup> grant awarded in September 2018 due to the timing of research activities eligible for funding. Revenue was unchanged during the three months ended March 31, 2021 under the TAAP/MPAR<sup>TM</sup> grant awarded in September 2019. Funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

## Research and development expenses

Research and development expenses were 0.3 million for the three months ended March 31, 2021, compared to 0.8 million for the three months ended March 31, 2020. The decrease was primarily the result of reduced external research and development costs related to the preclinical programs for PF614-MPAR<sup>TM</sup> and Phase 1 clinical trial activities of nafamostat. We do not currently track expenses on a program-by-program basis.

## General and administrative expenses

General and administrative expenses were \$0.5 million for the three months ended March 31, 2021, compared to \$0.3 million for the three months ended March 31, 2020. The increase was primarily a result of higher patent legal expenses and audit expenses during the three months ended March 31, 2021.

# Change in fair value of derivative liability

The change in fair value of the derivative liability was a decrease of less than \$0.1 million for the three months ended March 31, 2021, compared to a decrease of \$0.4 million for the three months ended March 31, 2020. The changes in fair value resulted from changes in interest rates and the likelihood of realization of the embedded derivative instrument in convertible notes payable.

#### Interest expense

Interest expense was \$0.3 million for the three months ended March 31, 2021 compared to \$0.3 million for the three months ended March 31, 2020. The totals reflect interest accrued on convertible notes payable and the amortization of debt discounts due to embedded derivative instruments in convertible notes payable.

### Comparison of the years ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	 Year Ended December 31,				
	2020		2019		Change
Federal grants	\$ 3,931,209	\$	1,763,961	\$	2,167,248
Operating expenses:					
Research and development	4,389,579		3,402,301		987,278
General and administrative	 1,154,917		6,929,904		(5,774,987)
Total operating expenses	5,544,496		10,332,205		(4,787,709)
Loss from operations	 (1,613,287)		(8,568,244)		6,954,957
Other income (expense):					
Change in fair value of derivative liability	2,447,908		(575,087)		3,022,995
Interest expense	 (995,496)		(958,949)		(36,547)
Total other income (expense), net	1,452,412		(1,534,036)		2,986,448
Net loss	\$ (160,875)	\$	(10,102,280)	\$	9,941,405

#### Federal grants

Revenue from federal grants totaled \$3.9 million for the year ended December 31, 2020, compared to \$1.8 million for the year ended December 31, 2019. The increase related to two grants from the NIH through NIDA. Revenue increases during the year ended December 31, 2020 under the MPAR<sup>TM</sup> grant awarded in September 2018 and the TAAP/MPAR<sup>TM</sup> grant awarded in September 2019 were \$1.3 million and \$0.8 million, respectively, due to the timing of research activities eligible for funding under the grants. Funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

## Research and development expenses

Research and development expenses were \$4.4 million for the year ended December 31, 2020, compared to \$3.4 million for the year ended December 31, 2019. The increase was primarily the result of increased external research and development costs related to the preclinical programs for PF614-MPAR<sup>TM</sup> and Phase 1 clinical trial activities of nafamostat. We do not currently track expenses on a program-by-program basis.

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# General and administrative expenses

General and administrative expenses were \$1.2 million for the year ended December 31, 2020, compared to \$6.9 million for the year ended December 31, 2019. The decrease was primarily a result of reduced equity grants to key management in 2020. Share based compensation expense recognized in 2019 related to awards granted in 2019 with immediate vesting.

# Change in fair value of derivative liability

The change in fair value of the derivative liability was a decrease of \$2.4 million for the year ended December 31, 2020, compared to an increase of \$0.6 million for the year ended December 31, 2019. The changes in fair value result from changes in the likelihood of realization of the embedded derivative instrument in convertible notes payable.

#### Interest expense

Interest expense was \$1.0 million for the year ended December 31, 2020 compared to \$1.0 million for the year ended December 31, 2019. The totals reflect interest accrued on convertible notes payable and the amortization of debt discounts due to embedded derivative instruments in convertible notes payable.

# Liquidity and Capital Resources

### Sources of Liquidity and Capital

Since inception, we have generated limited revenues and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations to date primarily with proceeds from the sale of common equity, funding under federal research grants and borrowings under promissory notes. Through March 31, 2021, we have received aggregate gross cash proceeds of \$42.7 million from sales of our common equity, \$6.2 million from funding under federal research grants and \$5.5 million from borrowings under promissory notes.

Remaining funding under two approved federal research grants totals \$4.4 million and is expected to be utilized by December 31, 2022. Pursuant to the terms and conditions of the two grants, we are required to submit progress reports to NIDA on an annual basis and a final research performance progress report within 120 days of the performance period end date. Additionally, the grants limit the use of funds to activities that are clearly severable and independent from activities that involve human subjects

until the receipt by NIDA of (i) Institutional Review Board ("*IRB*") approval, (ii) federal-wide assurance from the Office for Human Research Protections, (iii) a Data and Safety Monitoring Plan, (iv) certification that all key personnel have completed education on the protection of human subjects and (v) a Clinical Trials Dissemination Plan. We must also comply with the data sharing policies of NIDA and the NIH Public Access Policy, that require submission of final peer-reviewed journal manuscripts that arise from the use of grants to PubMed Central immediately upon acceptance for publication.

Neither grant has to be repaid. To receive the remaining funding for each respective study covered by a grant, we must meet the following milestones:

- For the grant no. 1UG3DA047682-01:
  - identification of an animal model that provides similar pharmacokinetic delay of release of oxycodone from PF614 without decrease in Cmax and AUC as was seen in the Phase I MPAR clinical trial with PF329;
  - o identification of an optimal oral formulation of nafamostat that attenuates the release of oxycodone from PF614, reducing Cmax and AUC with increasing multi-pill equivalents in minipigs/non-human primate as was found for rats and dogs, and
  - o submission of an IND application for an oral nafamostat formulation.
- For the grant no. 1UG3DA050271-01:
  - o Identification of a R-methadone-TAAP Clinical Candidate that meet the specified criteria.

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

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The notes payable principal balance of \$4.8 million as of March 31, 2021 includes \$4.4 million of convertible promissory notes (0.7 million of which is borrowed by Covistat) which may be converted into common stock upon the completion of certain equity financing transactions (except for the portion borrowed by Covistat which is convertible into common stock of Covistat). The convertible promissory notes are held by Wesley Sterman, Paul Vezolles, Bob Gower and Feliciano Global Enterprises Inc. and bear interest at rates ranging from 5% to 10% per annum with a weighted-average interest rate of 9.9% per annum. The notes are subject to repayment with accrued interest at various maturity dates through April 2023, unless previously converted into common stock. With respect to the notes convertible into our common stock, conversion into common stock is triggered upon certain events, including the sale of the Company, an initial public offering or an equity financing with gross proceeds above certain thresholds. See "Note 7 – Notes Payable" to our consolidated financial statements for additional details with respect to the terms of each note. Completion of the Merger resulted in conversion of \$3.7 million of the convertible as of March 31, 2021 into 1,283,105 shares of our common stock.

Pursuant to the GEM Agreement, we are entitled to draw down up to \$60 million of gross proceeds ("*Aggregate Limit*") from GEM Global in exchange for shares of common stock, subject to meeting the terms and conditions of the GEM Agreement. This equity line facility is available for a period of 36 months from the closing date of the Merger. A draw down is subject to limitations on the amount that is drawn under the facility and must comply with certain conditions precedent including the listing of our shares on a principal market, having the necessary number of shares that are issuable pursuant to the draw down registered under an effective registration statement and other notice and timing requirements. Upon our valid exercise of a draw down, pursuant to delivery of a notice and in accordance with other conditions, GEM Global is required to pay, in cash, a per-share amount equal to 90% of the average closing bid price of the shares of our common stock recorded by Nasdaq during the 30 consecutive trading days commencing on the first trading day that is designated on the draw down notice. In no event may our draw down requests exceed 400% ("*Draw Down Limit*") of the average daily trading volume for the 30 trading days immediately preceding the date we deliver the draw down notice. We are entitled to request a draw down of up to \$10 million, in the first month following the closing of the Merger, subject to Draw Down Limit and other conditions provided in the GEM Agreement.

Further, upon the closing of the Merger, GEM Global became entitled to a commitment fee in the form of cash or freely tradeable shares of our common stock in an amount equal to 2% of the Aggregate Limit, or \$1.2 million, to be paid in two tranches. The commitment fee for the first tranche, which is equal to 67% of the commitment fee, or \$800,000, becomes payable on the first anniversary of the closing of the Merger and the commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or \$400,000, becomes payable on the eighteen-month anniversary of the closing of the Merger.

Additionally, at the closing of the Merger, we were required to issue a warrant with a 36-month term granting GYBL the right to purchase shares of our common stock in an amount equal to 4% of the total number of common stock outstanding as of the closing date of the merger (subject to adjustments described below), calculated on a fully diluted basis, at a strike price per share equal to the closing bid price for such common stock on the closing date of the Merger. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GYBL's exercise will entitle GYBL to compensation in addition to other remedies. The number of shares underlying the warrant, as well as the strike price, is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits and issuances of additional common shares at a price per share less than the exercise price.

As of December 31, 2020, we had cash and cash equivalents of \$0.2 million. We have incurred operating losses and experienced negative operating cash flows since our inception, and we anticipate that we will continue to incur losses for at least the foreseeable future. Our net losses totaled \$0.2 million and \$10.1 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$56.0 million.

As of March 31, 2021, we had cash and cash equivalents of \$0.3 million. We have incurred operating losses and experienced negative operating cash flows since inception, and we anticipate that we will continue to incur losses for at least the foreseeable future. As of March 31, 2021, we had an accumulated deficit of \$56.9 million.

Until required for use in our business, we typically invest our cash in investments that are highly liquid, readily convertible to cash with original maturities of 90 days or less at the date of purchase. We attempts to minimize the risks related to our cash and cash equivalents by maintaining balances in accounts only with accredited financial institutions and, consequently, we do not believe we are subject to unusual credit risk beyond the normal credit risk associated with ordinary commercial banking relationships.

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# Cash flows for the three months ended March 31, 2021 and 2020

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

	 Three Months Ended March 31,				
	2021	2020			
Net cash used in operating activities	\$ (517,149)	\$	(303,418)		
Net cash provided by financing activities	612,862		200,000		
Net increase (decrease) in cash and cash equivalents	\$ 95,713	\$	(103,418)		

### Operating activities

During the three months ended March 31, 2021 and 2020, we used cash in operating activities of \$0.5 million and \$0.3 million, respectively, primarily resulting from legal and accounting fees, changes in accounts payable and accrued expenses due to the advancement of our product candidates, and the timing of vendor invoicing and payments.

#### Financing activities

During the three months ended March 31, 2021 and 2020, net cash provided by financing activities was \$0.6 million and \$0.2 million, respectively, consisting of proceeds from the issuance of promissory notes and the exercise of stock options.

#### Cash flows for the years ended December 31, 2020 and 2019

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

		Year Ended December 31,			
	2020			2019	
Net cash used in operating activities	\$	(1,247,342)	\$	(935,263)	
Net cash provided by financing activities		1,100,020		500,000	
Net decrease in cash and cash equivalents	\$	(147,322)	\$	(435,263)	

#### Operating activities

During the years ended December 31, 2020 and 2019, we used cash in operating activities of \$1.2 million and \$0.9 million, respectively, primarily resulting from changes in accounts payable and accrued expenses due to the advancement of our product candidates, and the timing of vendor invoicing and payments.

### Financing activities

During the years ended December 31, 2020 and 2019, net cash provided by financing activities was \$1.1 million and \$0.5 million, respectively, consisting primarily of proceeds from the issuance of our convertible promissory notes.

#### Funding requirements

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

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

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;

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- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- obtain, maintain, expand and protect our intellectual property portfolio;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending
  intellectual property related claims; and
- manage the costs of operating as a public company.

# **Going concern**

We have generated limited revenues and has incurred significant operating losses since our inception and, as of March 31, 2021, we have an accumulated deficit of \$56.9 million. In addition, as discussed above, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Management believes that our existing cash resources on hand at June 30, 2021, and existing financing agreements are sufficient to allow us to fund current planned operations through at least the next twelve months. This evaluation takes into consideration the effect of plans of management that have not been fully implemented as of the date of this registration statement/prospectus.

Upon the completion of the Merger, our pre-merger stockholders exchanged their equity interests in us, which included the conversion prior to the closing of the principal and accrued but unpaid interest on the outstanding Convertible Notes, into shares of our post-merger common stock at a weighted average per share conversion price of \$0.24.

Pursuant to the GEM Agreement, we are entitled to draw down up to the Aggregate Limit from GEM Global in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. See "-Sources of Liquidity and Capital" for a description of the material terms of the GEM Agreement.

Following the closing of the Merger, we received net proceeds of approximately \$7.8 million. Following the closing of the Merger, we may also pursue additional cash resources through public or private equity or debt financings.

Our expectations with respect to our ability to fund current planned operations are based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame

anticipated by us, and we may need to seek additional funds sooner than planned. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate certain of our research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to us, or pursue other merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders. If additional capital is raised through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue business plans and strategies. If we are unable to raise capital, we may need to delay, reduce or terminate planned activities to reduce costs.

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market by ourselves.

For additional information on risks associated with our substantial capital requirements, please read the section titled 'Risk Factors' included elsewhere in this registration statement/prospectus.

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# Working capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of biologic product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

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

# Critical accounting policies and significant judgments and estimates

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

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements and Note 3 to our unaudited interim consolidated financial statements appearing elsewhere in this registration statement/prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

## Accrued research and development expenses

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

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

We based our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we

do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, our estimated accruals have not differed materially from actual costs incurred.

### Stock-based compensation

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

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

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

# Determination of the fair value of common stock

As there has historically been no public market for our common stock prior to the date of the closing of the Merger, the estimated fair value of our common stock was determined by our most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using an option pricing method ("*OPM*"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under the OPM method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity of the common stock is then applied to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$0.09 per share as of July 1, 2017, \$0.12 per share as of February 28, 2018, \$0.17 per share as of October 1, 2018, and \$0.17 per share as of December 31, 2019.

In addition to considering the results of these third-party valuations, our Board considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;

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- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or our sale in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the specialty biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Shares of our common stock are now listed and traded on the Nasdaq. Once a public trading market for our common stock has been established for a sufficient period of time, it will no longer be necessary for our Board to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of the our common stock will be determined based on the publicly-traded quoted market price of our common stock.

# **Off-balance sheet arrangements**

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

## Internal controls over financial reporting

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2019, and our unaudited interim consolidated financial statements for the three months ended March 31, 2021 and 2020, we concluded that there were material weaknesses in our internal controls over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified are insufficient internal controls because of inadequate technical accounting expertise and inappropriate level of supervision and review due to the limited number of accounting personnel. We are taking steps to remediate the material weaknesses in our internal controls over financial reporting, including hiring a Chief Financial Officer in February 2021.

## Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3 to our financial statements included elsewhere in this registration statement/prospectus.

#### Quantitative and qualitative disclosures about market risks

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

Our cash and cash equivalents as of March 31, 2021 consisted of cash and a money market fund account. Because of the short-term nature of our money market fund, a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations.

#### Emerging growth company and smaller reporting company status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company we are not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised accounting standard.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds \$250 million as of the prior June 30, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30.

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# CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

## LACQ Related Party Transactions

# **Issuance of Founder Shares**

In September 2017, prior to the consummation of the initial public offering, LACQ issued an aggregate of 7,187,500 founder shares to its Sponsors, the Strategic Investor and certain members of its management or their affiliates for an aggregate purchase price of \$25,000 in cash, or approximately \$0.003 per share. The number of founder shares issued was determined based on the expectation that such founder shares would represent 20% of the outstanding shares upon completion of the initial public offering. In October 2017, its Hydra sponsor transferred 203,957 of its founder shares to certain of LACQ's officers and professionals. In October 2017, certain of LACQ's initial stockholders transferred 711,250 of their founder shares to the Strategic Investor, with 355,625 of the shares subject to return to such stockholders if certain specified market price levels for its common stock were exceeded. In November 2017, its Hydra sponsor transferred 21, its Completion of the initial public offering, its Hydra sponsor to business combination. In December 2017, in connection with the completion of the initial public offering, and in January 2018, following the expiration of the underwriter's over-allotment option, LACQ's initial stockholders at 20% of its outstanding shares immediately following the consummation of the initial public offering.

# **Private Warrants**

Affiliates of the Sponsors, the Strategic Investor and certain members of LACQ's management purchased an aggregate of 6,325,000 Private Placement Warrants for a purchase price of \$1.00 per whole warrant concurrent with the closing of the initial public offering. Each Private Placement Warrant entitles the holder to purchase one share of our common stock at an exercise price of \$11.50 per share. The Private Placement Warrants (including the common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder. LACQ issued an aggregate of an additional 1,000,001 private warrants to the Sponsors and Strategic Investor in connection with their conversion of promissory notes covering \$1,000,000 of loans to LACQ under LACQ's Expense Advancement Agreement (see section below for "*Expense Advancement Agreement*").

On January 31, 2021, in connection with entering into the Merger Agreement, LACQ entered into a Warrant Surrender Agreement with the Sponsors, pursuant to which each of the Sponsors agreed to irrevocably forfeit and surrender 250,000 Private Placement Warrants immediately prior to, and contingent upon, the closing of the business combination.

On June 7, 2021, the holders of the Private Placement Warrants and private warrants held by affiliates of the Sponsors, the Strategic Investor and certain members of LACQ's management exchanged their warrants for warrants on the same terms as the Private Placement Warrants and private warrants, except that they are not issued under the Warrant Agreement governing the private warrants and are non-transferable except to permitted transferees. This exchange enabled us to treat the private warrants as equity and not liabilities in our financial statements.

### **Contingent Forward Purchase Contract with Strategic Investor**

On December 1, 2017, the Strategic Investor entered into a contingent forward purchase contract with LACQ to purchase, in a private placement for gross proceeds of approximately \$62,500,000 to occur concurrently with the consummation of the business combination, 6,250,000 units on substantially the same terms as the sale of units in LACQ's initial public offering at \$10.00 per unit. On December 27, 2019, in connection with the previously proposed business combination with GTWY Holdings, an amendment to the contingent forward purchase contract was effected to provide that the contingent forward purchase contract would terminate as of, and contingent upon, the closing of the transaction with GTWY Holdings such that the Strategic Investor would instead purchase 3,000,000 units of GTWY Holdings' equity securities for a purchase price of \$10.00 per unit.

In addition, the Strategic Investor waived its rights under the contingent forward purchase contract to purchase private placement units in connection with the Merger.

### Administrative Services Agreement

On December 1, 2017, LACQ entered into an administrative services agreement with the Hydra sponsor under which it agreed to pay the Hydra sponsor, or its affiliates or assignees, a total of up to \$10,000 per month for office space, utilities and secretarial and administrative support until completion of its business combination. Effective June 30, 2020, the Hydra sponsor agreed to stop charging the monthly administrative fee and forgave the \$71,000 outstanding balance due under such administrative services agreement.

#### **Promissory Notes**

LACQ entered into promissory notes with the Sponsors in September 2017 whereby they agreed to loan LACQ up to an aggregate of \$400,000 to be used for a portion of the expenses of its initial public offering. These loans were non-interest bearing, unsecured and were due at the earlier of June 30, 2018 or the initial public offering closing date. These loans were repaid upon the closing of LACQ's initial public offering.

#### **Expense Advancement Agreement**

In order to finance transaction costs in connection with an intended business combination, LACQ entered into an Expense Advancement Agreement with the Sponsors and the Strategic Investor on December 1, 2017 under which they committed to loan LACQ an aggregate of \$1,000,000 pursuant to drawdowns from time to time in the event that funds held outside of the trust were insufficient to fund its expenses after its initial public offering and prior to its business combination (including investigating and selecting a

target business and other working capital requirements). On January 15, 2020, LACQ issued promissory notes pursuant to drawdowns under the Expense Advancement Agreement in the aggregate amount of \$1,000,000, which the holders elected to convert on June 25, 2020, in accordance with the terms thereunder, into warrants at a price of \$1.00 per warrant. LACQ entered into amendments to its Expense Advancement Agreement with the Sponsors and the Strategic Investor dated June 29, 2020, October 26, 2020, November 30, 2020 and February 23, 2021 which, in the aggregate increased the total amount of advances available to it under the Expense Advancement Agreement to \$1,460,000. LACQ issued unsecured promissory notes to such parties on October 26, 2020 and October 27, 2020, which were amended and restated on November 30, 2020 and February 24, 2021. Such promissory notes covered outstanding loans in an amount of \$460,000 at March 10, 2021. The promissory notes did not bear any interest. The Sponsors and the Strategic Investor had the option to convert the outstanding loaned amounts under the promissory notes to warrants at a price of \$1.00 per warrant. Prior to the consummation of the Merger, the Sponsors and the Strategic Investor exercised this option. Upon such exercise, we issued to the Sponsors and the Strategic Investors warrants to purchase 510,001 shares of common stock.

# **Registration Rights**

The holders of the founder shares, Private Placement Warrants and private warrants that may be issued upon conversion of working capital loans (and any shares of common stock issuable upon the exercise of the Private Placement Warrants and warrants that may be issued upon conversion of working capital loans) are entitled to registration rights pursuant to a registration rights agreement entered into by LACQ on the closing of its initial public offering, which requires us to register such securities for resale. Each of the Sponsors (collectively with their respective affiliates) and the Strategic Investor is entitled to make up to two demands, excluding short form demands, that we register such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of our business combination and rights to require us to register for resale such securities pursuant to Rule 415 under the Securities Act. However, the registration rights agreement filed under the Securities Act to become effective until termination of the applicable lock-up period, which occurs (i) in the case of the founder shares, on the earlier of (A) one year after the completion of our business combination or earlier if, subsequent to our business combination, the last sale price of the common stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30 trading day period commencing at least 150 days after our business combination, or (B) the date following the completion of our business combination on which we complete a liquidation, merger, stock exchange or other similar transaction that results in all of our stockholders having the right to exchange their shares of common stock for cash, securities or other property, and (ii) in the case of the Private Placement Warrants and the respective common stock underlying such warrants, 30 days after t

### **Ensysce's Related Party Transactions**

Other than the agreements and arrangements described under the section entitled "Executive & Director Compensation" in this registration statement/prospectus and the transactions described below, since our inception, there has not been and there is not currently proposed, any transaction or series of similar transactions to which (i) we were, or will be, a participant; (ii) the amount involved exceeded, or will exceed, \$120,000 or 1% of the average of our total assets at December 31, 2019 and 2020; and (iii) in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

## Covistat

We own 79.2% of the issued and outstanding shares of Covistat, a clinical stage pharmaceutical company that is developing a compound utilized in our overdose protection program for the treatment of COVID-19. The other 20.8% is owned by two affiliates of Ensysce and Mucokinetica. Specifically, our Chief Executive Officer and Director, Dr. Lynn Kirkpatrick, owns 9.9%, our Chief Business Officer, Richard Wright, owns 9.9% and Mucokinetica owns 1.0%. Dr. Kirkpatrick is also Chief Executive Officer of Covistat. There is no revenue sharing agreement between us and Covistat.

# **Promissory Notes**

Covistat holds a promissory note issued by us in the principal amount of \$200,000. The note accrues simple interest at a rate of 12% until the note is paid in full. The principal amount of the note, together with accrued and unpaid interest, is payable in full on the earlier of (i) July 31, 2022 or (ii) receipt by us of an aggregate of least \$5 million in gross proceeds from the sale of our securities. We may prepay the note in our sole discretion. The note is secured by 2,000 shares of Covistat's common stock (representing 1.98% of the outstanding common stock of Covistat). The note contains customary covenants to protect Covistat's collateral thereunder. Upon an event of default, as described in the note, the collateral shall be immediately enforceable and Covistat shall hold all rights, title and interest in the collateral and exercise any other rights, powers or remedies, authorized under the note.

Dr. Kirkpatrick and Andrew Benton, two of our directors, each hold a promissory note issued by us in the principal amount of \$50,000. The notes carried 0% interest until November 1, 2020, at which point the notes each bear interest at the rate of 10% per annum until the notes are paid in full. The principal amount of the notes are due upon the earlier of (i) December 31, 2021 or (ii) our receipt of at least \$2 million in gross proceeds from the sale of our securities. We may prepay the notes in our sole discretion. The notes held by Dr. Kirkpatrick and Mr. Benton are unsecured. The notes were repaid in July 2021.

On March 16, 2021, Dr. Kirkpatrick loaned \$100,000 to us and Bob Gower, our Chairman, loaned \$200,000 to us and each of them was issued a promissory note. The notes are the same except as to holder and principal amount. The principal amount and accrued interest are due upon the earlier of (i) June 30, 2022 or (ii) our receipt of at least \$2,000,000 in gross proceeds from the sale of our securities. We may prepay the notes in our sole discretion. The notes bear interest at a rate of 10% and are unsecured. The notes were repaid in July 2021.

# **Convertible Notes**

Bob Gower, our Chairman, holds an Unsecured 10% Convertible Promissory Notes of Ensysce in the aggregate amount of \$2,500,000 issued on the following dates for the following amounts:

- May 4, 2018 in the amount of \$600,000;
- September 14, 2018 in the amount of \$1,000,000;
- December 31, 2018 in the amount of \$500,000;
- October 17, 2019 in the amount of \$100,000;
- January 23, 2020 in the amount of \$100,000;
- March 9, 2020 in the amount of \$100,000; and
- April 15, 2020 in the amount of \$100,000 (together, the "Gower Notes").

The Gower Notes carry simple interest at rate of 10% per annum and the principal amounts and accrued and unpaid interest thereunder become due and payable upon Mr.

Gower's demand two years after the issue date of such note or upon an event of a default as provided in such note. We cannot prepay the Gower Notes without the consent of holders representing a majority of the aggregate principal amount of all the notes then outstanding, but not including the Gower Notes. The Gower Notes contain an acceleration provision and will automatically convert into shares of our common stock at a conversion price of \$0.23 per share. The Gower Notes were converted into shares of our common stock in the Merger.

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# Procedures with Respect to Review and Approval of Related Person Transactions

Upon consummation of the Merger, the Board adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

An "Immediate Family Member" means a child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, or any person sharing the household (other than a tenant or employee).

A "Related Party" means any (a) person who is or was (since the beginning of the last fiscal year for which we have filed a Form 10-K and proxy statement, even if they do not presently serve in that role) an executive officer, director or nominee for election as a director of the Company, (b) greater than 5% beneficial owner of the Company's outstanding common stock, or (c) Immediate Family Member of any of the foregoing.

A "Related Person Transaction" is any Transaction involving the Company in which a Related Party has or will have a direct or indirect material interest, as determined by the Audit Committee.

A "Transaction" means any financial transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, including indebtedness and guarantees of indebtedness and transactions involving employment and similar relationships.

Under the policy, the following types of Transactions are deemed not to create or involve a material interest on the part of the Related Party, nor will they require approval or ratification, under the policy:

- Transactions involving the purchase or sale of products or services in the ordinary course of business, not exceeding \$50,000 or, if the Company is a "smaller reporting company" as defined under the Securities Act, if less, one percent of the average of the Company's total assets as of December 31st for the last two completed fiscal years.
- Transactions in which the Related Party's interest derives solely from his or her service as a director of another corporation or organization that is a party to the Transaction.
- Transactions in which the Related Party's interest derives solely from his or her ownership of less than 5% of the equity interest in another person (other than a general partnership interest) which is a party to the Transaction.
- Transactions in which the Related Party's interest derives solely from his or her ownership of a class of equity securities of the Company and all holders of that class of equity securities received the same benefit on a pro rata basis (e.g., dividends).
- Transactions in which the Related Party's interest derives solely from his or her service as a director, trustee or officer (or similar position) of a not-for-profit organization or charity that receives donations from the Company, which donations are made pursuant to the Company's matching program, as a result of contributions by employees, that is available on the same terms to all employees of the Company.
- Compensation arrangements of any executive officer, other than an individual who is an Immediate Family Member of a Related Party, if such arrangements have been
  approved or recommended to the Board for approval by the Compensation Committee.
- Director compensation arrangements, if such arrangements have been approved by the Board or the Compensation Committee of the Board.
- Transactions with a Related Party in which the rates or charges involved in the Transaction are determined by competitive bids, or the Transaction involves the rendering
  of services as a common or contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority.
- Indemnity payments made to directors and executive officers in accordance with the Company's then existing certificate of incorporation, bylaws and applicable laws.
- Transactions with a Related Party involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture or similar services.

Pursuant to its Audit Committee charter, the Audit Committee will have the responsibility to review, approve or ratify any Related Person Transactions.

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# MANAGEMENT

# **Executive Officers and Directors**

The following persons are our directors and executive officers:

Name	Age*	Position
Executive Officers	_	
Dr. Lynn Kirkpatrick	64	President, Chief Executive Officer and Class III Director
David Humphrey, CPA	53	Chief Financial Officer, Secretary and Treasurer
Richard Wright, MBA	49	Chief Business Officer
Geoffrey Birkett	59	Chief Commercial Officer
William Schmidt, Ph.D.	70	Chief Medical Officer
Jeffrey Millard, Ph.D.	46	Chief Operating Officer
Directors		
Andrew Benton	69	Class I Director
William Chang	65	Class I Director
Bob Gower	83	Class II Director and Chairman of the Board
Adam Levin	42	Class III Director
Steve Martin	60	Class III Director

64 Class II Director

# \*Ages presented as of July 28, 2021

## Information about our Executive Officers and Directors

# **Executive Officers**

*Dr. Lynn Kirkpatrick, Ph.D.* has served as our Chief Executive Officer since January 12, 2009. Dr. Kirkpatrick has spent over 30 years in drug discovery and development, has initiated the clinical development of four novel drug candidates and now strives to bring highly novel and safe pain therapies to commercialization. She received a Doctor of Philosophy ("*Ph.D.*") degree in Medicinal and Biomedicinal Chemistry at the University of Saskatchewan, completed a Post-Doctoral Fellowship at the Yale University School of Medicine, and became a tenured full professor in the Department of Chemistry at the University of Regina. She co-founded ProIX Pharmaceuticals, Corp. ("*ProIX*") an oncology discovery company, becoming Chief Executive Officer and successfully bringing three small molecules from discovery into clinical development, two of these her own discoveries from academia. ProIX was acquired by Biomira Inc., and Dr. Kirkpatrick became the Chief Scientific Officer of the merged company to focus on the development of oncology products and vaccines. In 2009, she co-founded PHusis Therapeutics, developing targeted small molecule precision medicines for oncology. At the same time, she became our Chief Executive Officer. Dr. Kirkpatrick has published extensively in the area of targeted drug discovery, abuse deterrent pain products and holds numerous patents for novel drugs and modalities. We believe Dr. Kirkpatrick is qualified to serve on our Board because of her extensive executive officer.

*David Humphrey, CPA* has served as our Chief Financial Officer since February 2021. Prior to joining the Company, Mr. Humphrey was most recently Chief Financial Officer of Senomyx, Inc. ("*Senomyx*"), a publicly held biotechnology company focused on taste science. In his previous employment, he guided public company financial reporting, including Forms 10-K, 10-Q, 8-K, S-3, S-8, proxy statements and SOX internal controls compliance, and acted as primary liaison with the audit committee and external auditors. Mr. Humphrey advised Senomyx's board of directors, as part of core executive management team, in a \$75 million acquisition by Firmenich SA, a private Swiss multinational flavor and fragrance company. Previously, he held finance and accounting leadership positions and consulted at numerous life sciences companies, including ActivX Biosciences, Aurora Biosciences and Gensia. Mr. Humphrey started his career as an accountant at Price Waterhouse. He holds a Bachelor of Science with Honors in Accountancy from the University of Illinois at Urbana-Champaign and is a Certified Public Accountant in California.

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*Richard Wright* has served as our Chief Business Officer since January 2016. Mr. Wright is the Chief Executive Officer of Magnostics, Ltd, a superparamagnetic nanomaterial company based in Dublin, Ireland. Previously, he served as Venture Partner at Ren Capital Partners ("*Ren Capital*"), a healthcare fund of funds based in Beijing. Prior to Ren Capital, he was a strategic advisor to Bangkok Dusit Medical Service, the largest healthcare conglomerate in Southeast Asia, assisting in drug commercialization efforts. Mr. Wright was Managing Director at Newstock Capital, an intellectual property investment advisory firm based in Stockholm, Sweden. While at Newstock, he worked with venture capital and corporate funds on divestitures, mergers and acquisitions, patent transactions, licensing and infringement. Previously Mr. Wright was fund manager for General Electric / Technology Ventures where he managed an intellectual property healthcare fund. He was the Co-Founder and Chief Executive Officer of TherimuneX, a company that has been developing endogenous lipopeptides for their immune regulating properties. Mr. Wright was principal of Guardian Technology Partners, a chemical and life sciences intellectual property advisory firm that was sold to investment bank Boenning and Scattergood. Mr. Wright started his career on the business development team of Endo Pharmaceuticals, plc. Mr. Wright has over 24 years of experience spanning start-up, fast growth pharmaceutical companies combined with intellectual property and healthcare investment acumen from varied international markets. Mr. Wright holds a Master of Science in Engineering, Management of Technology with a focus of biotechnology from University of Pennsylvania's School of Engineering and Applied Sciences and Wharton School of Business, and a Master of Business Administration from London School of Economics TRIUM program.

*Geoffrey Birkett* has served as our Chief Commercial Officer since October 1, 2018. He has over 30 years of experience in the Pharmaceutical and Biotechnology area. He started his career as a biochemist at the Royal Victoria Infirmary in Newcastle-upon-Tyne, England. He then moved into the pharmaceutical industry, where he focused on pain/addiction and neuroscience throughout his career. He has developed and launched several groundbreaking therapies, including Nicorette (POM) and (OTC), Lexapro and several other psychiatry agents with Lundbeck. Mr. Birkett assisted on the launch of Prozac and Humatrope (human growth hormone) with Eli Lilly. He assisted in moving Seroquel from Phase 2 to global market leader with multi-billion dollar sales and he also participated in the launch of Zomig for migraines, which became a European market leader. He worked for most of his pharmaceutical career at AstraZeneca plc in both the United Kingdom and the United States, where he held many roles including overseeing the global oncology division. When the AstraZeneca merger took place, Mr. Birkett ran the merger process outside the United States across all markets, and ran a corporate change program to streamline research and development involving 67,000 staff. Since leaving AstraZeneca, Mr. Birkett has held multiple roles in biotech companies as senior officer or as a consultant. He is co-founder of a novel drug delivery company and has consulted for IPSOS, a large global research and consulting firm. He also served as president for North America/Canada of INDIVIOR, a large company producing addiction treatment drugs. Mr. Birkett joined us in 2018 and is focused on building a world class commercial team. Mr. Birkett attended Henley Business College in London and INSEAD Business School in France where he studied general management and a global leadership.

*Dr. William K. Schmidt, Ph.D.*, has served as our Chief Medical Officer since January 1, 2016. He is also the Head of NorthStar Consulting, the Parliamentarian and a former president of the Eastern Pain Association, the largest regional affiliate of the American Pain Society. He has over 25 years of pharmaceutical industry experience with a special emphasis on the discovery and development of novel analgesic and narcotic antagonist drugs. He was previously Vice President of Clinical Development for CrystalGenomics (Seoul, South Korea) and its United States subsidiary, CG Pharmaceuticals (Emeryville, CA); Senior Vice President of Development at Limerick BioPharma; Vice President, Clinical Research, for Renovis, Inc.; and Vice President, Scientific Affairs and acting Vice President, Clinical Research, and Development, and Yadolor Corporation. At Adolor Corporation, Dr. Schmidt was a key member of the team leading to the clinical development, NDA filing, and FDA approval of Entereg® (alvimopan), a peripherally-acting opioid antagonist. Currently Dr. Schmidt serves as an expert on pain medicine pharmaceutical development with pharmaceutical and biotech companies throughout North America, Europe, Asia, Latin America, and Australia. Dr. Schmidt received a Bachelor of Arts degree from the University of California-San Francisco.

Jeffrey Millard, Ph.D. has served as our Chief Operating Officer since January 2019. Dr. Millard has both academic and industrial experience in chemistry and pharmaceutical sciences covering all aspects of chemistry, manufacturing, and controls, or CMC. He has been involved in both start-up biotech as well as small and mid-sized public biopharmaceutical companies. Dr. Millard has been directly responsible for research and development activities and writing of more than seven IND submissions and Investigational Medicinal Product Dossiers, or IMPDs. He has directed the CMC efforts from discovery and in-licensing through commercial launch activities. His experience covers the application programming interface, or API, lifecycle (from synthetic route scouting, process chemistry, analytical chemistry development and validation, cGMP production and release of API, to QbD and process validation), and drug product development through manufacture. Dr. Millard received a Bachelor of Arts from Rice University and a Ph.D. in Pharmaceutical Sciences from the University of Arizona.

# Directors

Andrew Benton, J.D. has served as a member of our Board since December 2, 2019. Mr. Benton was the President, Chief Executive Officer and Trustee of Pepperdine University from June 2000 to July 2019. Mr. Benton was the former chairman of both the American Council of Education, the major coordinating body for all of the nation's higher education institutions, and the National Association of Independent Colleges and Universities. Mr. Benton is also past chair of the Association of Independent California Colleges and Universities and a member of the American Bar Association, the Council for Higher Education Accreditation, the President's Cabinet of the West

Coast Conference, the Association of Presidents of Independent Colleges and Universities, and the Los Angeles World Affairs Council. Mr. Benton holds an undergraduate degree in American studies from Oklahoma Christian University and a J.D. from Oklahoma University. Mr. Benton was awarded the Distinguished Alumnus Award by Oklahoma University. We believe that Mr. Benton's experience governing academic and other institutions qualifies him to serve on our Board.

*William Chang* serves as Chief Executive Officer of Westlake Realty Group and Chairman of Westlake International Group where he has worked for more than 40 years. Mr. Chang runs Edge Venture Capital Fund and is a founder and the managing partner of Digikeyih. Mr. Chang is an investor in the San Francisco Giants of Major League Baseball. Mr. Chang is also a member of YPO Gold, Northern California and is the former Chairman of U.S. Rugby Football Union. He also served on the Board of the Asia Foundation and San Francisco Port and Social Services Commissions. Mr. Chang holds a Bachelor degree in Economics from Harvard University. We believe that Mr. Chang's experience in corporate governance qualifies him to serve on our Board.

**Bob Gower, Ph.D.** has served as our Chairman since 2008. Dr. Gower was Chief Executive Officer of Lyondell Petrochemical from 1985 through his retirement at the end of 1996. Together with Dr. Richard Smalley, Dr. Gower founded Carbon Nanotechnologies, Inc. ("*CNP*") in 2000 developing fullerene carbon nanotubes for multiple applications. CNI was acquired by Unidym in 2007. Dr. Gower founded Specified Fuels and Chemicals and in early 2008 and founded our company for the specific focus of using carbon nanotubes in therapeutic areas. He served on the board of directors of numerous companies, including Kirby Corporation and OmNova. In addition, Dr. Gower received his Ph.D. from the University of Minnesota. We believe that Mr. Gower's previous board and industry experience qualifies him to serve on our Board.

Adam S. Levin, MD, is the Vice Chair of Faculty Development for the Department of Orthopaedic Surgery at Johns Hopkins University, where he has been on faculty since 2014. He is an Associate Professor of Orthopaedic Surgery and Associate Professor of Oncology, researching treatments related to musculoskeletal oncology, while also maintaining an active clinical practice. He has served as the Associate Director of the Orthopaedic Surgery Residency Training Program since 2015, and has led novel curricular efforts through the Musculoskeletal Tumor Society and the American Academy of Orthopedic Surgeons. He has overseen Departmental Compliance since 2016, in addition to holding additional leadership roles related to billing, coding, and practice management for the Musculoskeletal Tumor Society and the American Academy of Orthopaedic Surgeons. Prior to joining Johns Hopkins University, Dr. Levin was an Assistant Professor of Orthopaedic Surgery at the Zucker School of Medicine at Hofstra University, and Attending Physician at Long Island Jewish Medical Center and North Shore University Hospital in New York between 2012 and 2014. From 2010 to 2012, he was a fellow of musculoskeletal oncology and Clinical Instructor at Memorial Sloan-Kettering Cancer Center, following his residency training at the North Shore/LIJ Health System (now Northwell Health) from 2005 to 2010. He was a member of the North Shore/LIJ Physician High Potential Program from 2013 until his departure in 2014, and the American Academy of Orthopaedic Surgeons' Leadership Fellows Program from 2019 to 2020; he has maintained membership in the American Orthopaedic Association of Emerging Leaders Program since 2015. Dr. Levin has also continued to serve as Associate Editor for CME for the Journal of Bone and Joint Surgery since 2016, and is on the Steering Committee for the Musculoskeletal Tumor Registry where he leads the Publications Subcommittee. Dr. Levin served as a subject-matter consultant to our predecessor, LACQ, during their initial review of our preclinical and Phase I clinical trial results. Dr. Levin holds a B.S. in Biology with a concentration in Animal Physiology from Cornell University, an M.D. from New York Medical College, and is currently studying at the Johns Hopkins University Carey School of Business for an M.B.A. with a specialization in Healthcare Management, Innovation, and Technology. We believe that Mr. Levin is well qualified to serve as a member of our Board based on his academic and practice experience and his detailed knowledge of value-based care, acute and chronic pain management, novel drug design, and health care operations and management.

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Steve R. Martin has served as a member of our Board since August 2020. Mr. Martin also currently serves as Senior Vice President and Chief Financial Officer of Armata Pharmaceuticals, Inc., a clinical development stage biotechnology company listed on New York Stock Exchange, since January 2016. Previously, Mr. Martin served as Senior Vice President and Chief Financial Officer of Applied Proteomics, Inc., a molecular diagnostics company, from December 2014 to August 2015. From June 2011 to December 2014, Mr. Martin served as Senior Vice President and Chief Financial Officer of Apricus Biosciences, Inc. ("*Apricus*"), a publicly traded pharmaceutical company, and served as the Interim Chief Executive Officer of Apricus from November 2012 through March 2013. From 2008 to January 2011, Mr. Martin served as Senior Vice President and Chief Financial Officer of Apricus from November 2012 through March 2013. From 2008 to January 2011, Mr. Martin served as Senior Vice President and Chief Financial Officer of BakBone Software ("*BakBone*"), a publicly traded software company. During his final 10 months with BakBone until the company's acquisition in January 2011, Mr. Martin also served as BakBone's Interim Chief Executive Officer. From 2005 to 2007, Mr. Martin served as Chief Financial Officer of Stratagene Corporation, a publicly traded molecular diagnostics company, as well as 10 years with Deloitte & Touche LLP, a public accounting firm. Mr. Martin holds a Bachelor in Science in Accounting from San Diego State University and is a certified public accountant (inactive). We believe that Mr. Martin's expertise in biopharmaceutical industry and accounting expertise qualifies him to serve on our Board.

*Curtis Rosebraugh, M.D., MPH* is a member of Griebel and Rosebraugh Consulting LLC since May 2018, where he is a regulatory consultant for small molecule and biological drug development. Prior to forming a consulting firm, he was with the Food and Drug Administration since 2000 and was the Director of the Office of Drug Evaluation II ("*ODEII*") within the Center for Drug Evaluation and Research ("*CDER*") from 2007 until his retirement in 2018, with supervisory responsibility for the evaluation of all drug products within 3 divisions: the Division of Pulmonary, Allergy and Rheumatology Products, the Division of metabolism and Endocrinology Products and the Division of Anesthesia, Analgesia, and Addiction Products. He has overseen the development and approval of over 50 new drugs, was responsible for the planning of over 100 advisory committee meetings, led ODE II through several controversial safety issues and has received many honors and awards. Dr. Rosebraugh has been involved in the development of abuse deterrent opioid formulations and has also been involved in the development of the biosimilar program as well as many other CDER initiatives. Dr. Rosebraugh received his undergraduate degree in pharmacy in 1981, his Medical Degree in 1986 and completed a residency in Internal Medicine in 1989, all at the University of Kansas. He completed a Masters of Public Health at Johns Hopkins School of Public Health in 1999 and a Clinical Pharmacology Fellowship at Georgetown University in 2000. Dr. Rosebraugh joined the FDA in 2000 as a Medical Reviewer in the Division of Public restor in 2007. We believe that Dr. Rosebraugh's regulatory experience and overseeing and participating in drug development in the biopharmaceutical industry qualifies him to serve on our Board.

# **Director Independence**

Nasdaq listing rules require that a majority of the board of directors of a company listed on Nasdaq be composed of "independent directors," which is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship that, in the opinion of the company's board of directors, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Based on information provided by each director concerning his or her background, employment and affiliations, including family relationships, the Board determined that each of Bob Gower, William Chang, Andrew Benton, Steve R. Martin, Adam S. Levin, and Curtis Rosebraugh is an independent director under the Nasdaq listing rules and Rule 10A-3 of the Exchange Act. In making these determinations, the Board considered the current and prior relationships that each non-employee director has and will have with us and all other facts and circumstances that the Board deems relevant in determining independence, including the beneficial ownership of our common stock by each non- employee director (and related entities) and the transactions involving them described in the section entitled "*Certain Relationships and Related Party Transactions.*"

# Role of Board in Risk Oversight

The Board has extensive involvement in the oversight of risk management related to us and our business and accomplishes this oversight through the regular reporting to the Board by the audit committee. The audit committee represents the Board by periodically reviewing our accounting, reporting and financial practices, including the integrity of our financial statements, the surveillance of administrative and financial controls and our compliance with legal and regulatory requirements. Through its regular meetings with management, including the finance, legal, internal audit and information technology functions, the audit committee reviews and discuss all significant areas of our business and summarize for the Board all areas of risk and the appropriate mitigating factors. In addition, our Board receives periodic detailed operating performance reviews from management.

### **Composition of the Board**

Our business and affairs are managed under the direction of the Board. Our Board consists of up to seven (7) directors, which are divided into three classes (Class I, II and III) with Class I and II each consisting of two directors and Class III consisting of three directors.

#### **Board Committees**

The standing committees of our Board consist of an audit committee, a compensation committee and a nominating and corporate governance committee. Our Board may from time to time establish other committees. Each of the committees reports to the Board.

Our president and chief executive officer and other executive officers regularly report to the non-executive directors and the audit, the compensation and the nominating and corporate governance committees to ensure effective and efficient oversight of our activities and to assist in proper risk management and the ongoing evaluation of management controls.

#### Audit Committee

We have an audit committee consisting of Steve R. Martin, who serves as the chairperson, Bob Gower and Andrew Benton. Each member of the audit committee qualifies as an independent director under the Nasdaq corporate governance standards and the independence requirements of Rule 10A-3 of the Exchange Act. Our Board has determined that Steve R. Martin qualifies as an "audit committee financial expert" as such term is defined in Item 407(d)(5) of Regulation S-K and possesses financial sophistication, as defined under the rules of Nasdaq.

The purpose of the audit committee is to prepare the audit committee report required by the SEC to be included in our proxy statement and to assist our Board in overseeing and monitoring (1) the quality and integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) our independent registered public accounting firm's qualifications and independence, (4) the performance of our internal audit function and (5) the performance of our independent registered public accounting firm.

Our Board adopted a written charter for the audit committee, which is be available on our website.

#### **Compensation Committee**

We have a compensation committee consisting of Adam Levin, who serves as the chairperson, Bob Gower and William Chang.

The purpose of the compensation committee is to assist our Board in discharging its responsibilities relating to (1) setting our compensation program and compensation of our executive officers and directors, (2) monitoring our incentive and equity-based compensation plans and (3) preparing the compensation committee report, if required to be included in our proxy statement under the rules and regulations of the SEC.

Our Board adopted a written charter for the compensation committee, which is available on our website.

#### Nominating and Corporate Governance Committee

We have a nominating and corporate governance committee, consisting of Bob Gower, who serves as chairperson, Steve R. Martin and Curtis Rosebraugh. The purpose of our nominating and corporate governance committee is to assist our Board in discharging its responsibilities relating to (1) identifying individuals qualified to become new Board members, consistent with criteria approved by the Board, (2) reviewing the qualifications of incumbent directors to determine whether to recommend them for reelection and selecting, or recommending that the Board select, the director nominees for the next annual meeting of stockholders, (3) identifying Board members qualified to fill vacancies on any Board committee and recommending that the Board appoint the identified member or members to the applicable committee, (4) reviewing and recommending to the Board corporate governance principles applicable to us, (5) overseeing the evaluation of the Board and management and (6) handling such other matters that are specifically delegated to the committee by the Board from time to time.

Our Board adopted a written charter for the nominating and corporate governance committee, which is available on our website.

# **Code of Business Conduct**

We adopted a code of business conduct that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer, which is available on our website. Our code of business conduct is a "code of ethics," as defined in Item 406(b) of Regulation S-K. We will make any legally required disclosures regarding amendments to, or waivers of, provisions of our code of ethics on our website.

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# **EXECUTIVE & DIRECTOR COMPENSATION**

# LACQ

None of LACQ's officers or directors received any cash (or non-cash) compensation for services rendered. Commencing on December 1, 2017, under an administrative services agreement, LACQ agreed to pay its Hydra sponsor, or its affiliates or assignees, a total of up to \$10,000 per month for office space, utilities and secretarial and administrative support until completion of our business combination. Effective June 30, 2020, its Hydra sponsor agreed to stop charging the monthly administrative fee and forgave the \$71,000 outstanding balance due under the administrative services agreement.

#### Ensysce

References in this section to "we," "our," "us," "the Company" or "Ensysce" generally refer to Ensysce and its consolidated subsidiaries.

This section discusses the material components of the executive compensation program for our named executive officers. Our named executive officers, consisting of our principal executive officer and the next two most highly compensated executive officers, for the year ended December 31, 2020, were:

- D. Lynn Kirkpatrick, Ph.D., Chief Executive Officer;
- Richard Wright, MBA, Chief Business Officer; and
- Geoff Birkett, Chief Commercial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt in the future may differ materially from the currently planned programs summarized in this discussion.

# **Summary Compensation Table**

The following table provides summary information concerning compensation earned by our named executive officers for the year ended December 31, 2020 for services rendered for the year ended December 31, 2020.

				All Other			
		Salary	Bonus	Option	Compensation	Total	
Name and Principal Position	Year	(\$)(1)	(\$)	Awards (\$)	(\$)	(\$)	
D. Lynn Kirkpatrick, PhD.							
Chief Executive Officer	2020	155,868	-	-	-	155,868	
Richard Wright							
Chief Business Officer	2020	76,000	-	-	-	76,000	
Geoff Birkett							
Chief Commercial Officer	2020	72,000	-	-	-	72,000	

(1) The amounts reported represent the named executive officer's base salary earned during the fiscal year ended December 31, 2020.

#### Narrative Disclosure to Summary Compensation Table

## **Employment Agreements**

As of December 31, 2020, we did not enter into a written employment contract with our CEO, Dr. Kirkpatrick. However, the Board, pursuant to resolutions dated January 15, 2016, approved her base salary, which was (a) prior to the date the Company received qualified funding of at least two million dollars, Dr. Kirkpatrick would receive no base salary, (b) once the Company received qualified funding of at least two million dollars but no more than ten million dollars, Dr. Kirkpatrick would receive an annual base salary of \$150,000 and (c) once the Company received qualified funding of at least ten million dollars, Dr. Kirkpatrick would receive an annual base salary of \$150,000 and (c) once the Company received qualified funding of at least ten million dollars, Dr. Kirkpatrick would receive an annual base salary of these milestones were attained in or prior to calendar year 2020; however, as set forth more fully below, the Company did pay Dr. Kirkpatrick base salary in calendar year 2020.

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We entered into an offer letter with Mr. Wright dated July 31, 2017 (the "*Offer Letter*"), memorializing the terms of his employment as the Company's Chief Business Officer. Pursuant to the Offer Letter, Mr. Wright's base salary was also dependent on the Company obtaining a qualified financing, as (a) prior to the date the Company received qualified funding of at least two million dollars, Mr. Wright would receive no base salary, (b) once the Company received qualified funding of at least five million dollars, Mr. Wright would receive an annual base salary of \$185,000 (the "*Initial Trigger*") and (c) once the Company received qualified funding of at least fifteen million dollars, Mr. Wright would receive an annual base salary of \$250,000. Additionally, upon the occurrence of certain financing event, Mr. Wright was eligible to receive a special one-time bonus of \$200,000, however, prior to closing, none of the events occurred and no bonus was paid. Upon a termination of Mr. Wright's employment by the Company without cause and after the occurrence of the Initial Trigger, Mr. Wright would be eligible to receive severance equal to one month of base salary. None of these milestones were attained in or prior to calendar year 2020; however, as set forth more fully below, the Company did pay Mr. Wright base salary in calendar year 2020.

As of December 31, 2020, we did not enter into a written employment contract with Mr. Birkett with respect to his employment as Chief Commercial Officer. Prior to his employment as Chief Commercial Officer, we entered into an agreement with Mr. Birkett dated July 18, 2018 (the "*Birkett Agreement*"). Pursuant to the terms of the Birkett Agreement, Mr. Birkett was to provide consulting services. The Birkett Agreement is terminable upon one (1) weeks advance notice. Under the Birkett Agreement, Mr. Birkett was entitled to a consulting fee of \$20,000. The Birkett Agreement also contained standard confidentiality and assignment of inventions provisions.

We, as a condition of employment following the consummation of the Merger, and to the extent permitted by law, have entered, or intend to enter, into agreements with all full-time employees, including each of our named executive officers, which includes the following restrictive covenants: (i) perpetual confidentiality and non-disclosure; (ii) 12-month non-competition; (iii) 12-month no-solicitation of customers and non-interference with franchisees, joint ventures, suppliers, vendors or contractors; and (iv) 12-month non-solicitation and no-hire of employees.

## **Base Salary**

Prior to the closing of the Merger, the Company was mainly financed through federal government grants. Dr. Kirkpatrick is the principal investigator on the two grants and as such, was paid based on the percentage identified in each grant. Such amount paid in the 2020 calendar year is reflected in the base salary column of our summary compensation table above. Mr. Birkett was paid a monthly fee from one of the grants. Such amount paid in the 2020 calendar year is reflected in the base salary column of our summary compensation table above. Mr. Wright was paid the same monthly amount as Mr. Birkett, which was outside of the specific grant, and such amount paid in the 2020 calendar year is reflected in the base salary column of our summary compensation table above.

After closing, we have provided, or intend to provide, each named executive officer with a base salary for the services that the executive officer performs for us. Base salaries were initially set at the time each named executive officer commenced employment with us and are reviewed annually and may be increased based on the individual performance of the named executive officer, company performance, any change in the executive's position within our business, the scope of his or her responsibilities and any changes thereto.

### Annual Bonus

As of December 31, 2020, the Company did not have a formal bonus plan and no bonuses were paid or payable to any of our named executive officer.

### Stock Incentive Plan

The following is a summary of the Ensysce Biosciences, Inc. 2021 Omnibus Incentive Plan (the '*Incentive Plan*''), which replaced the Ensysce Biosciences, Inc. 2016 Stock Incentive Plan (the "*Former Plan*") and became effective upon the closing of the Merger. In connection with the Merger, LACQ adopted, and its stockholders approved, the Incentive Plan in order to facilitate the grant of cash and equity incentives to directors, employees, including our named executive officers, and consultants to help us attract and retain services of these individuals, which is essential to our long-term success. Following the effectiveness of the Incentive Plan, no further awards could be made under the Former Plan and all outstanding awards under the Former Plan were converted into awards under the Incentive Plan.

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The Incentive Plan includes the following key provisions designed to protect stockholder interests, promote effective corporate governance, and reflect use of corporate governance best practices:

- Aggregate Share Reserve. A total of 5,444,068 shares of common stock is reserved for issuance under the Incentive Plan, consisting of (i) 4,444,068 shares of common stock underlying awards under the Incentive Plan and (ii) 1,000,000 additional shares of common stock reserved for issuance under the Incentive Plan. The Board believes that the Incentive Plan benefits our compensation structure and strategy. Our ability to attract, retain and motivate top quality management, employees and non-employee directors is material to our success, and the Board has concluded that this would be enhanced by the ability to make grants under the Omnibus Incentive Plan. In addition, the Board believes that the interests of the Company and the post-combination company's stockholders will be advanced if the Company can offer employees, consultants and non-employee directors the opportunity to acquire or increase their proprietary interests in the Company.
- Non-Employee Director Compensation Limit. The Omnibus Incentive Plan limits the aggregate amount of stock-based and cash-based awards which may be granted to
  any non-employee member of our Board in respect of any fiscal year, solely with respect to his or her service to the Board, at \$250,000.
- No Discounted Options. Stock options may not be granted with exercise prices lower than the fair market value of the underlying shares on the grant date.
- No Repricing of Under-water Options. The terms of the Omnibus Incentive Plan do not allow for the repricing of "under-water" stock options, including the cancellation
  and reissuance of new options in exchange for stock options whose strike price is above the then-current fair value of LACQ common stock.
- No Cash Buyout without Stockholder Approval. No cash buyouts of outstanding stock options are permitted under the Omnibus Incentive Plan where the option strike
  price exceeds the then-current fair value of LACQ common stock.
- No Automatic Vesting on a Change in Control. The terms of the Omnibus Incentive Plan do not provide for automatic vesting on a change in control for any awards.
- Minimum Vesting Requirements. Awards granted to employees and consultants under the Omnibus Incentive Plan generally will not vest prior to the first anniversary of
  the date of grant, except in certain limited circumstances, including a change in control and a participant's death, disability or other termination.
- No Dividends on Unvested Awards. Stock options granted under the Omnibus Incentive Plan are not eligible to receive dividends, and other awards may only receive dividends upon vesting of the underlying shares subject to the award.
- No Share Recycling for Net Exercises or Tax Withholding. Shares surrendered or withheld to pay either the exercise price of an award or to withhold taxes in respect of
  an award do not become available for issuance as future awards under the Omnibus Incentive Plan.
- No Evergreen Provision. There is no "evergreen" or automatic replenishment provision pursuant to which the shares authorized for issuance under the Omnibus Incentive Plan are automatically replenished.
- No Automatic Grants. The Omnibus Incentive Plan does not provide for automatic grants to any participant.

The following is a brief summary of the principal provisions of the Omnibus Incentive Plan, and is qualified in its entirety by reference to the full text of the Incentive Plan.

#### Purpose

The purpose of the Omnibus Incentive Plan are to enhance our profitability and value for the benefit of our stockholders by enabling us to offer our employees, directors and other service providers and our affiliates stock and stock-based incentive awards to create a means to raise the level of stock ownership by employees, directors and service providers in order to attract, retain and reward such individuals and strengthen the mutuality of interests between such individuals and our common stockholders.

#### Administration

The Incentive Plan is administered by a committee (referred to as the "Committee"). With respect to application of the Incentive Plan to employees and consultants, the Committee is comprised of not less than two individuals appointed by our Board, each of whom is an "independent director" as defined under Nasdaq Listing Rule 5605(a)(2) and at least two of whom are "non-employee directors" to the extent required by Rule 16b-3 of the Exchange Act. The Compensation Committee of the Board, which will meet these requirements, was appointed by the Board as the Committee that administers the Incentive Plan with regard to employees and consultants. The Board serves as the Committee with respect to the application of the Incentive Plan to non-employee directors. The Committee may make rules and regulations and establish procedures for the administration of the Incentive Plan as it deems advisable.

A member of the Compensation Committee who does not meet the "non-employee director" standard within the meaning of Rule 16b-3 of the Exchange Act is required to abstain from the actions of the Compensation Committee, as the Compensation Committee may determine, in order to comply with Rule 16b-3 of the Exchange Act. The Compensation Committee may also establish a subcommittee of the Compensation Committee that is intended to qualify as a committee consisting solely of two or more "non-employee directors," and may delegate to the subcommittee all approvals, certifications and administrative and other determinations with respect to compensation intended to be exempt under Rule 16b-3 of the Exchange Act.

#### Eligibility

All of our current and prospective eligible employees and consultants, as well as non-employee directors, and our affiliates are eligible to receive grants of non-qualified stock options, restricted stock and other stock-based awards under the Incentive Plan. Only our employees and of our subsidiaries are eligible to receive grants of stock options that are intended to qualify as "incentive stock options" under the Code.

Immediately after the closing of the Merger there were approximately eight eligible employees, six eligible consultants and four non-employee directors who are eligible to participate in and receive awards under the Incentive Plan. However, eligibility for awards under the Incentive Plan is determined by the Committee its sole discretion.

#### Available Shares

The aggregate number of shares of common stock that may be subject to awards under the Incentive Plan will not exceed 5,444,068 shares, consisting of (i) 4,444,068 shares subject to outstanding awards under the prior Ensysce equity plans that were converted into awards under the Incentive Plan upon consummation of the business combination and (ii) 1,000,000 additional shares of common stock reserved for issuance under the Incentive Plan. The foregoing aggregate share limitation is subject to adjustment in the event of a recapitalization, stock split, stock dividend or similar corporate transaction. The shares subject to awards under the Incentive Plan may be either authorized or unissued shares or shares held in treasury. The maximum number of shares of common stock that may be issued pursuant to stock options intended to be incentive stock options is 5,444,068. The closing market price of a share of common stock reported on the Nasdaq on August 4, 2021 was \$4.09 per share.

Shares of common stock that are subject to awards will be counted against the overall limit as one share for every share granted or covered by an award. If any award is cancelled, expires or terminates unexercised for any reason, the shares covered by that award will again be available for the grant under the Incentive Plan, except that any shares that are not issued as the result of a net exercise or settlement or that are used to pay any exercise price or tax withholding obligation will not be available for the grant of awards. Shares of common stock that we repurchase on the open market with the proceeds of an option exercise price also will not be available for the grant of awards. Awards that may be settled solely in cash will not be deemed to use any shares.

The aggregate value of stock-based awards and cash-based compensation granted to any non-employee director in any fiscal year solely with respect to his or her service as a non-employee director may not exceed \$250,000 based on the fair market value of stock-based awards and the aggregate value of cash-based compensation, each of which is determined as of the date of grant.

### Minimum Vesting Limitations

Awards granted under the Incentive Plan to employees and consultants will have a minimum vesting period of one year. However, the Committee may provide for earlier vesting upon a change of control or a participant's death, disability or other termination retirement. In addition, awards may be granted with respect to up to 5% of the total number of shares reserved for awards under the Incentive Plan which are not subject to such minimum vesting provisions.

#### Term of the Incentive Plan

Awards under the Incentive Plan may not be made after May 26, 2031, which is the tenth anniversary of the date the Board adopted the Incentive Plan, although awards granted prior to that date may remain outstanding in accordance with their terms and conditions.

# Types of Awards under the Incentive Plan

The Incentive Plan provides for the grant of any or all of the following types of awards: (i) stock options, including incentive stock options and non-qualified stock options; (ii) restricted stock; and (iii) other stock-based awards, including restricted stock units.

Stock Options. Stock options granted under the Incentive Plan entitle the participant to purchase a specified number of shares of the Company's common stock, subject to vesting provisions, at an exercise price set by the Committee at the time of grant. The Incentive Plan authorizes the Committee to grant stock options that are intended to qualify as "incentive stock options" under the Code to eligible employees of the Company, its subsidiaries or its parent (if any) and non-qualified stock options to current and prospective employees and consultants and to non-employee directors. The exercise price of a stock option may not be less than 100% of the fair market value of the Company's common stock on the grant date (not less than 110% in the case of incentive stock options granted to owners of stock possessing more than 10% of the Committee at grant, but may not exceed ten years from the grant date (five years in the case of incentive stock options granted to owners of stock possessing more than 10% of the Company's total combined voting power). The Committee determines when each stock option may be exercised.

Unless otherwise specified in an award agreement, an option may be exercised only during the participant's employment, consultancy or directorship or within thirty days after termination. However, if the participant's termination occurs as a result of death or disability, then the participant (or his or her legal representative or estate) may exercise vested options for one year after termination. Notwithstanding the foregoing, in the event of a participant's termination for Cause or a voluntary termination within 90 days after the occurrence of an event which would be grounds for a termination for Cause, any stock option held by the participant at the time of occurrence of the event which would be grounds for a termination for Cause will immediately terminate and expire.

The Incentive Plan provides that optionees may pay the exercise price in cash or check; by delivery to the Company of shares of the Company's common stock owned by the participant; solely to the extent permitted by law and authorized by the Committee, through the delivery of irrevocable instructions to a broker reasonably acceptable to the Committee to promptly deliver to the Company an amount equal to the purchase price; on such other terms and conditions as may be acceptable to the Committee (which may include a reduction in the number of shares of stock issuable upon exercise); or any combination of the foregoing.

*Restricted Stock.* The Committee may grant "restricted" shares of the Company's common stock to eligible participants. Restricted stock awards are grants of shares of the Company's common stock that are subject to risk of forfeiture or other restrictions. Upon the award of restricted stock, the participant generally has the rights of a stockholder with respect to the right to receive dividends and the right to vote the shares. The payment of dividends or other distributions, if any, will not be paid unless and until the shares of restricted stock to which the dividends or distributions relate are no longer subject to a risk of forfeiture. Participants who receive restricted stock are required to enter into a restricted stock agreement with the Company, which sets forth the restrictions to which the shares are subject, including, as applicable, the date or dates on which the restrictions will lapse or any performance goals that must be satisfied for the restrictions to lapse. Awards of restricted stock may or may not be performance-based.

If the grant of restricted stock or the lapse of the relevant restrictions is based on the attainment of performance goals, the Committee will establish for each participant the applicable performance goals, formulae or standards and the applicable vesting percentages with reference to the attainment of the goals or satisfaction of the formulas or standards while the outcome of the performance goals are substantially uncertain. Unless otherwise determined by the Committee on the date of grant, upon a participant's termination all unvested restricted stock will be forfeited.

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Other Stock-Based Awards. The Committee may grant other stock-based awards to eligible participants that are payable in, or valued in whole or part by reference to, or otherwise based on or related to shares of the Company's common stock. Other stock-based awards may be granted, among others, as shares of common stock awarded as a bonus and not subject to restrictions or conditions, as shares of common stock paid in respect of an amount due under an incentive or performance plan sponsored by the Company or an affiliate or as restricted stock units. The Committee determines the terms and conditions of any other stock-based awards, which may include continued employment or service over a period of time or the achievement of performance goals. Unless otherwise determined at grant, participants who receive other stock-based awards will not be entitled to receive dividends or dividend equivalents with respect to the shares of common stock on the date of grant and the award may not be exercised later than the date specified by the Committee, which will be a maximum of ten years from the date of grant.

# Performance Goals

As noted above, performance-based awards granted under the Incentive Plan will be granted or vest based on attainment of specified performance goals established by the Committee. These awards may be made in the form of restricted stock or other stock-based awards. The performance goals relating to such awards may include the following criteria, among others: (i) the attainment of certain target levels of, or a specified percentage increase in, revenues, earnings, income before taxes and non-recurring items, net income, operating income, earnings before income tax, earnings before interest, taxes, depreciation and amortization or a combination of any or all of the foregoing; (ii) the attainment of certain target levels of, or a percentage increase in, after-tax or pre-tax profits including, without limitation, that attributable to continuing and/or other operations; (iii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (iv) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, the Company's bank debt or other long-term or short-term public or private debt or other similar financial obligations of the Company, which may be calculated net of such cash balances and/or other offsets and adjustments as may be established by the Committee; (v) earnings per share or the attainment of a specified percentage increase in earnings per share or certain target levels of, or a specified increase in return on invested capital; (vii) the attainment of certain target levels of, or a specified percentage increase in age return on invested capital; (vii) the attainment of certain target levels of, or a specified increase in, after-tax or pre-tax return on stockholders' equity; (viii) the attainment of certain target levels of, or a specified increase in after-tax or pre-tax return on stockholders' equity; (viii) the attainment of certain target levels of, or a specified increase in, aft

growth in the value of an investment in the Company's common stock assuming the reinvestment of dividends; (xi) the filing of a new drug application ("*NDA*") or the approval of the NDA by the Food and Drug Administration; (xii) the achievement of a launch of a new drug; (xiii) research and development milestones; (xiv) the successful completion of clinical trial phases, (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level in or increase in, all or a portion of controllable expenses or costs or other expenses or costs; (xvi) gross or net sales, revenue and growth of sales revenue (either before or after cost of goods, selling and general administrative expenses, research and development expenses and any other expenses or interest); (xvii) total stockholder return; (xviii) return on assets or net assets; (xix) operating profit or net operating profit; (xxi) operating margin; (xxii) gross or net profit margin; (xxiii) cost reductions or savings or other expense control targets; (xvi) productivity or productivity ratios; (xxv) operating efficiency; (xxvi) customer satisfaction; (xvii) working capital; (xxviii) market share; (xxix) strategic business criteria, consisting of one or more objectives based on meeting specified revenue, market penetration, geographic business expansion goals, objectively identified project milestones, producti volume levels, cost targets, and goals relating to acquisitions or divestitures; (xxx) aggregate product price and other products, and/or business aftery record; (xxxii) personal management objectives or achievement of objective business and operational goals, such as market share, new products, and/or business and operational goals is not exhaustive and the Committee has discretion to determine other performance goals as it deems appropriate from time to time.

### Change in Control

Unless otherwise determined by the Committee at grant, in the event of a Change in Control (as defined in the Incentive Plan), awards granted under the Incentive Plan will not vest on a Change in Control. Outstanding awards will be treated in accordance with one of the following methods, as determined by the Committee in its sole discretion:

- Awards, whether or not then vested, may be continued, assumed, have new rights substituted for them, or with respect to awards of restricted stock, receive the same distribution as other holders of shares of the Company's common stock on the terms as determined by the Committee;
- Awards may be canceled in exchange for an amount of cash equal to the price per share paid in the Change in Control (less, in the case of stock options or other
  appreciation awards, the exercise or base price per share of common stock covered by the award), as adjusted by the Committee for any contingent purchase price,
  escrow obligations, indemnification obligations or other adjustments to the purchase price after the consummation of the Change in Control; or
- Stock options or other stock-based appreciation awards may be cancelled if the change in control price is less than the applicable exercise or base price per share of
  common stock subject to the award.

The Committee may in its sole discretion accelerate the vesting and lapse of restrictions of an award at any time in connection with a change in control.

In the event of a merger or consolidation in which the Company is not the surviving corporation or in the event of a transaction that results in the acquisition of all or substantially all of the Company's common stock or assets, the Committee may elect to terminate all outstanding exercisable awards granted under the Incentive Plan, provided that during the period from notification of termination to the date of consummation of the relevant transaction (which must be at least 20 days) each participant shall have the right to exercise all of his or her exercisable awards in full (without regard to any restrictions on exercisability), contingent on the consummation.

# Miscellaneous

Awards granted under the Incentive Plan generally are not transferable, except that the Committee may, in its sole discretion and subject to certain limitations, permit the transfer of non-qualified stock options at the time of grant or thereafter to certain "family members" of the participant.

The Board may from time to time amend, suspend or terminate the Incentive Plan in whole or in part, except that the rights of a participant with respect to an award granted prior to the amendment, suspension or termination may not be impaired without the participant's consent. Without approval of the Company's common stockholders, no amendment to the Incentive Plan may be made that would increase the aggregate number of shares that may be issued under the Incentive Plan; increase the maximum individual limitations; change the classification of individuals eligible to receive awards; extend the maximum term of a stock option; amend the Incentive Plan or an outstanding award to reduce the exercise price of an exercisable award or cancel out-of-the-money outstanding exercisable awards in exchange for cash, other awards or exercisable awards with an exercise price that is less than the exercise price of the original exercisable award; or otherwise require stockholder approval. The Board may amend the Incentive Plan or any award agreement at any time without a participant's consent to comply with applicable law, including Code Section 409A.

# Material U.S. Federal Income Tax Consequences Relating to the Incentive Plan

The following discussion of the principal U.S. federal income tax consequences with respect to stock options granted under the Incentive Plan is based on statutory authority and judicial and administrative interpretations as of the date of this registration statement, which are subject to change at any time (possibly with retroactive effect) and may vary in individual circumstances. The discussion is limited to the U.S. federal income tax consequences (state, local and other tax consequences are not addressed below) to individuals who are citizens or residents of the U.S., other than those individuals who are taxed on a residence basis in a foreign country. In addition, the following discussion does not set forth any gift, estate, social security or state or local tax consequences that may be applicable.

The U.S. federal income tax law is technical and complex and the discussion below represents only a general summary. The following summary is included for general information only and does not purport to address all the tax considerations that may be relevant. Each recipient of a grant is urged to consult his or her own tax advisor as to the specific tax consequences to the grantee and the disposition of common stock.

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Incentive Stock Options. The grant or exercise of an incentive stock option generally has no income tax consequences for the optionee or the Company. No taxable income results to the optionee upon the grant or exercise of an incentive stock option. However, the amount by which the fair market value of the stock acquired pursuant to the exercise of an incentive stock option exceeds the exercise price is an adjustment item and will be considered income for purposes of alternative minimum tax.

The aggregate fair market value of common stock (determined at the time of grant) with respect to which incentive stock options can be exercisable for the first time by an optionee during any calendar year cannot exceed \$100,000. Any excess will be treated as a non-qualified stock option.

The sale of common stock received pursuant to the exercise of an option that satisfied all of the incentive stock option requirements, as well as the holding period requirement described below, will result in a long-term capital gain or loss equal to the difference between the amount realized on the sale and the exercise price. To receive incentive stock option treatment, an optione must be an employee of the Company (or certain affiliates) at all times during the period beginning on the date of the grant of the incentive stock option and ending on the day three months before the date of exercise, and the optionee must not dispose of the common stock purchased pursuant to the exercise of the stock option either (i) within two years from the date the incentive stock option was granted, or (ii) within one year from the date of exercise of the shares will be treated as a long-term capital gain or loss to the optionee (depending on the applicable holding period). The Company will not be entitled to a tax deduction upon the exercise of an incentive stock option, or upon a subsequent disposition of the shares, unless the disposition occurs prior to the expiration of the holding periods described above.

In general, if the optionee does not satisfy the foregoing holding periods, any gain (in an amount equal to the lesser of the fair market value of the common stock on the

date of exercise (or, with respect to officers subject to Section 16(b) of the Exchange Act, the date that sale of the common stock would not create liability, referred to as Section 16(b) liability, under Section 16(b) of the Exchange Act) minus the exercise price, or the amount realized on the disposition minus the exercise price) will constitute ordinary income. In the event of such a disposition before the expiration of the holding periods described above, subject to the limitations under the Code Sections 162(m) and 280G (as described below), the Company is generally entitled to a deduction at that time equal to the amount of ordinary income recognized by the optionee. Any gain in excess of the amount recognized by the optionee as ordinary income would be taxed to the optionee as short-term or long-term capital gain (depending on the applicable holding period).

*Non-Qualified Stock Options.* In general, an optionee will realize no taxable income upon the grant of a non-qualified stock option and the Company will not receive a deduction at the time of grant unless the option has a readily ascertainable fair market value (as determined under applicable tax law) at the time of grant. Upon exercise of a non-qualified stock option, an optionee generally will recognize ordinary income in an amount equal to the excess of the fair market value of the stock on the date of exercise over the exercise price. Upon a subsequent sale of the stock by the optionee, the optionee will recognize short-or long-term capital gain or loss depending the optionee's holding period for the stock. Subject to the limitations under Code Sections 162(m) and 280G, the Company will generally be allowed a deduction equal to the amount of ordinary income recognized by the optionee.

Section 16(b). Any of our officers and directors subject to Section 16(b) of the Exchange Act may be subject to Section 16(b) liability with regard to both incentive stock options and non-qualified stock options as a result of special tax rules regarding the income tax consequences concerning their stock options.

*Code Section 162(m).* In general, Code Section 162(m) denies a deduction to any publicly held corporation for compensation paid to certain "covered employees" in its taxable year to the extent that such compensation exceeds \$1,000,000. "Covered employees" are a company's chief executive officer and the chief financial officer at any time during the taxable year and certain former and current executive officers of the company, including certain individuals whose compensation is or was required to be reported to stockholders in the Company's proxy statement under the Exchange Act.

*Parachute Payments*. In the event that the payment or vesting of any award under the Incentive Plan is accelerated because of a change in ownership (as defined in Section 280G(b)(2) of the Code) and such payment of an award, either alone or together with any other payments made to certain participants, constitute parachute payments under Section 280G of the Code, then subject to certain exceptions, a portion of such payments would be nondeductible to the Company and the participant would be subject to a 20% excise tax on such portion of the payment.

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Section 409A of the Code. Section 409A of the Code provides that all amounts deferred under a nonqualified deferred compensation plan are includible in a participant's gross income to the extent such amounts are not subject to a substantial risk of forfeiture, unless certain requirements are satisfied. If the requirements are not satisfied, in addition to current income inclusion, interest at the underpayment rate plus 1% will be imposed on the participant's underpayments that would have occurred had the deferred compensation been includible in gross income for the taxable year in which first deferred or, if later, the first taxable year in which such deferred compensation is not subject to a substantial risk of forfeiture. The amount required to be included in income is also subject to an additional 20% tax. While most awards under the Incentive Plan are anticipated to be exempt from the requirements of Section 409A of the Code, awards that are not exempt are intended to comply with Section 409A of the Code.

### **Directors Stock Option Plan**

Prior to the closing of the Merger, we provided for grants of non-qualified stock options to our directors pursuant to the Ensysce Biosciences, Inc. Amended and Restated Directors Stock Option Plan (the "Directors Plan"), which terminated at the closing of the Merger. No further awards may be granted under our Directors Plan following the closing of the Merger and all non-employee director awards will be made pursuant to the Incentive Plan.

# 401(k) Plan

While we do maintain a tax-qualified 401(k) Plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis; no active employees currently participate in such plan.

### **Outstanding Equity Awards at December 31, 2020**

The following table provides information regarding outstanding equity awards made to our named executive officers as of December 31, 2020 (prior to adjustment for the exchange ratio of 0.06585 due to the Merger).

		Option Awards					
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		ion Exercise Price (\$)	Option Expiration Date	
D. Lynn Kirkpatrick, PhD.	12/31/2015	1,517,845	0	\$	0.211	12/1/2022	
	12/31/2015	151.784	0	\$	0.211	12/21/2022	
	1/5/2016	4,000,000	0	\$	0.210	1/15/2026	
	1/4/2017	5,250,000	1,750,000(1)	\$	0.120	1/4/2027	
	2/5/2018	12,415,500	0	\$	0.110	2/5/2028	
	3/1/2019	10,000,000	0	\$	0.170	2/28/2029	
	3/15/2019	100,000	0	\$	0.170	3/14/2029	
Richard Wright, MBA	12/31/2015	758,922	0	\$	0.211	8/1/2023	
	11/1/2016	1,000,000	0	\$	0.120	11/1/2026	
	8/1/2017	3,416,657	583,343(2)	\$	0.120	7/31/2027	
	10/1/2018	300,000	0	\$	0.170	10/1/2028	
	3/1/2019	15,000,000	0	\$	0.170	2/28/2029	
Geoff Birkett	10/1/2018	300,000	0	\$	0.170	10/1/2028	
	3/1/2019	5,000,000	0	\$	0.170	2/28/2029	

(1) Subject to the participant's continuous service with the Company through the applicable vesting date, 25% of the total number of shares underlying the option vest on the first anniversary of the grant date, with an additional 25% vesting on each successive anniversary for the next three years. The remaining unvested shares in this award became fully vested on January 4, 2021.

(2) Subject to the participant's continuous service with the Company through the applicable vesting date, 25% of the total number of shares underlying the option vest on the first anniversary of the grant date, with an additional 1/48<sup>th</sup> of the award vesting on each successive month thereafter for the next three years. Additionally, subject generally to Mr. Wright's continued service through such date, the entire unvested portion of the option award would be fully vested upon the closing of a change in control, including the closing.

#### 2021 Compensation Decisions

Upon the consummation of the Merger, each outstanding option granted under the Plan and Directors Plan converted into an option to purchase newly issued shares of stock under the Incentive Plan, which options will generally have the same terms and conditions as options granted under the Plan and Directors Plan, respectively, outstanding immediately prior to the Merger.

The below chart shows the number of unexercised Company options held by our named executive officers and non-employee directors and the applicable exercise price prior to the Merger and the number of options that each such person holds after the conversion (using the exchange ratio of 0.06585) due to the Merger:

Name	Grant Date	Original Number of Company Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options – Post- Conversion (#)	ginal Option cise Price (\$)	 Option Exercise Price Post- Conversion (\$)
D. Lynn Kirkpatrick, PhD.	12/31/2015	1,517,845	99,950	\$ 0.211	\$ 3.21
	12/31/2015	151,784	9,994	\$ 0.211	\$ 3.21
	1/5/2016	4,000,000	263,400	\$ 0.210	\$ 3.19
	1/4/2017	7,000,000	460,950	\$ 0.120	\$ 1.83
	2/5/2018	12,415,500	817,560	\$ 0.110	\$ 1.68
	3/1/2019	10,000,000	658,500	\$ 0.170	\$ 2.59
	3/15/2019	100,000	6,585	\$ 0.170	\$ 2.59
Richard Wright, MBA	12/31/2015	758,922	49,975	\$ 0.211	\$ 3.21
-	11/1/2016	1,000,000	65,850	\$ 0.120	\$ 1.83
	8/1/2017	4,000,000	263,400	\$ 0.120	\$ 1.83
	10/1/2018	300,000	19,755	\$ 0.170	\$ 2.59
	3/1/2019	15,000,000	987,750	\$ 0.170	\$ 2.59
Geoff Birkett	10/1/2018	300,000	19,755	\$ 0.170	\$ 2.59
	3/1/2019	5,000,000	329,250	\$ 0.170	\$ 2.59
Bob Gower	3/15/2019	100,000	6,585	\$ 0.170	\$ 2.59
Andrew Benton	1/24/2020	1,000,000	65,850	\$ 0.220	\$ 3.35
Steve Martin	8/10/2020	1,000,000	65,850	\$ 0.220	\$ 3.35

After the end of the fiscal year on December 31, 2020, we entered into an offer letter with David Humphrey dated February 11, 2021 (the *CFO Offer Letter*") pursuant to which he became the Company's Chief Financial Officer. Mr. Humphrey's annual base salary is \$72,000 but such annual base salary increased to \$320,000 following the consummation of the Merger. Pursuant to the CFO Offer Letter, Mr. Humphrey's annual target performance bonus is 30% of his base salary.

Upon completion of the Merger Mr. Humphrey received a grant of 50,000 restricted stock units, which, subject generally to Mr. Humphrey's continued employment through each such date, would vest as to 30,000 restricted stock units on December 15, 2021 and an additional 15,000 restricted stock units on each of December 15, 2022, and December 15, 2023. It is expected that Mr. Humphrey will receive an option grant to purchase 275,000 shares of our common stock. Each such grant was made or will be made pursuant to the Incentive Plan as described above and are subject to the terms and conditions of standard award agreements and were granted at the fair market value on the date of grant and vest ratably over four years. Upon a termination of Mr. Humphrey's employment by the Company without "cause" or by Mr. Humphrey for "good reason" (as such terms are defined in the CFO Offer Letter), Mr. Humphrey would be eligible to receive severance equal to six months of base salary, subject to his timely execution of a release in favor of the Company. In addition, if such termination occurs within one month prior to a change of control or within 12 months after such a change in control, all time-based equity awards would become full vested.

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#### **Director Compensation**

Following the Merger, we expect to provide compensation to our non-employee directors for their services. Our Board expects to review non-employee director compensation periodically to ensure that our non-employee director compensation remains competitive such that we are able to recruit and retain qualified directors. We intend to develop a non-employee directors' compensation program designed to align compensation with our business objectives and the creation of stockholder value, while enabling us to attract, retain, incentivize and reward directors who contribute to our long-term success. Our non-employee director compensation will be reported in our reports pursuant to the Exchange Act as required by the Exchange Act and regulations promulgated thereunder.

For the year ended December 31, 2020, we did not pay cash compensation to our non-employee directors for their service on our Board. Two new Board members, Andrew Benton and Steve Martin, were added in December 2019. In January 2020, each such new Board member was granted a stock option for 65,850 shares with an exercise price of \$3.35 per share (using the exchange ratio of 0.06585 due to the Merger). In addition, our directors are eligible to be reimbursed for reasonable travel and related expenses associated with attendance at Board or committee meetings, however no such travel expenses or other expenses were incurred by any of our non-employee directors in 2020.

The following table provides summary information concerning compensation paid or accrued by us to or on behalf of our non-employee directors for services rendered to us as of December 31, 2020 (using the exchange ratio of 0.06585 due to the Merger).

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)(2)</sup>	All Other Compensation (\$)	Total (\$)
Bob Gower	0	0	0	0
William Chang	0	0	0	0
Andrew Benton	0	150,000(3)	0	150,000
Steve Martin	0	140,000(4)	0	140,000

(1) The amounts reported represent the aggregate grant-date fair value of the options awarded to the named executive officer in 2020, calculated in accordance with FASB ASC Topic 718 ("*Topic 718*"). Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in Note 3 of the notes to our audited consolidated financial statements.

(2) As of December 31, 2020, our non-employee directors had the following number of stock options outstanding(using the exchange ratio of 0.06585 due to the Merger):

Name	Aggregate Options Vested/Unvested Outstanding
	Ousunding

Bob Gower	6,585	100,000 /0
William Chang(5)	269,834	269,834 /0
Andrew Benton	65,850	0/65,850
Steve Martin	65,850	0/65,850

- (3) Subject generally to continued service, the options granted to Mr. Benton on January 24, 2020 generally vest as to approximately one-third of the award on the first anniversary of the date of grant and thereafter 1,829 share underlying such award would continue to vest monthly for the two year period thereafter, such that the entire award would be fully vested on the third anniversary of the grant date. Additionally, subject generally to Mr. Benton's continued service through such date, the entire unvested portion of the option award would be fully vested upon the closing of a change in control.
- (4) Subject generally to continued service, the options granted to Mr. Martin on August 10, 2020 generally vest as to approximately one-third of the award on the first anniversary of the date of grant and thereafter 1,829 share underlying such award would continue to vest monthly for the two year period thereafter, such that the entire award would be fully vested on the third anniversary of the grant date. Additionally, subject generally to Mr. Martin's continued service through such date, the entire unvested portion of the option award would be fully vested upon the closing of a change in control.

(5) Subsequent to December 31, 2020, these options were exercised by Mr. Chang.

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# DESCRIPTION OF CAPITAL STOCK

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities. The full text of our third amended and restated certificate of incorporation is attached to this registration statement/prospectus. 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 securities.

Pursuant to the third amended and restated certificate of incorporation, our authorized capital stock consists of 150,000,000 of common stock, \$0.0001 par value, and 1,500,000 shares of undesignated preferred stock, \$0.0001 par value. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you.

# **Common Stock**

# As of August 4, 2021, there were 24,275,541 shares of our common stock 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, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of 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.

# Preferred Stock

Our amended and restated certificate of incorporation provides that shares of preferred stock may be issued from time to time in one or more series. Our Board is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our Board is able to, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of our common stock and could have anti-takeover effects. The ability of our Board to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preferred stock outstanding as of the date hereof.

#### Warrants

#### **Public Warrants**

As of August 4, 2021, there were an aggregate of approximately 10,000,000 outstanding Public Warrants, which entitle the holder to acquire our common stock. Each whole Public Warrant entitles the registered holder to purchase one whole share of our common stock at a price of \$11.50 per share, subject to adjustment as discussed below, at any time commencing 30 days after the completion of the business combination. Pursuant to the warrant agreement, a warrantholder may exercise its Public Warrants only for a whole number of shares of our common stock. This means that only a whole Public Warrant may be exercised at any given time by a warrantholder. The Public Warrants will expire five years after the completion of the business combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of common stock pursuant to the exercise of a Public Warrant and will have no obligation to settle such Public Warrant exercise unless a registration statement under the Securities Act with respect to the shares of common stock underlying the Public Warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No Public Warrant will be exercisable and we will not be obligated to issue shares of common stock upon exercise of a Public Warrant unless common stock issuable upon such Public Warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the Public Warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a Public Warrant, the holder of such Public Warrant will not be entitled to exercise such Public Warrant and such Public Warrant may have no value and expire worthless.

We have agreed that as soon as practicable, but in no event later than 15 business days, after the closing of the business combination, we will use our best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the Public Warrants. We will use our best efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the Public Warrants in accordance with the provisions of the warrant agreement. Notwithstanding the above, if our common stock is at the time of any exercise of a Public Warrants not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of Public Warrants who exercise their Public Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event we oelect, we will not be required to file or maintain in effect a registration statement, but we will be required to use our best efforts to register or qualify the shares under applicable

blue sky laws to the extent an exemption is not available.

Once the Public Warrants become exercisable, we may call the Public Warrants for redemption:

- in whole and not in part;
- at a price of \$0.01 per Public Warrant;
- upon not less than 30 days' prior written notice of redemption (the "30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the common stock equals or exceeds \$18.00 per share for any 20 trading days within a 30-trading day period ending three business days before we send the notice of redemption to the warrantholders.

If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the Public Warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Public Warrants, each warrant holder will be entitled to exercise its Public Warrant prior to the scheduled redemption date. However, the price of the common stock may fall below the \$18.00 redemption trigger price as well as the \$11.50 (for whole shares) Public Warrant exercise price after the redemption notice is issued.

If we call the Public Warrants for redemption as described above, our management will have the option to require any holder that wishes to exercise its Public Warrant to do so on a "cashless basis." In determining whether to require all holders to exercise their Public Warrants on a "cashless basis," our management will consider, among other factors, our cash position, the number of Public Warrants that are outstanding and the dilutive effect on our stockholders of issuing the maximum number of shares of common stock issuable upon the exercise of our Public Warrants. If our management takes advantage of this option, all holders of Public Warrants would pay the exercise price by surrendering their Public Warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the Public Warrants, multiplied by the difference between the exercise price of the Public Warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of Public Warrants. As an example, if we elect to call the Public Warrants for redemption on a "cashless basis" in accordance with the redemption criteria described above and the "fair market value" is determined to be \$18.00 per share, then a holder of Public Warrants for the purchase of 100 shares of our common stock would receive 36 shares of our common stock upon such exercise. The "fair market value" for these purposes may be higher or lower than the \$18.00 redemption trigger price and will only be determinable when we elect to send a notice of redemption to holders of the Public Warrants. If a holder does not exercise his or her Public Warrants within the redemption period, then he or she will be forced to accept the nominal redemption price of \$0.01 per Public Warrant which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of such Public Warrants. If we call our Public Warrants for redemption and our management does not take advantage of this option, the initial purchasers of the Private Placement Warrants and their permitted transferees would still be entitled to exercise their Private Placement Warrants for cash or on a cashless basis using the same formula described above that other warrant holders would have been required to use had all warrant holders been required to exercise their warrants on a cashless basis, as described in more detail below.

If the number of outstanding shares of common stock is increased by a stock dividend payable in shares of common stock, or by a split-up of shares of common stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of common stock issuable on exercise of each Public Warrant will be increased in proportion to such increase in the outstanding shares of common stock. A rights offering to holders of common stock entitling holders to purchase shares of common stock at a price less than the fair market value will be deemed a stock dividend of a number of shares of common stock equal to the product of (i) the number of shares of common stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering divided by (y) the fair market value. For these purposes (i) if the rights offering is for securities convertible into or exercisable for common stock, in determining the price payable for common stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) fair market value means the volume weighted average price of common stock as reported during the ten (10) trading day period ending on the trading day prior to the first date on which the shares of common stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the Public Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of common stock on account of such shares of common stock (or other shares of our capital stock into which the Public Warrants are convertible), other than (a) as described above, (b) certain ordinary cash dividends, (c) to satisfy the redemption rights of the holders of common stock in connection with the business combination, then the Public Warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of common stock in respect of such event.

If the number of outstanding shares of our common stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of common stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of common stock issuable on exercise of each Public Warrant will be decreased in proportion to such decrease in outstanding shares of common stock.

Whenever the number of shares of common stock purchasable upon the exercise of the Public Warrants is adjusted, as described above, the Public Warrant exercise price will be adjusted by multiplying the Public Warrants exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of common stock purchasable upon the exercise of the Public Warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of common stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of common stock (other than those described above or that solely affects the par value of such shares of common stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding shares of common stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the Public Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Public Warrants and in lieu of the shares of our common stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and number of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Public Warrants would have received if such holder had exercised their Public Warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of common stock in such a transaction is payable in the form of common stock in the successor entity that is listed for trading or quoted immediately following such event, and if the registered holder of the Public Warrant properly exercises the Public Warrant within thirty days following public disclosure of such transaction, the Public Warrant exercise price will be reduced as specified in the warrant agreement based on the Black-Scholes value (as defined in the warrant agreement) of the Public Warrant.

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The Public Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the Public Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants.

The Public Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of Public Warrants being exercised. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Public Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Public Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the Public Warrants. If, upon exercise of the Public Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number of shares of common stock to be issued to the warrant holder.

### Private Placement Warrants

As of August 4, 2021, there were 6,325,000 Private Placement Warrants outstanding. The Private Placement Warrants (including the common stock issuable upon exercise of the Private Placement Warrants) were not transferable, assignable or salable until 30 days after the completion of the Merger (except, among certain limited circumstances to certain permitted transferees, consisting primarily of our officers and directors and other persons or entities affiliated with the Sponsors) and they will not be redeemable by us so long as they are held by the Sponsors or their permitted transferees. Otherwise, the Private Placement Warrants have terms and provisions that are identical to the warrants sold as part of the units in LACQ's initial public offering, including as to exercise price, exercisability and exercise period. If the Private Placement Warrants are held by warrants included in the units sold in LACQ's initial public offering.

If holders of the Private Placement Warrants elect to exercise them on a cashless basis, they would pay the exercise price by surrendering their warrants for that number of shares of common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" shall mean the average reported last sale price of the common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of warrant exercise is sent to the warrant agent. The reason that we have agreed that these warrants will be exercisable on a cashless basis so long as they are held by the initial purchasers of the Private Placement Warrants or their permitted transferees is because it is not known at this time whether they will be affiliated with us following the business combination. If they remain affiliated with us, their ability to sell our securities in the open market will be significantly limited. We have policies in place that prohibit insiders from selling our securities except during specific periods of time. Even during such periods of time when insiders will be permitted to sell our securities, an insider cannot trade in our securities if he or she is in possession of material non-public information. Accordingly, unlike public stockholders who could sell the shares of common stock issuable upon exercise of the warrants freely in the open market, the insiders could be significantly restricted from doing so. As a result, we believe that allowing the holders to exercise such warrants on a cashless basis is appropriate.

On June 7, 2021, each of the holders of the Private Placement Warrants exchanged their warrants for new private warrants which are on the same terms as the Private Placement Warrants, except that they are not issued under the Warrant Agreement and are non-transferable except to permitted transferees.

#### Private Warrants

The other private warrants are warrants issued to the Sponsors and the Strategic Investor to purchase 1,000,001 shares of our common stock in exchange for outstanding loans under the Expense Advancement Agreement and warrants issued to Gateway Casinos & Entertainment Limited to purchase 566,288 shares of our common stock in exchange for outstanding loans under the GTWY Expense Advancement Agreement. The additional private warrants are warrants issued to DelMorgan to purchase 500,000 shares of common stock under the terms of the Email Agreement and warrants issued to the Sponsors and the Strategic Investors to purchase 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants issued at the closing of the business combination in exchange for outstanding loans under the Expense Advancement Agreement. The other private warrants and additional private warrants are on the same terms as the Private Placement Warrants. On June 7, 2021, each of the holders of the other private warrants, except that they are non-transferable except to permitted transferees.

# **GEM** Warrants

At the closing of the Merger, we issued GYBL a warrant with a 36-month term to purchase 1,106,108 shares of our common stock (an amount equal to 4% of the total number of our common stock outstanding as of the closing date of the Merger (subject to adjustments described below), calculated on a fully diluted basis), at a strike price per share equal to \$10.01, which was the closing bid price for such common stock on the first day of trading on Nasdaq. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GYBL's exercise will entitle GYBL to compensation in addition to other remedies. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits, and issuances of additional common shares at a price per share less than the exercise price.

#### **Consultant Warrants**

In July 2021, we issued to each of the Consultants warrants with a five-year term to purchase 500,000 shares of our common at a strike price per share equal to \$6.28, which was the closing price for such common stock on the date of execution of the letter agreement with the Consultants.

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

The third amended and restated certificate of incorporation and our 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.

### **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  $90^{th}$  day nor earlier than the close of business on the  $120^{th}$  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.

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### Amendment of Charter or Bylaws

The third amended and restated certificate of incorporation provides that certain provisions of the third amended and restated certificate of incorporation, notwithstanding that a lesser percentage may be permitted from time to time by applicable law, and our bylaws may only be amended or repealed by, in addition to any vote required by the third amended and restated certificate of incorporation or by applicable law, the vote of at least a majority of the holders of the voting power of all of the then-outstanding shares entitled to vote generally in the election of directors, voting together as a single class.

### **Exclusive** Forum

Under the 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;
- 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.

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### SECURITIES ACT RESTRICTIONS ON RESALE OF ENSYSCE'S SECURITIES

In general, Rule 144 of the Securities Act, ("*Rule 144*"), permits the resale of restricted securities without registration under the Securities Act if certain conditions are met. Rule 144 is not available for the resale of restricted securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company, including us. However,

Rule 144 also includes an important exception to this prohibition if the following conditions are met at the time of such resale:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting our status as an entity that is not a shell company.

Upon the consummation of the Transactions, we ceased to be a shell company, and as long as the conditions set forth in the exceptions listed above are satisfied, Rule 144 will be available for the resale of our restricted securities.

If the above conditions have been met and Rule 144 is available, a person who has beneficially owned restricted shares of common stock or warrants for at least one year would be entitled to sell their securities pursuant to Rule 144, provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale. If such persons are our affiliates at the time of, or at any time during the three months preceding, a sale. If such persons would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of shares of our common stock or warrants, as applicable, then outstanding; or
- the average weekly reported trading volume of our common stock or warrants, as applicable, during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by affiliates under Rule 144, when available, are also limited by manner of sale provisions and notice requirements.

#### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information known to us regarding the beneficial ownership of our common stock as of August 4, 2021:

- each person who is the beneficial owner of more than 5% of the outstanding shares of our common stock;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership for the purposes of the following table is determined in accordance with the rules and regulations of the SEC. A person is a "beneficial owner" of a security if that person has or shares "voting power", which includes the power to vote or to direct the voting of the security, or "investment power", which includes the power to dispose of or to direct the disposition of the security or has the right to acquire such powers within 60 days. Accordingly, we have included all shares of common stock issuable to such person upon the exercise of warrants or options currently exercisable or exercisable within 60 days of the date hereof. We did not deem such shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, we believe that each of the persons and entities named in the table has sole voting and investment power with respect to their beneficially owned shares of common stock. Unless otherwise noted, the address of each beneficial owner is c/o Ensysce Biosciences, Inc., 7946 Ivanhoe Avenue, Suite 201, La Jolla California, 92037, Attention: Corporate Secretary.

The beneficial ownership of our Common stock is based on 24,275,541 shares of common stock issued and outstanding immediately following consummation of the Transactions. The amount of shares of common stock issued and outstanding immediately following consummation of the Transactions excludes the 5,000 shares of LACQ common stock that were redeemed in connection with the Merger.

# **Beneficial Ownership Table**

Name and Address of Beneficial Owners	Number of Shares	Percentage
Officers and Directors After the Transactions		
Dr. Lynn Kirkpatrick (1)	2,601,790	9.8%
Richard Wright (2)	1,386,730	5.4%
Geoff Birkett (3)	349,005	1.4%
David Humphrey	-	*
Bob Gower (4)	7,925,611	32.6%
William Chang (5)	2,595,640	10.7%
Andrew Benton (6)	65,850	*
Steve R. Martin (7)	65,850	*
Adam Levin	-	*
Curtis Rosebraugh	-	*
All directors and executive officers as a group (nine individuals)	14,990,476	52.7%
All		
Greater than 5% Holders		
Bob Gower (4)	7,925,611	32.6%
HG Vora Capital Management, LLC (8)(9)	7,630,000	26.8%
A. Lorne Weil and affiliated entities (10)	3,002,747	11.5%
Daniel B. Silvers and affiliated entities (11)	2,882,867	11.1%
William Chang (5)	2,595,640	10.7%
Dr. Lynn Kirkpatrick (1)	2,601,790	9.8%
BV Advisory Partners, LLC (10)(11)	1,422,423	5.9%
Richard Wright (2)	1,386,730	5.4%

\* Indicates less than 1%

(1) Includes 2,316,939 shares subject to options.

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(2) Consists of shares subject to options.

(3) Consists of shares subject to options.

- (4) Includes 6,585 shares subject to options. The business address for Mr. Gower is 101 Westcott, Unit 303, Houston, Texas 77007.
- (5) Includes 750,293 shares owned directly by Mr. Chang and his wife and 1,845,347 shares of LACQ common stock owned through trusts in which Mr. Chang has sole or shared voting and dispositive power. Does not include 1,282,710 shares held by trusts for family members in which Mr. Chang does not have beneficial ownership. The business address for Mr. Chang is 520 El Camino Real, 9th Floor, San Mateo, CA 94402.
- (6) Consists of shares subject to options.

(7) Consists of shares subject to options.

(8) Based on a Schedule 13G/A filed with the SEC on February 14, 2019 by HG Vora Capital Management, LLC, the investment manager of HG Vora Special Opportunities Master Fund. The business address of HG Vora Capital Management is 330 Madison Avenue, 20th Floor, New York, New York 10017. Holdings include 4,167,500 shares subject to warrants.

- (9) On behalf of one or more funds or accounts managed by HG Vora Capital Management, LLC. According to a Schedule 13G filed with the SEC on February 14, 2019 and a Form 4 filed with the SEC on January 17, 2018 by HG Vora Capital Management, LLC., the investment manager of HG Vora Special Opportunities Master Fund, Ltd. Parag Vora may be deemed to directly or indirectly exercise voting and/or investment powers with respect to the shares directly held on behalf of one or more funds or accounts managed by HG Vora Capital Management, LLC.
- (10) Based on a Schedule 13G/A filed with the SEC on July 7, 2021 by Hydra LAC, LLC and Mr. Weil. Represents 266,900 shares held of record my Mr. Weil and 867,842 shares held of record by Hydra LAC, LLC, and 730,110 warrants held of record by Mr. Weil, 1,000,000 warrants held of record by Hydra LAC, LLC and 137,895 warrants held by Hydra Management LLC, which warrants became exercisable on July 30, 2021. Mr. Weil is the managing member of Hydra LAC, LLC and the sole member of Hydra Management LLC and disclaims beneficial ownership with respect to the securities except to the extent of his pecuniary interest therein. The business address of Mr. Weil is 250 West 57th Street, Suite 415, New York, NY 10107.
- (11) Based on a Schedule 13D filed with the SEC on July 6, 2021 (the "Silvers Schedule 13D") by Mr. Silvers, Matthews Lane Capital Partners LLC ("Matthews Lane") and MLCP GLL Funding LLC ("MLCP" and together with Mr. Silvers and Matthews Lane, the "Silvers Group"). According to the Silvers Schedule 13D, the Silvers Group hold 1,128,370 shares of record and 1,754,497 shares are subject to warrants that became exercisable on July 30, 2021, resulting in 2,882,867 shares of common stock. Matthews Lane is the manager of MLCP, and Mr. Silvers is the managing member of Matthews Lane. The business address of the Silvers Group is 250 West 57th Street, Suite 415, New York, NY 10107.
- (12) The business address for BV Advisory Partners, LLC is 903 Hudson Street, Hoboken, NJ 07030.
- (13) Based on information provided by BV Advisory Partners, LLC, we believe Keith Barksdale controls 100% of the voting shares held by BV Advisory Partners, LLC.

# SELLING SECURITYHOLDERS

This prospectus relates to the resale by the Selling Securityholders from time to time of up to 27,132,398 shares of our common stock. The Selling Securityholders may from time to time offer and sell any or all 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.

Except as set forth in the footnotes below, the following table sets forth, based on written representations from the Selling Securityholders, certain information as of August 4, 2021 regarding the beneficial ownership of our common stock by the Selling Securityholders and the shares of common stock being offered by the selling security holders. The applicable percentage ownership of common stock is based on approximately 24,275,541 shares of common stock outstanding as of August 4, 2021. Information with respect to shares of common stock owned beneficially after the offering assumes the sale of all of the shares of common stock registered hereby. The Selling Securityholders may offer and sell some, all or none of their shares of common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the Selling Securityholders have sole voting and investment power with respect to all shares of common stock and warrants that they beneficially own, subject to applicable community property laws. Except as otherwise described below, based on the information provided to us by the Selling Securityholders, no selling securityholder is a broker-dealer or an affiliate of a broker dealer.

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Please see the section titled "Plan of Distribution" in this prospectus for further information regarding the selling securityholder's method of distributing these shares.

		Shares of Cor	nmon Stock		Shares Underlying Warrants to Purchase Common Stock			
Name	Number Beneficially Owned Prior to Offering	Number Registered for Sale Hereby (12)	Number Beneficially Owned After Offering	Percent Owned After Offering	Number Beneficially Owned Prior to Offering	Number Registered For Sale Hereby	Number Beneficially Owned After Offering	Percent Owned After Offering
EarlyBird Capital, Inc. (1)	125,000	125,000						
DelMorgan Group LLC (2)	500,000	500,000	_		500,000	500,000	_	
GEM Yield Bahamas Limited (3)			—	_	1,106,108	1,106,108	—	
Gateway Holdings Limited (4)				_	566,288	566,288	—	_
Hydra LAC LLC (5)	867,842	867,842	—	_	1,000,000	1,000,000	_	
A. Lorne Weil (5)	266,900	266,900	—	—	868,005	868,005	_	_
Daniel B. Silvers and affiliated entities (6)	1,128,370	1,128,370	—	—	1,754,497	1,754,497	—	—
HG Vora Capital Management, LLC (7)	3,462,500	2,462,500	1,000,000	4.1%	4,667,500	4,167,500	500,000	2.1%
Eric Carrera (8)	54,701	54,701	—	—	30,000	30,000	—	—
George Peng (9)	87,014	87,014	—	—	15,000	15,000	—	—
David J. Kovacs (10)	250,000	250,000	_	_	500,000	500,000	_	_
Mercury FundingCo, LLC (11)	250,000	250,000	—	—	500,000	500,000	—	—
Marc J. Falcone	25,000	25,000	_	_	_	_	_	_
Steven M. Rittvo	25,000	25,000	—	—	—	—	—	—
David L. Weinstein	25,000	25,000	_	_	_	_	_	_
Marion Rainone	3,977	3,977	—	—	—	—	—	—
Joann O'Shea	3,977	3,977	_	_	_	_	_	_
Nancy Torres	3,977	3,977	—	—	—	—	—	—
Nicholas Weil	39,776	39,776						
Debra Aronowitz	3,977	3,977	_	_	_	_	_	_
Jennifer Calabrese	1,989	1,989		_	—	_	—	

(1) Consists of 125,000 shares of common stock held by EarlyBird Capital, Inc., the underwriters in LACQ's initial public offering to satisfy deferred underwriting fees payable to such underwriters. Steve Levine, as Chief Executive Officer of this entity, has voting and/or investment power of the securities held by this entity. Mr. Levine disclaims beneficial ownership of the shares held by this entity except to the extent of his individual pecuniary interest therein. The address of this entity is 366 Madison Avenue, 8th Floor, New York, NY 10017.

(2) Consists of 500,000 shares of common stock and warrants exercisable for 500,000 shares of common stock held by DelMorgan under the terms of the Email Agreement. Neil B. Morganbesser, as President and Chief Executive Officer of this entity, has voting and/or investment power of the securities held by this entity. Mr. Morganbesser disclaims beneficial ownership of the securities held by this entity except to the extent of his individual pecuniary interest therein. The address of this entity is 100 Wilshire Blvd., Suite 750, Santa Monica, CA 90401.

- (3) Consists of warrants exercisable for 1,106,108 shares of common stock held by GEM Yield Bahamas Limited. The address of this entity is 3 Bayside Executive Park, West Bay Street & Blake Road, P.O. Box N-4875, Nassau, The Bahamas.
- (4) Consists of warrants exercisable for 566,288 shares of common stock held by Gateway Holdings Limited in exchange for previously outstanding loans to LACQ pursuant to the GTWY Expense Advancement Agreement. The address of this entity is 100-4400 Dominion Street, Burnaby, British Columbia, Canada V5G 4G3.
- (5) Based on a Schedule 13G/A filed with the SEC on July 7, 2021 by Mr. Weil and Hydra LAC LLC. Represents 266,900 shares of common stock held of record by Mr. Weil, 867,842 shares of common stock held of record by Hydra LAC LLC, 868,005 warrants held of record by Mr. Weil and 1,000,000 warrants held of record by Hydra LAC LLC, which warrants became exercisable on July 30, 2021. Mr. Weil is the managing member of Hydra LAC LLC and disclaims beneficial ownership with respect to the securities except to the extent of his pecuniary interest therein. The business address of Mr. Weil and Hydra LAC, LLC is 250 West 57th Street, Suite 415, New York, NY 10107.
- (6) Based on a Schedule 13D filed with the SEC on July 6, 2021 by Mr. Silvers, Matthews Lane Capital Partners LLC ("Matthews Lane") and MLCP GLL Funding LLC ("MLCP"). According to the Schedule 13D, Matthews Lane holds 241,243 shares of record, MLCP holds 887,127 shares of record and Matthews Lane holds 1,754,497 shares that are subject to warrants that became exercisable on July 30, 2021. Matthews Lane is the manager of MLCP, and Mr. Silvers is the managing member of Matthews Lane. The business address of Matthews Lane, MLCP and Mr. Silvers is 250 West 57th Street, Suite 415, New York, NY 10107.
- (7) On behalf of one or more funds or accounts managed by HG Vora Capital Management, LLC. According to a Schedule 13G filed with the SEC on February 14, 2019 and a Form 4 filed with the SEC on January 17, 2018 by HG Vora Capital Management, LLC., the investment manager of HG Vora Special Opportunities Master Fund, Ltd., Parag Vora, may be deemed to directly or indirectly exercise voting and/or investment powers with respect to the shares directly held on behalf of one or more funds or accounts managed by HG Vora Capital Management, LLC. The business address of HG Vora Capital Management is 330 Madison Avenue, 20th Floor, New York, New York 10017. Holdings include 4,667,500 shares subject to warrants.
- (8) Based on the Prospectus (Registration Statement No. 333-254279) filed with the SEC and declared effective on June 16, 2021.
- (9) Based on the Prospectus (Registration Statement No. 333-254279) filed with the SEC and declared effective on June 16, 2021.
- (10) Consists of non-transferable warrants with a five-year term to purchase 500,000 shares of common stock at a strike price per share equal to \$6.28 and up to 250,000 shares of common stock based on certain service and market price conditions.
- (11) Consists of non-transferable warrants with a five-year term to purchase 500,000 shares of common stock at a strike price per share equal to \$6.28 and up to 250,000 shares of common stock based on certain service and market price conditions.
- (12) Of the 6,125,000 shares listed in this column, 5,000,000 of those shares are held by Selling Securityholders who have agreed, subject to certain exceptions, not to transfer, pledge, assign, sell or otherwise dispose of those shares until the earlier to occur of (a) one year after the Merger and (b) the date on which we complete a liquidation, merger, share exchange or other similar transaction after closing that results in all of our stockholders having the right to exchange their common shares for cash, securities or other property. However, if the closing price of our common shares equals or exceeds \$12.00 per share (as adjusted for share splits, share capitalizations, recognizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Merger, the shares of those Selling Securityholders will be released from these restrictions.

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# PLAN OF DISTRIBUTION

The Selling Securityholders, which as used herein includes donees, pledgees, transferees, distributes or other successors-in-interest selling shares of our common stock or warrants or interests in our common stock or warrants received after the date of this prospectus from the Selling Securityholders as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer, distribute or otherwise dispose of certain of their shares of common stock or warrants or interests in our common stock or warrants or any stock exchange, market or trading facility on which shares of our common stock or warrants are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The Selling Securityholders may use any one or more of the following methods when disposing of their shares of common stock or warrants or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- one or more underwritten offerings;
- block trades in which the broker-dealer will attempt to sell the shares of common stock or warrants 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 accounts;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- distributions to their members, partners or shareholders;
- short sales effected after the date of the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- in market transactions, including transactions on a national securities exchange or quotations service or over-the-counter market;
- directly to one or more purchasers;
- through agents;
- broker-dealers may agree with the Selling Securityholders to sell a specified number of such shares of common stock or warrants at a stipulated price per share or warrant; and
- a combination of any such methods of sale.

The Selling Securityholders may, from time to time, pledge or grant a security interest in some shares of our common stock or warrants owned by them and, if a Selling Securityholder defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell such shares of common stock or warrants, as applicable, from time to time, under this prospectus, or under an amendment or supplement to this prospectus amending the list of the Selling Securityholders to include the pledgee, transfere or other successors in interest as the Selling Securityholders under this prospectus. The Selling Securityholders also may transfer shares of our common stock or warrants in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

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

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The aggregate proceeds to the Selling Securityholders from the sale of shares of our common stock or warrants offered by them will be the purchase price of such shares of our common stock or warrants less discounts or commissions, if any. The Selling Securityholders reserve the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of share of our common stock or warrants to be made directly or through agents. We will not receive any of the proceeds from any offering by the Selling Securityholders.

The Selling Securityholders also may in the future resell a portion of our common stock or warrants in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule, or pursuant to other available exemptions from the registration requirements of the Securities Act.

The Selling Securityholders and any underwriters, broker-dealers or agents that participate in the sale of shares of our common stock or warrants or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of shares of our common stock or warrants may be underwriting discounts and commissions under the Securities Act. If any Selling Securityholder is an "underwriter" within the meaning of Section 2(11) of the Securities Act, then the Selling Securityholder will be subject to the prospectus delivery requirements of the Securities Act. Underwriters and their controlling persons, dealers and agents may be entitled, under agreements entered into with us and the Selling Securityholders, to indemnification against and contribution toward specific civil liabilities, including liabilities under the Securities Act.

To the extent required, our common stock or warrants to be sold, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable discounts, commissions, concessions or other compensation with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

To facilitate the offering of shares of our common stock and warrants offered by the Selling Securityholders, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock or warrants. This may include over-allotments or short sales, which involve the sale by persons participating in the offering of more shares of common stock or warrants than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of our common stock or warrants by bidding for or purchasing shares of common stock or warrants in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if shares of common stock or warrants at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

We and the Selling Securityholders may agree to indemnify any underwriter, broker-dealer or agent against certain liabilities related to the selling of the securities, including liabilities arising under the Securities Act.

We have agreed to maintain the effectiveness of this registration statement pursuant to the terms of the agreement governing such securities or the registration rights related thereto. We have agreed to pay all expenses in connection with this offering, other than underwriting fees, discounts, selling commissions, stock transfer taxes and certain legal expenses. The Selling Securityholders will pay, on a pro rata basis, any underwriting fees, discounts, selling commissions, stock transfer taxes and certain legal expenses relating to the offering. We estimate that our total expenses relating to this offering will approximately be  $[\bullet]$ , which includes \$28,489 for registration fees and  $[\bullet]$  in legal and accounting fees.

Selling Securityholders may use this prospectus in connection with resales of shares of our common stock and warrants. This prospectus and any accompanying prospectus supplement will identify the Selling Securityholders, the terms of our common stock or warrants and any material relationships between us and the Selling Securityholders. Selling Securityholders may be deemed to be underwriters under the Securities Act in connection with shares of our common stock or warrants they resell and any profits on the sales may be deemed to be underwriting discounts and commissions under the Securities Act. Unless otherwise set forth in a prospectus supplement, the Selling Securityholders will receive all the net proceeds from the resale of shares of our common stock or warrants.

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A Selling Securityholder that is an entity may elect to make an in-kind distribution of common stock or warrants to its members, partners or shareholders pursuant to the registration statement of which this prospectus is a part by delivering a prospectus. To the extent that such members, partners or shareholders are not affiliates of ours, such members, partners or shareholders would thereby receive freely tradable shares of common stock or warrants pursuant to the distribution through a registration statement.

Of the total number of shares of common shares being offered through this Registration Statement/Prospectus, 5,000,000 are held by Selling Securityholders who have agreed, subject to certain exceptions, not to transfer, pledge, assign, sell or otherwise dispose of those shares until the earlier to occur of (a) one year after the Merger and (b) the date on which we complete a liquidation, merger, share exchange or other similar transaction after closing that results in all of our stockholders having the right to exchange their common shares for cash, securities or other property. However, if the closing price of our common shares equals or exceeds \$12.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Merger, the shares of those Selling Securityholders will be released from these restrictions.

# LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Troutman Pepper Hamilton Sanders 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

The financial statements of LACQ as of December 31, 2019 and 2020 and the years ended December 31, 2019 and 2020 included in this registration statement/prospectus, have been audited by Marcum LLP, independent registered public accounting firm, as set forth in their report thereon, appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Ensysce as of and for the years ended December 31, 2019 and 2020, included in this registration statement/prospectus, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report (which includes an explanatory paragraph related to the existence of substantial doubt about Ensysce's ability to continue as a going concern), appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing, in giving said reports.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1, including exhibits, under the Securities Act of 1933, as amended, with respect to the securities offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our securities, you should refer to the registration statement and our exhibits.

In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public on a website maintained by the SEC located at www.sec.gov. We also maintain a website at www.ensyce.com. Through our website, we make available, free of charge, annual, quarterly and current reports, proxy statements and other information as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Leisure Acquisition Corp.

#### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Leisure Acquisition Corp. (the "*Company*") as of December 31, 2020 and 2019, the related statements of operations, changes in stockholders' equity and cash flows for each of the years ended December 31, 2020 and 2019, and the related notes (collectively referred to as the "*financial statements*"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years ended December 31, 2020 and 2019, in conformity with accounting principles generally accepted in the United States of America.

# **Restatement of the Financial Statements**

As discussed in Note 2 to the financial statements, the accompanying financial statements as of December 31, 2020, and 2019 have been restated.

#### **Explanatory Paragraph – Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's business plan is dependent on the completion of a business combination and the Company's cash and working capital as of December 31, 2020 are not sufficient to complete its planned activities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these

matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (the "*PCAOB*") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP Marcum LLP

We have served as the Company's auditor since 2017.

West Palm Beach, FL

March 15, 2021, except for the effects of the restatements discussed in Note 2 and Contingent Forward Purchase Contract in Note 7 as to which the date is June 7, 2021.

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# LEISURE ACQUISITION CORP. BALANCE SHEETS (As Restated)

	December 31,				
	2020			2019	
ASSETS					
ASSETS Current assets					
Cash	\$	49,202	\$	1,061,151	
Prepaid expenses	¢	157,483	Ф	1,001,131	
Prepaid income taxes		19,779		138,571	
Total Current Assets		226,464		1,199,722	
I otal Current Assets		220,404		1,199,722	
Cash and marketable securities held in Trust Account		12,628,170		195,312,177	
TOTAL ASSETS	\$	12,854,634	\$	196,511,899	
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY					
Current liabilities					
Accounts payable and accrued expenses	\$	260,404	\$	2,771,025	
Total Current Liabilities	φ	260,404	φ	2,771,025	
		200,404		2,771,025	
Promissory note		566,288		566,288	
Convertible promissory notes - related party		225,000			
Warrant liability		6,260,000		7,166,250	
Deferred underwriting fee payable		6,750,000		7,000,000	
TOTAL LIABILITIES		14,061,692		17,503,563	
Commitments					
Common stock subject to possible redemption, 0 and 16,808,829 shares at redemption value at December 31,					
2020 and 2019, respectively		_		174,008,335	
Che dale all and An effection in writes					
Stockholders' (Deficit) Equity Preferred stock, \$0.0001 par value; 1,000,000 shares authorized; none issued and outstanding					
Common stock, \$0.0001 par value; 1,000,000 shares authorized; 6,224,268 and 7,067,422 shares issued and		—		—	
outstanding (excluding 0 and 16,808,829 shares subject to possible redemption) at December 31, 2020 and 2019,					
respectively		622		707	
Additional paid-in capital				5,136,000	
Accumulated Deficit		(1,207,680)		(136,706)	
Total Stockholders' (Deficit) Equity		(1,207,058)		5,000,001	
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	\$	12,854,634	\$	196,511,899	
		<u> </u>		· · ·	

The accompanying notes are an integral part of the financial statements.

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Year Ended December 31,				
2020	2019			
1 368 841	\$	3,328,674		
, ,	+	(3,328,674)		
719,646		4,249,828		
(220,000)		—		
220,000		—		
1,906,250		(1,433,250)		
3,298,207		_		
5,924,103		2,816,578		
4,555,262		(512,096)		
(244,493)		(555,200)		
4,310,769	\$	(1,067,296)		
3,949,616		18,270,950		
0.00	¢	0.17		
0.00	<b>ə</b>	0.17		
6,642,759		6,621,293		
0.65	\$	(0.63)		
	1,368,841         (1,368,841)         719,646         (220,000)         220,000         1,906,250         3,298,207         5,924,103         4,555,262         (244,493)         4,310,769         3,949,616         0.00         6,642,759	1,368,841       \$         (1,368,841)       \$         719,646       (220,000)         220,000       1,906,250         3,298,207       5,924,103         4,555,262       (244,493)         4,310,769       \$         3,949,616       \$         6,642,759       \$		

The accompanying notes are an integral part of the financial statements.

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# LEISURE ACQUISITION CORP. STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (As Restated)

				Additional		Retained Earnings/	St	Total ockholders'
	Commo	n Stock		Paid in	(A	Accumulated		Equity
	Shares	Amo	unt	Capital		Deficit)		(Deficit)
Balance – January 1, 2019	6,064,800	\$	660	\$ 4,068,751	\$	930,590	\$	5,000,001
Change in value of common stock subject to possible								
redemption	463,342		47	1,067,249		—		1,067,296
Net income (loss)			_			(1,067,296)		(1,067,296)
Balance – December 31, 2019	7,067,422		707	5,136,000		(136,706)		5,000,001
Change in value of common stock subject to possible								
redemption	(843,154)		(85)	(5,136,000)	)	(5,631,743)		(10,767,828)
•								
Waiver of a portion of deferred underwriting fee	_		_	_		250,000		250,000
Net income	_			_		4,310,769		4,310,769
Balance – December 31, 2020	6,224,268	\$	622	\$ —	\$	(1,207,680)	\$	(1,207,058)

The accompanying notes are an integral part of the financial statements.

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# LEISURE ACQUISITION CORP. STATEMENTS OF CASH FLOWS (As Restated)

	Year	Ended December 31, 2020	Year	Ended December 31, 2019
Cash Flows from Operating Activities:				
Net income (loss)	\$	4,310,769	\$	(1,067,296)
Adjustments to reconcile net income (loss) to net cash used in operating activities:				
Interest earned on marketable securities held in Trust Account		(719,646)		(4,249,828)
Forgiveness of accounts payable		(3,298,207)		—
Change in fair value of warrant liability		(1,906,250)		1,433,250
Amortization of debt discount on convertible promissory note		220,000		_
Change in fair value of conversion option liability		(220,000)		_
Deferred tax benefit				(1,764)
Changes in operating assets and liabilities:				

Prepaid expenses	(157,483)		87,083
Prepaid income taxes	118,792		31,964
Accounts payable and accrued expenses	787,586		2,341,799
Net cash used in operating activities	(864,439)		(1,424,792)
Cash Flows from Investing Activities:			
Investment of cash in Trust Account	(1,698,862)		(566,288)
Cash withdrawn from Trust Account for redemption of common stock	184,776,163		11,583,473
Cash withdrawn from Trust Account for franchise taxes and income taxes	326,352		836,205
Net cash provided by investing activities	183,403,653		11,853,390
Cash Flows from Financing Activities:			
Proceeds from promissory note	—		566,268
Proceeds from convertible promissory notes – related parties	1,225,000		_
Redemption of common stock	(184,776,163)		(11,583,473)
Payment of offering costs			(8,640)
Net cash used in financing activities	(183,551,163)		(11,025,845)
Net Change in Cash	(1,011,949)		(597,247)
Cash – Beginning	1,061,151		1,658,398
Cash – Ending	\$ 49,202	\$	1,061,151
Supplementary cash flow information:			
Cash paid for income taxes	<u>\$ 125,701</u>	\$	525,000
Non-Cash investing and financing activities:			
Change in value of common stock subject to possible redemption	\$ 10,767,828	\$	(1,067,296)
Waiver of a portion of deferred underwriting fee payable	\$ 250,000	\$	
Waiver of a portion of deferred underwriting fee payable	<u>\$ 250,000</u>	<u>\$</u>	_

The accompanying notes are an integral part of the financial statement

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### NOTE 1. — DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Leisure Acquisition Corp. (the "Company") is a blank check company incorporated in Delaware on September 11, 2017. The Company was formed for the purpose of acquiring, through a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, recapitalization, exchangeable share transaction or other similar business transaction, with one or more operating businesses or assets (a "Business Combination").

At December 31, 2020, the Company had not yet commenced operations. All activity through December 31, 2020 relates to the Company's formation, its initial public offering (*"Initial Public Offering*"), which is described below, identifying a target company for a Business Combination, activities in connection with the proposed acquisition of Ensysce Biosciences, Inc., a Delaware corporation (*"Ensysce"*) (see Note 12) and activities in connection with the previously proposed business combination with GTWY Holdings Limited, a Canadian corporation (*"GTWY Holdings"*), which was terminated on July 16, 2020.

The registration statement for the Company's Initial Public Offering was declared effective on December 1, 2017. On December 5, 2017, the Company consummated the Initial Public Offering of 20,000,000 units ("Units" and, with respect to the common stock included in the Units, the 'Public Shares"), generating gross proceeds of \$200,000,000, which is described in Note 4.

Simultaneously with the closing of the Initial Public Offering, the Company consummated the sale of 6,825,000 warrants (the "*Private Placement Warrants*") at a price of \$1.00 per warrant in a private placement to Hydra LAC, LLC, an affiliate of Hydra Management, LLC (the *Hydra Sponsor*"), MLCP GLL Funding LLC, an affiliate of Matthews Lane Capital Partners, LLC (the "Matthews Lane Sponsor," and, together with the Hydra Sponsor, the "*Sponsors*"), HG Vora Special Opportunities Master Fund, Ltd. ("*HG Vora*") and certain members of the Company's management team, generating gross proceeds of \$6,825,000, which is described in Note 5.

Following the closing of the Initial Public Offering on December 5, 2017, an amount of 200,000,000 (\$10.00 per Unit) from the net proceeds of the sale of the Units in the Initial Public Offering and the Private Placement Warrants was placed in a trust account (the "*Trust Account*") and invested in U.S. government securities, within the meaning set forth in Section 2(a)(16) of the Investment Company Act of 1940, as amended (the "*Investment Company Act*"), with a maturity of 180 days or less or in any open-ended investment company that holds itself out as a money market fund selected by the Company meeting the conditions of Rule 2a-7 of the Investment Company Act, as determined by the Company, until the earlier of: (i) the consummation of a Business Combination or (ii) the distribution of the Trust Account, as described below.

Transaction costs amounted to \$11,548,735, consisting of \$4,000,000 of underwriting fees, \$7,000,000 of deferred underwriting fees and \$548,735 of Initial Public Offering costs.

The Company's management has broad discretion with respect to the specific application of the net proceeds of the Initial Public Offering and Private Placement Warrants, although substantially all of the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company's initial Business Combination must be with one or more target businesses that together have a fair market value equal to at least 80% of the balance in the Trust Account (excluding deferred underwriting commissions and franchise and income taxes payable on the income earned on the Trust Account) at the time of the signing of an agreement to enter into a Business Combination. The Company will only complete a Business Combination if the post-Business Combination company owns or acquires 50% or more of the outstanding voting securities of the target or otherwise acquires a controlling interest in the target sufficient for it not to be required to register as an investment company under the Investment Company Act. There is no assurance that the Company will be able to successfully effect a Business Combination.

The Company will provide its stockholders with the opportunity to redeem all or a portion of their Public Shares upon the completion of a Business Combination either (i) in connection with a stockholder meeting called to approve the Business Combination or (ii) by means of a tender offer. The decision as to whether the Company will seek stockholder approval of a Business Combination or conduct a tender offer will be made by the Company, solely in its discretion. The stockholders will be entitled to redeem their shares for a pro rata portion of the amount then on deposit in the Trust Account (\$10.00 per share, plus any deposits made to the Trust Account in connection with extension payments and any pro rata interest earned on the funds held in the Trust Account and not previously released to the Company to pay franchise and income taxes). The per share amount to be distributed to stockholders who redeem their shares will not be reduced by the deferred underwriting commissions the Company will pay to the underwriters (see Note 8).

The Company will proceed with a Business Combination if the Company has net tangible assets of at least \$,000,001 upon consummation of a Business Combination and, if the Company seeks stockholder approval, a majority of the outstanding shares voted are voted in favor of the Business Combination. If a stockholder vote is not required by law and the Company does not decide to hold a stockholder vote for business or other legal reasons, the Company will, pursuant to its Second Amended and Restated Certificate of Incorporation, conduct the redemptions pursuant to the tender offer rules of the Securities and Exchange Commission ("SEC"), and file tender offer documents with the SEC prior to completing a Business Combination. If, however, a stockholder approval of the transaction is required by law, or the Company decides to obtain stockholder approval for business or other legal reasons, the Company will offer to redeem shares in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules. If the Company seeks stockholder approval in connection with a Business Combination, the Sponsors and the Company's other initial stockholders (collectively, the "*Initial Stockholders*") have agreed to vote their Founder Shares (as defined in Note 6) and any Public Shares held by them in favor of approving a Business Combination. Additionally, each public stockholder may elect to redeem their Public Shares irrespective of whether they vote for or against the proposed transaction.

Notwithstanding the foregoing, the Company's Second Amended and Restated Certificate of Incorporation provides that a public stockholder, together with any affiliate of such stockholder or any other person with whom such stockholder is acting in concert or as a "group" (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")), will be restricted from redeeming its shares with respect to an aggregate of 20% or more of the common stock sold in the Initial Public Offering.

The Company has until June 30, 2021 to consummate a Business Combination (the 'Combination Period'). If the Company is unable to complete a Business Combination within the Combination Period, the Company will (i) cease all operations except for the purpose of winding up, (ii) as promptly as reasonably possible but no more than ten business days thereafter, redeem 100% of the outstanding Public Shares, at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, including interest earned and not previously released to pay franchise and income taxes (less up to \$75,000 of interest to pay dissolution expenses), divided by the number of then outstanding Public Shares, which redemption will completely extinguish public stockholders' rights as stockholders (including the right to receive further liquidation distributions, if any), subject to applicable law, and (iii) as promptly as reasonably possible following such redemption, subject to the approval of the remaining stockholders and the Company's board of directors, proceed to commence a voluntary liquidation and thereby a formal dissolution of the Company, subject in each case to its obligations to provide for claims of creditors and the requirements of applicable law. The underwriters have agreed to waive their rights to the deferred underwriting commission held in the Trust Account that will be available to fund the redemption of the Company's Public Shares. In the event, such amounts will be included with the funds held in the Trust Account that will be available to fund the redemption of the Company's Public Shares. In the event of such distribution, it is possible that the per share value of the assets remaining available for distribution (including Trust Account assets) will be less than the \$10.00 per Unit in the Initial Public Offering.

On November 26, 2019, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from December 5, 2019 to April 5, 2020 (the "*Initial Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of \$11,23,749 shares of the Company's common stock. As a result, an aggregate of \$11,583,473 (or approximately \$10.31 per share) was released from the Company's Trust Account to pay such stockholders.

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The Company agreed to contribute (the "*Contribution*") \$0.03 for each share of the Company's common stock that was not redeemed in connection with the extension for each of the four monthly periods covered by the extension (commencing on December 6, 2019 through the Initial Extension Date), subject to certain conditions.

On each of December 5, 2019, January 3, 2020, February 4, 2020 and March 4, 2020, the Company made a Contribution of \$0.03 for each of the Public Shares outstanding, for an aggregate Contribution of \$2,265,150, which amounts were deposited into the Trust Account.

On December 5, 2019, the Company entered into an expense advancement agreement with GTWY Holdings (the 'GTWY Expense Advance Agreement'), pursuant to which GTWY Holdings committed to provide \$566,288 to fund contributions to the Trust Account. The Company drew down the full amount under the GTWY Expense Advance Agreement to fund the required Contribution to the Trust Account for the period December 6, 2019 to January 5, 2020 by issuing an unsecured promissory note to GTWY Holdings. The note was converted into warrants on January 31, 2021 (see Note 7).

On January 15, 2020, the Company drew down 1,000,000 under the expense advancement agreement with the Company's Sponsors and strategic investor dated December 1, 2017 in exchange for issuing unsecured promissory notes to fund its working capital requirements and to fund required Contributions to the Trust Account. The holders had the option to convert the promissory notes into warrants at a price of 1.00 per warrant subject to the same terms and conditions as Private Placement Warrants. The notes were converted into warrants to purchase 1,000,001 shares of the Company's common stock at an exercise price of 1.50 per share on June 25, 2020 (see Note 6).

On March 26, 2020, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from April 5, 2020 to June 30, 2020 (the "*Second Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of 16,837,678 shares of the Company's common stock. As a result, an aggregate of \$176,283,492 (or approximately \$10.47 per share) was released from the Company's Trust Account to pay such stockholders. Of the amount paid to redeeming stockholders, \$136,283,492 was paid as of March 31, 2020 and the balance of \$40,000,000 was paid on April 1, 2020.

On June 26, 2020, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from June 30, 2020 to December 1, 2020 (the *"Third Extension Date"*). In connection with the approval of the extension, stockholders elected to redeem an aggregate of 776,290 shares of the Company's common stock. As a result, an aggregate of \$8,099,292 (or approximately \$10.43 per share) was released from the Company's Trust Account to pay such stockholders.

On November 24, 2020, the Company's stockholders approved extending the Combination Period from December 1, 2020 to June 30, 2021 (the *Fourth Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of \$393,380 (or approximately \$10.34 per share) was released from the Company's Trust Account to pay such stockholders.

The Initial Stockholders have agreed to (i) waive their redemption rights with respect to their Founder Shares in connection with the completion of a Business Combination, (ii) to waive their rights to liquidating distributions from the Trust Account with respect to their Founder Shares if the Company fails to complete a Business Combination within the Combination Period and (iii) not to propose an amendment to the Company's Second Amended and Restated Certificate of Incorporation that would affect the substance or timing of the Company's obligation to redeem 100% of its Public Shares if the Company does not complete a Business Combination, unless the Company provides the public stockholders with the opportunity to redeem their shares in conjunction with any such amendment.

In order to protect the amounts held in the Trust Account, the Sponsors have agreed to be liable to the Company if and to the extent any claims by a vendor for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amount of funds in the Trust Account to below the lesser of (i) \$10.00 per Public Share or (ii) such lesser amount per share held in the Trust Account as of the date of the liquidation of the Trust Account due to reductions in the value of the trust assets. This liability will not apply with respect to any claims by a third party who executed a waiver of any right, title, interest or claim of any kind in or to any monies held in the Trust Account or to any claims under the Company's indemnity of the underwriters of the Initial Public Offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"). Moreover, in the event that an executed waiver is deemed to be unefforeable against a third party, the Sponsors will not be responsible to the extent of any liability for such third -party claims. The Company will seek to reduce the

possibility that the Sponsors will have to indemnify the Trust Account due to claims of creditors by endeavoring to have all vendors, service providers, prospective target businesses or other entities with which the Company does business, execute agreements with the Company waiving any right, title, interest or claim of any kind in or to monies held in the Trust Account.

# Nasdaq Notifications

On November 30, 2020, the Company received a notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC stating that the Company was not in compliance with Listing Rule IM-5101-2 (the "Rule"), which requires that a special purpose acquisition company complete one or more business combinations within 36 months of the effectiveness of the registration statement filed in connection with its initial public offering. Since the Company's registration statement became effective on December 1, 2017, it was required to complete an initial business combination by no later than December 1, 2020. The Rule also provides that failure to comply with this requirement will result in the Listing Qualifications Department issuing a Staff Delisting Determination under Rule 5810 to delist the Company's securities. In addition, the Nasdaq Notice states that the Company was not in compliance with Nasdaq's minimum publicly held shares requirement under Listing Rule 5550(a)(4), which requires a listed company's primary equity security to maintain a minimum of 500,000 publicly held shares.

The Listing Qualifications Department has advised the Company that its securities would be subject to delisting unless the Company timely requests a hearing before an independent Hearings Panel (the "Panel"). Accordingly, the Company intends to timely request a hearing. The hearing request will stay any suspension or delisting action pending the completion of the hearing and the expiration of any additional extension period granted by the Panel following the hearing.

On January 27, 2021, the Panel granted the Company's request for continued listing of the Company's equity securities on the Nasdaq Capital Market pursuant to an extension, subject to certain milestones, through June 1, 2021 (see Note 12). See. "*Risk Factors — If the Nasdaq delists our Common Stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, this could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.*"

#### **Risks and Uncertainties**

Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's financial position, results of its operations and/or search for a target company, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Liquidity and Going Concern

As of December 31, 2020, the Company had \$49,202 in its operating bank accounts, \$12,628,170 in securities held in the Trust Account to be used for a Business Combination or to repurchase or redeem its common stock in connection therewith and working capital deficit of \$127,869, which excludes \$93,929 of prepaid income and franchise taxes.

As of December 31, 2020, the Company had \$75,000 available for drawdown under the Company's expense advancement agreement with the Company's Sponsors and HG Vora (see "*Related Party Loans*" in Note 6).

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The Company will need to raise additional capital through loans or additional investments from its Sponsors, HG Vora, stockholders, officers, directors, or third parties. The Company's Sponsors and HG Vora may, but are not obligated to, loan the Company funds, from time to time or at any time, in whatever amount they deem reasonable in their sole discretion, to meet the Company's working capital needs. Accordingly, the Company may not be able to obtain additional financing. If the Company is unable to raise additional capital, it may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations, suspending the pursuit of a potential transaction, and reducing overhead expenses. The Company cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all. These conditions raise substantial doubt about the Company's ability to continue as a going concern through June 30, 2021, the date that the Company will be required to cease all operations, except for the purpose of winding up, if a Business Combination is not consummated. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

# NOTE 2. — RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

The Company previously accounted for its outstanding Private Placement Warrants issued in connection with its Initial Public Offering and its working capital warrants issued on conversion of its convertible promissory notes (collectively, the "*Private Warrants*") as components of equity instead of as derivative liabilities. In addition, the Company did not account for its convertible promissory notes as a derivative liability (together with the Private Warrants, the "*Derivative Instruments*"). The Warrant Agreement governing the Private Warrants (the "*Warrant Agreement*") includes a provision that provides for potential changes to the settlement amounts dependent upon the characteristics of the holder of the warrant. In addition, the Warrant Agreement includes a provision that in the event of a tender offer or exchange offer made to and accepted under circumstances in which, upon completion of such tender offer, the maker thereof, together with members of any group of which such maker is a part own beneficially more than 50% of the outstanding shares of more than 50% of the Company's common stock, all holders of the Private Warrants and Public Warrants would be entitled to receive cash for their Warrants (the "*tender offer provision*").

On April 12, 2021, the Acting Director of the Division of Corporation Finance and Acting Chief Accountant of the Securities and Exchange Commission together issued a statement regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "SEC Statement"). Specifically, the SEC Statement focused on potential changes to the settlement amounts dependent upon the characteristics of the holder of the warrant and provisions related to certain tender offers following a business combination, which terms are similar to those contained in the Warrant Agreement, although the Company does not believe the portion of the SEC Statement referring to the tender offer are applicable to the Company's warrants because the Company has only a single class of common stock.

In further consideration of the SEC Statement, the Company's management further evaluated the warrants under Accounting Standards Codification ("ASC") Subtopic 815-40, Contracts in Entity's Own Equity. ASC Section 815-40-15 addresses equity versus liability treatment and classification of equity-linked financial instruments, including warrants, and states that a warrant may be classified as a component of equity only if, among other things, the warrant is indexed to the issuer's common stock if the terms of the warrant require an adjustment to the exercise price upon a specified event and that event is not an input to the fair value of the warrant. Based on management's evaluation, the Company's audit committee, in consultation with management, concluded that the Company's Private Placement Warrants are not indexed to the Company's common stock in the manner contemplated by ASC Section 815-40-15 because the holder of the instrument is not an input into the pricing of a fixed-for-fixed option on equity shares. In addition, based on management's evaluation, the Company's evaluation, with management, concluded that the Private Warrants fail the "classified in stockholders' equity" criteria as contemplated by ASC Section 815-40-25, but that the Public Warrants could continue to be classified as stockholders' equity.

As a result of the above, the Company should have classified the Derivative Instruments as derivative liabilities in its previously issued financial statements. Under this accounting treatment, the Company is required to measure the fair value of the Derivative Instruments at the end of each reporting period and recognize changes in the fair value from the prior period in the Company's operating results for the current period.

The change in the Company's accounting to treat its outstanding Private Warrants and its convertible promissory notes as derivative liabilities did not have any effect on the Company's previously reported investments held in trust, cash flows or cash.

The table below summarizes the effects of the restatement on the financial statements for all periods being restated:

	As Previously Reported		Adjustments		As Restated
		•			
Balance sheet as of December 5, 2017 (audited)					
Total Liabilities	\$	7,206,932	\$	4,572,750	\$ 11,779,682
Common Stock Subject to Possible Redemption		190,296,100		(4,572,750)	185,723,350
Common Stock		672		46	718
Additional Paid-in Capital		5,004,493		(46)	5,004,447
Accumulated Deficit		(5,161)		_	(5,161)
Total Stockholders' Equity		5,000,004		—	5,000,004
Number of shares subject to redemption		19,029,610		(457,275)	18,572,335
Balance sheet as of December 31, 2017 (audited)					
Total Liabilities	\$	7,156,239	\$	5,664,750	\$ 12,820,989
Common Stock Subject to Possible Redemption		190,270,071		(5,664,750)	184,605,321
Common Stock		673		57	730
Additional Paid-in Capital		5,030,521		1,091,943	6,122,464
Accumulated Deficit		(31,193)		(1,092,000)	(1,123,193)
Total Stockholders' Equity		5,000,001		—	5,000,001
Number of shares subject to redemption		19,015,680		(566,138)	18,449,542
Balance sheet as of March 31, 2018 (unaudited)					
Total Liabilities	\$	7,197,431	\$	5,323,500	\$ 12,520,931
Common Stock Subject to Possible Redemption		190,676,137		(5,323,500)	185,352,637
Common Stock		599		53	652
Additional Paid-in Capital		4,624,529		750,697	5,375,226
(Accumulated Deficit) / Retained Earnings		374,873		(750,750)	(375,877)
Total Stockholders' Equity		5,000,001		_	5,000,001
Number of shares subject to redemption		19,010,039		(530,743)	18,479,296
Balance sheet as of June 30, 2018 (unaudited)					
Total Liabilities	\$	7,135,244	\$	5,596,500	\$ 12,731,744
Common Stock Subject to Possible Redemption		191,091,247		(5,596,500)	185,494,747
Common Stock		601		56	657
Additional Paid-in Capital		4,209,417		1,023,694	5,233,111
(Accumulated Deficit) / Retained Earnings		789,983		(1,023,750)	(233,767)
Total Stockholders' Equity		5,000,001		—	5,000,001
Number of shares subject to redemption		18,989,851		(556,157)	18,433,694
Balance sheet as of September 30, 2018 (unaudited)					
Total Liabilities	\$	7,359,152	\$	7,302,750	\$ 14,661,902
Common Stock Subject to Possible Redemption		191,668,896		(7,302,750)	184,366,146
Common Stock		603		72	675
Additional Paid-in Capital		3,631,766		2,729,928	6,361,694
(Accumulated Deficit) / Retained Earnings		1,367,632		(2,730,000)	(1,362,368)
Total Stockholders' Equity		5,000,001		—	5,000,001
Number of shares subject to redemption		18,974,158		(722,932)	18,251,226
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	 As Previously Reported	 Adjustments	 As Restated
Balance sheet as of December 31, 2018 (audited)			
Total Liabilities	\$ 7,439,650	\$ 5,733,000	\$ 13,172,650
Common Stock Subject to Possible Redemption	192,392,104	(5,733,000)	186,659,104
Common Stock	604	56	660
Additional Paid-in Capital	2,908,557	1,160,194	4,068,751
Retained Earnings	2,090,840	(1,160,250)	930,590
Total Stockholders' Equity	5,000,001	_	5,000,001
Number of shares subject to redemption	18,960,928	(565,008)	18,395,920
Balance sheet as of March 31, 2019 (unaudited)			
Total Liabilities	\$ 7,387,249	\$ 5,391,750	\$ 12,778,999
Common Stock Subject to Possible Redemption	193,168,017	(5,391,750)	187,776,267
Common Stock	605	53	658
Additional Paid-in Capital	2,132,643	818,947	2,951,590

Retained Earnings		2,866,753		(819,000)		2,047,753
Total Stockholders' Equity		5,000,001		_		5,000,001
Number of shares subject to redemption		18,952,136		(528,996)		18,423,140
Balance sheet as of June 30, 2019 (unaudited)	0	5 550 0.50	۵	5 201 550	¢	10.1(0.100
Total Liabilities	\$	7,770,352	\$	5,391,750	\$	13,162,102
Common Stock Subject to Possible Redemption		193,586,919		(5,391,750)		188,195,169
Common Stock		610		53		663
Additional Paid-in Capital		1,713,736		818,947		2,532,683
Retained Earnings		3,285,655		(819,000)		2,466,655
Total Stockholders' Equity		5,000,001		—		5,000,001
				(55 ( 50 ()		10.050.000
Number of shares subject to redemption		18,899,782		(526,394)		18,373,388
Balance sheet as of September 30, 2019 (unaudited)						
Total Liabilities	\$	8,134,091	\$	5,528,250	\$	13,662,341
Common Stock Subject to Possible Redemption		194,076,642		(5,528,250)		188,548,392
Common Stock		614		54		668
Additional Paid-in Capital		1,224,009		955,446		2,179,455
Retained Earnings		3,775,378		(955,500)		2,819,878
Total Stockholders' Equity		5,000,001		<u> </u>		5,000,001
Number of shares subject to redemption		18,860,476		(537,238)		18,323,238
Balance sheet as of December 30, 2019 (audited)	0	10.005.010	۵	F 1 ( ( 250	¢	17 500 550
Total Liabilities	\$	10,337,313	\$	7,166,250	\$	17,503,563
Common Stock Subject to Possible Redemption		181,174,585		(7,166,250)		174,008,335
Common Stock		638		69		707
Additional Paid-in Capital		2,542,569		2,593,431		5,136,000
(Accumulated Deficit) / Retained Earnings		2,456,794		(2,593,500)		(136,706
Total Stockholders' Equity		5,000,001		_		5,000,001
Number of shares subject to redemption		17,501,073		(692,244)		16,808,829
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	1 15					

	 As Previously Reported	 Adjustments	 As Restated
Balance sheet as of March 31, 2020 (unaudited)			
Total Liabilities	\$ 52,060,483	\$ 5,023,678	\$ 57,084,161
Common Stock Subject to Possible Redemption	4,541,236	(4,541,236)	—
Common Stock	660	43	703
Additional Paid-in Capital	2,892,404	(31,557)	2,860,847
Retained Earnings	2,106,940	(450,928)	1,656,012
Total Stockholders' Equity	5,000,004	(482,442)	4,517,562
Number of shares subject to redemption	433,788	(433,788)	—
Balance sheet as of June 30, 2020 (unaudited)			
Total Liabilities	\$ 8,359,869	\$ 7,746,750	\$ 16,106,619
Common Stock Subject to Possible Redemption	52,179	(52,179)	—
Common Stock	626	(4)	622
Additional Paid-in Capital	282,203	(282,203)	0.00
(Accumulated Deficit) / Retained Earnings	4,717,174	(7,412,364)	(2,695,190)
Total Stockholders' Equity	5,000,003	(7,694,571)	(2,694,568)
Number of shares subject to redemption	5,156	(5,156)	—
Balance sheet as of September 30, 2020 (unaudited)			
Total Liabilities	\$ 8,018,370	\$ 3,756,000	\$ 11,774,370
Common Stock Subject to Possible Redemption	270,999	(270,999)	—
Common Stock	624	(2)	622
Additional Paid-in Capital	63,385	(63,385)	—
(Accumulated Deficit) / Retained Earnings	4,935,997	(3,421,614)	1,514,383
Total Stockholders' Equity	5,000,006	(3,485,001)	1,515,005
Number of shares subject to redemption	26,189	(26,189)	—
Balance sheet as of December 30, 2020 (audited)			
Total Liabilities	\$ 7,801,692	\$ 6,260,000	\$ 14,061,692
Common Stock Subject to Possible Redemption	52,935	(52,935)	—
Common Stock	622	_	622
Additional Paid-in Capital	_		_
(Accumulated Deficit) / Retained Earnings	4,999,385	(6,207,065)	(1,207,680)
Total Stockholders' Equity	5,000,007	(6,207,065)	(1,207,058)
Number of shares subject to redemption	5,094	(5,094)	—

Statement of Operations for the period from September 11, 2017 (inception) to December 31, 2017 (audited)				
Net loss	\$	(31,193)	\$ (1,092,000)	\$ (1,123,193)
Basic and diluted weighted average shares outstanding, Common stock subject to				
possible redemption		_	18,572,335	18,572,335
Basic and diluted net income per share, Common stock subject to possible				
redemption		—	0.00	0.00
Basic and diluted weighted average shares outstanding, Common stock		6,184,506	107,109	6,291,615
Basic and diluted net loss per share, Common Stock		(0.01)	(0.18)	(0.19)
Statement of Operations for the three months ended March 31, 2018				
(unaudited)				
Net income (loss)	\$	406,066	\$ 341,250	\$ 747,316
Basic and diluted weighted average shares outstanding, Common stock subject to				
possible redemption		—	18,449,542	18,449,542
Basic and diluted net income (loss) per share, Common stock subject to possible				
redemption		—	0.03	0.03
Basic and diluted weighted average shares outstanding, Common stock		5,984,320	566,138	6,550,458
Basic and diluted net (loss) income per share, Common Stock		(0.02)	0.05	0.03
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		As Previously Reported		Adjustments		As Restated
Statement of Operations for the three months ended June 30, 2018 (unaudited)						
Net income	\$	415,110	\$	(273,000)	\$	142,110
Basic and diluted weighted average shares outstanding, Common stock subject to		,	-	(,)	+	,
possible redemption		—		18,479,296		18,479,296
Basic and diluted net income per share, Common stock subject to possible						
redemption		_		0.04		0.04
Basic and diluted weighted average shares outstanding, Common stock		5,989,961		530,743		6,520,704
Basic and diluted net loss per share, Common Stock		(0.05)		(0.04)		(0.09)
Statement of Operations for the six months ended June 30, 2018 (unaudited)						
Net income	\$	821,176	\$	68,250	\$	889,426
Basic and diluted weighted average shares outstanding, Common stock subject to						
possible redemption		—		18,464,501		18,464,501
Basic and diluted net income (loss) per share, Common stock subject to possible						
redemption		—		0.08		0.08
Basic and diluted weighted average shares outstanding, Common stock		5,981,156		548,343		6,535,499
Basic and diluted net loss per share, Common Stock		(0.10)		0.02		(0.08)
Statement of Operations for the three months ended September 30, 2018 (unaudited)						
Net income (loss)	\$	577,649	\$	(1,706,250)	\$	(1,128,601)
Basic and diluted weighted average shares outstanding, Common stock subject to						
possible redemption		—		18,433,694		18,433,694
Basic and diluted net income per share, Common stock subject to possible redemption				0.05		0.05
Basic and diluted weighted average shares outstanding, Common stock		6,010,149		566,157		6,566,306
Basic and diluted weighted average shares outstanding, common stock		(0.05)		(0.25)		(0.30)
Busie and diluted net 1055 per sindle, common stock		(0.05)		(0.23)		(0.50)
Statement of Operations for the nine months ended September 30, 2018 (unaudited)						
Net income (loss)	\$	1,398,825	\$	(1,638,000)	\$	(239,175)
Basic and diluted weighted average shares outstanding, Common stock subject to						
possible redemption		—		18,454,119		18,454,119
Basic and diluted net income (loss) per share, Common stock subject to possible redemption				0.15		0.12
Basic and diluted weighted average shares outstanding, Common stock		5,994,905		550,976		6,545,881
Basic and diluted weighted average shares outstanding, common stock		(0.14)		(0.24)		(0.38)
		(****)		(*)		(****)
Statement of Operations for the year ended December 31, 2018 (audited)						
Net income	\$	2,122,033	\$	(68,250)	\$	2,053,783
Basic and diluted weighted average shares outstanding, Common stock subject to				10,400,070		10,400,070
possible redemption		—		18,402,979		18,402,979
Basic and diluted net income per share, Common stock subject to possible redemption				0.19		0.19
Basic and diluted weighted average shares outstanding, Common stock		6,002,703		549,318		6,597,021
		(0.22)		0.01		(0.21)
Basic and diluted net (loss) income per share, Common Stock		()				()
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As		
Previously		As
Reported	Adjustments	Restated

Statement of Operations for the three months ended March 31, 2019						
(unaudited)						
Net income	\$	775,913	\$	341,250	\$	1,117,163
Basic and diluted weighted average shares outstanding, Common stock subject to	Ψ	115,715	Ψ	541,250	Ψ	1,117,105
possible redemption		_		18,935,920		18,395,920
Basic and diluted net income (loss) per share, Common stock subject to possible				10,000,020		10,000,020
redemption		_		0.06		0.06
Basic and diluted weighted average shares outstanding, Common stock		6,039,072		565,008		6,604,080
Basic and diluted net (loss) income per share, Common Stock		(0.04)		0.05		0.01
Statement of Operations for the three months ended June 30, 2019						
(unaudited)						
Net income	\$	418,902	\$	_	\$	418,902
Basic and diluted weighted average shares outstanding, Common stock subject to						
possible redemption		_		18,123,140		18,423,140
Basic and diluted net income (loss) per share, Common stock subject to possible						
redemption		—		0.05		0.05
Basic and diluted weighted average shares outstanding, Common stock		6,047,864		528,996		6,576,860
Basic and diluted net loss per share, Common Stock		(0.09)		0.01		(0.08)
Statement of Operations for the six months ended June 30, 2019 (unaudited)	¢	1 104 015	Φ.	241.250	٩	1.526.065
Net income	\$	1,194,815	\$	341,250	\$	1,536,065
Basic and diluted weighted average shares outstanding, Common stock subject to				19 400 605		19 400 605
possible redemption		—		18,409,605		18,409,605
Basic and diluted net income (loss) per share, Common stock subject to possible redemption				0.10		0.10
Basic and diluted weighted average shares outstanding, Common stock		6,043,492		546,903		6,590,395
Basic and diluted weighted average shares outstanding, Common Stock		(0.10)		0.06		(0.04)
basic and unded net (1055) meonic per share, common stock		(0.10)		0.00		(0.04)
Statement of Operations for the three months ended September 30, 2019						
(unaudited)						
Net income	\$	489.723	\$	(136,500)	\$	353,223
Basic and diluted weighted average shares outstanding, Common stock subject to				( ) )		, -
possible redemption		_		18,373,388		18,373,388
Basic and diluted net income (loss) per share, Common stock subject to possible						
redemption		—		0.05		0.05
Basic and diluted weighted average shares outstanding, Common stock		6,100,218		526,394		6,626,612
Basic and diluted net loss per share, Common Stock		(0.08)		(0.01)		(0.09)
Statement of Operations for the nine months ended September 30, 2019						
(unaudited)						
Net income (loss)	\$	1,684,538	\$	204,750	\$	1,889,288
Basic and diluted weighted average shares outstanding, Common stock subject to						
possible redemption		—		18,397,400		18,397,400
Basic and diluted net income (loss) per share, Common stock subject to possible				0.15		0.15
redemption		( 0(2 (00		0.15		0.15
Basic and diluted weighted average shares outstanding, Common stock		6,062,609		539,991		6,602,600
Basic and diluted net (loss) income per share, Common Stock		(0.18)		0.05		(0.13)
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	 As Previously Reported	 Adjustments	 As Restated
Statement of Operations for the year ended December 31, 2019 (audited)			
Net income (loss)	\$ 365,954	\$ (1,433,250)	\$ (1,067,296)
Basic and diluted weighted average shares outstanding, Common stock subject to			
possible redemption	—	18,270,950	18,270,950
Basic and diluted net income (loss) per share, Common stock subject to possible redemption	_	0.17	0.17
Basic and diluted weighted average shares outstanding, Common stock	6,081,996	539,297	6,621,293
Basic and diluted net loss per share, Common Stock	(0.47)	(0.16)	(0.63)
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Statement of Operations for the three months ended March 31, 2020 (unaudited)			
Net income (loss)	\$ (349,854)	\$ 2,142,572	\$ 1,792,718
Basic and diluted weighted average shares outstanding, Common stock subject to			
possible redemption	_	15,885,267	15,885,267
Basic and diluted net income (loss) per share, Common stock subject to possible redemption	_	0.01	0.01
Basic and diluted weighted average shares outstanding, Common stock	6,375,178	690,659	7,065,837
Basic and diluted net (loss) income per share, Common Stock	(0.07)	0.31	0.24
Statement of Operations for the three months ended June 30, 2020 (unaudited)			
Net income	\$ 2,610,234	\$ (1,723,072)	\$ 887,162
Basic and diluted weighted average shares outstanding, Common stock subject to possible redemption	_	_	_
Basic and diluted net income (loss) per share, Common stock subject to possible redemption			
Basic and diluted weighted average shares outstanding, Common stock	6,604,785	399,665	7,004,450

Basic and diluted net (loss) income per share, Common Stock		0.40	(0.27)	0.13
Statement of Operations for the six months ended June 30, 2020 (unaudited)				
Net income	\$	2,260,380	\$ 419,500	\$ 2,679,880
Basic and diluted weighted average shares outstanding, Common stock subject to				
possible redemption		—	7,942,633	7,942,633
Basic and diluted net income (loss) per share, Common stock subject to possible				
redemption		—	0.00	0.00
Basic and diluted weighted average shares outstanding, Common stock		6,489,982	545,162	7,035,144
Basic and diluted net income per share, Common Stock		0.35	0.03	0.38
Statement of Operations for the three months ended September 30, 2020				
(unaudited)				
Net income	\$	218,823	\$ 3,990,750	\$ 4,209,573
Basic and diluted weighted average shares outstanding, Common stock subject to				
possible redemption		—	—	—
Basic and diluted net income (loss) per share, Common stock subject to possible				
redemption		( ) ( ) ( )		
Basic and diluted weighted average shares outstanding, Common stock		6,257,127	5,156	6,262,283
Basic and diluted net income per share, Common Stock		0.03	0.64	0.67
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		As Previously Reported		Adjustments		As Restated
Statement of Operations for the nine months ended September 30, 2020 (unaudited)						
Net income	\$	2,479,203	\$	4,410,250	\$	6,889,453
Basic and diluted weighted average shares outstanding, Common stock subject to		, ,		, , , , ,		- , ,
possible redemption		—		5,275,764		5,275,764
Basic and diluted net income (loss) per share, Common stock subject to possible						
redemption		—		0.00		0.00
Basic and diluted weighted average shares outstanding, Common stock		6,411,797		363,846		6,775,643
Basic and diluted net income per share, Common Stock		0.39		0.63		1.02
Statement of Operations for the year ended December 31, 2020 (audited)						
Net income	\$	2,404,519	\$	1,906,250	\$	4,310,769
Basic and diluted weighted average shares outstanding, Common stock subject to		, , ,		···· · · · ·		<i>yy</i>
possible redemption		4,457,537		(507,921)		3,949,616
Basic and diluted net income (loss) per share, Common stock subject to possible						
redemption		0.00		—		0.00
Basic and diluted weighted average shares outstanding, Common stock		6,367,631		275,128		6,642,759
Basic and diluted net loss per share, Common Stock		0.38		0.27		0.65
Cash Flow Statement for the period from September 11, 2017 (inception) to						
December 31, 2017 (audited)						
Net loss	\$	(31,193)	\$	(1,092,000)	\$	(1,123,193)
Initial classification of warrant liability		—		4,572,750		4,572,750
Change in fair value of warrant liability		_		1,092,000		1,092,000
Initial classification of common stock subject to redemption		190,296,100		(4,572,750)		185,723,350
Change in value of common stock subject to redemption		(26,029)		(1,092,000)		(1,118,029)
Cash Flow Statement for the three months ended March 31, 2018						
(unaudited)						
Net income	\$	406.066	\$	341,250	\$	747,316
Change in fair value of warrant liability				(341,250)		(341,250)
Change in value of common stock subject to redemption						
		406,066		341,250		747,316
Cash Flow Statement for the six months ended June 30, 2018 (unaudited)						
Net income	\$	821,176	\$	68,250	\$	889,426
Change in fair value of warrant liability	Ŷ		Ψ	(68,250)	φ	(68,250)
Change in value of common stock subject to redemption		821,176		68,250		889,426
Cash Flow Statement for the nine months ended September 30, 2018						
(unaudited)	¢	1 200 025	¢	(1.(20.000)	¢	(000,175)
Net income (loss)	\$	1,398,825	\$	(1,638,000) 1,638,000	\$	(239,175)
Change in fair value of warrant liability Change in value of common stock subject to redemption		1,398,825		(1,638,000)		1,638,000 (239,175)
Change in value of common stock subject to redemption		1,590,025		(1,038,000)		(239,175)
Cash Flow Statement for the year ended December 31, 2018 (audited)						
Net income	\$	2,122,033	\$	(68,250)	\$	2,053,783
Change in fair value of warrant liability		_		68,250		68,250
Change in value of common stock subject to redemption		2,122,033		(68,250)		2,053,783
Cash Flow Statement for the three months ended March 31, 2019						
(unaudited)						
Net income	\$	775,913	\$	341,250	\$	1,117,163
Change in fair value of warrant liability				(341,250)		(341,250)

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341,250

775,913

		As reviously ceported	A	djustments		As Restated
Cash Flow Statement for the six months ended June 30, 2019 (unaudited)			-			
Net income	\$	1,194,815	\$	341,250	\$	1,536,065
Change in fair value of warrant liability		—		(341,250)		(341,250)
Change in value of common stock subject to redemption		1,194,815		341,250		1,536,065
Cash Flow Statement for the nine months ended September 30, 2019 (unaudited)						
Net income (loss)	\$	1.684.538	\$	204,750	\$	1,889,288
Change in fair value of warrant liability	φ	1,004,550	φ	(204,750)	φ	(204,750)
Change in value of common stock subject to redemption		1,684,538		204,750		1,889,288
Change in value of common stock subject to redemption		1,084,338		204,730		1,009,200
Cash Flow Statement for the year ended December 31, 2019 (audited)	¢	265.054	¢	(1,422,250)	¢	(1.0(7.20)
Net income (loss)	\$	365,954	\$	(1,433,250)	\$	(1,067,296
Change in fair value of warrant liability		265.054		1,433,250		1,433,250
Change in value of common stock subject to redemption		365,954		(1,433,250)		(1,067,296
Cash Flow Statement for the three months ended March 31, 2020 (unaudited)						
	\$	(240.954)	¢	2 1 4 2 5 7 2	\$	1.792.718
Net (loss) income	\$	(349,854)	\$	2,142,572 (2,184,000)	Э	,,
Change in fair value of warrant liability		_				(2,184,000
Amortization of debt discount on convertible promissory note		—		31,428		31,428
Change in value of conversion option liability		—		10,000		10,000
Change in value of common stock subject to redemption		(349,857)		(4,191,379)		(4,541,236
Cash Flow Statement for the six months ended June 30, 2020 (unaudited)						
Net income	\$	2,260,380	\$	419,500	\$	2,679,880
Change in fair value of warrant liability		—		(419,500)		(419,500
Amortization of debt discount on convertible promissory note		—		220,000		220,000
Change in value of conversion option liability		—		(220,000)		(220,000
Change in value of common stock subject to redemption		3,260,378		(3,312,557)		(52,179
Issuance of warrants in connection with conversion of promissory note - related						
party		1,000,000		(1,000,000)		
Cash Flow Statement for the nine months ended September 30, 2020						
(unaudited)	<u>_</u>	0.470.000	<i>•</i>	4 410 250	۵	6 000 450
Net income	\$	2,479,203	\$	4,410,250	\$	6,889,453
Change in fair value of warrant liability		—		(4,410,250)		(4,410,250
Amortization of debt discount on convertible promissory note		_		220,000		220,000
Change in value of conversion option liability		2 470 100		(220,000)		(220,000
Change in value of common stock subject to redemption		3,479,198		(3,750,197)		(270,999
Issuance of warrants in connection with conversion of promissory note – related party		1,000,000		(1,000,000)		_
Cash Flow Statement for the year ended December 31, 2020 (audited)						
Net income	\$	2,404,519	\$	1,906,250	\$	4,310,769
Change in fair value of warrant liability	Ψ		Ψ	(1,906,250)	÷	(1,906,250
Amortization of debt discount on convertible promissory note		_		220,000		220,000
Change in value of conversion option liability				(220,000)		(220,000
Change in value of common stock subject to redemption		3,654,513		3,707,448		(52,935
Issuance of warrants in connection with conversion of promissory note – related		5,054,515		5,707,770		(52,755
party		1,000,000		(1,000,000)		_

# NOTE 3. — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### **Basis of Presentation**

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America (GAAP") and pursuant to the rules and regulations of the SEC.

# Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future events. Accordingly, the actual results could differ significantly from the Company's estimates.

# Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less, when purchased, to be cash equivalents. The Company did not have any cash equivalents as of December 31, 2020 and 2019.

#### Marketable Securities Held in Trust Account

At December 31, 2020 and 2019, the assets held in the Trust Account were substantially held in a money market fund that invests primarily in U.S. Treasury Bills. During the year ended December 31, 2020 and 2019, the Company withdrew \$326,352 and \$836,205 of interest income from the Trust Account to pay franchise and income taxes.

### Derivative Instruments

The Company accounts for debt and equity issuances as either equity-classified or liability-classified instruments based on an assessment of the instruments specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the instruments are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own common shares and whether the holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of issuance of the instruments and as of each subsequent quarterly period end date while the instruments are outstanding.

For issued or modified instruments that meet all of the criteria for equity classification, the instruments are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified instruments that do not meet all the criteria for equity classification, the instruments are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the instruments are recognized as a non-cash gain or loss on the statements of operations.

#### **Common Stock Subject to Possible Redemption**

The Company accounts for its common stock subject to possible redemption in accordance with the guidance in Accounting Standards Codification (*ASC*<sup>\*</sup>) Topic 480 "Distinguishing Liabilities from Equity." Common stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redemable common stock (including common stock that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, common stock is classified as stockholders' equity. The Company's common stock features certain redemption rights that are considered to be outside of the Company's control and subject to occurrence of uncertain future events. Accordingly, common stock subject to possible redemption is presented at redemption value as temporary equity, outside of the stockholders' equity section of the Company's balance sheets.

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#### Income Taxes

The Company complies with the accounting and reporting requirements of Accounting Standards Codification ("*ASC*") Topic 740 "Income Taxes," which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed for differences between the financial statement and tax bases of assets and liabilities that will result in future taxable or deductible amounts, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC Topic 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2020 and 2019. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position.

The Company may be subject to potential examination by federal, state and city taxing authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with federal, state and city tax laws. The Company's management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

# Net Income (Loss) Per Common Share

Net income (loss) per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, excluding shares of common stock subject to forfeiture. The Company has not considered the effect of the warrants sold in the Initial Public Offering and private placement to purchase an aggregate of 17,825,001 shares in the calculation of diluted loss per share, since the inclusion of such warrants would be anti-dilutive.

The Company's statement of operations includes a presentation of income (loss) per share for common shares subject to possible redemption in a manner similar to the two-class method of income (loss) per share. Net income (loss) per common share, basic and diluted, for Common stock subject to possible redemption is calculated by dividing the proportionate share of income or loss on marketable securities held by the Trust Account, net of applicable franchise and income taxes, by the weighted average number of Common stock subject to possible redemption outstanding since original issuance.

Net loss per share, basic and diluted, for non-redeemable common stock is calculated by dividing the net income (loss), adjusted for income or loss on marketable securities attributable to Common stock subject to possible redemption, by the weighted average number of non-redeemable common stock outstanding for the period.

Non-redeemable common stock includes Founder Shares and non-redeemable shares of common stock as these shares do not have any redemption features. Non-redeemable common stock participates in the income or loss on marketable securities based on non-redeemable shares' proportionate interest.

The following table reflects the calculation of basic and diluted net income (loss) per common share (in dollars, except per share amounts):

	For the year ended December 31,				
		2020		2019	
Common stock subject to possible redemption					
Numerator: Earnings attributable to Common stock subject to possible redemption					
Interest earned on marketable securities held in Trust Account	\$	_	\$	3,784,472	
Less: interest available to be withdrawn for payment of taxes				(672,550)	
Net income	\$	_	\$	3,111,922	
Denominator: Weighted Average Common stock subject to possible redemption					
Basic and diluted weighted average shares outstanding		3,949,616		18,270,950	
Basic and diluted net income per share	\$	0.00	\$	0.17	

Non-Redeemable Common Stock		
Numerator: Net Income (Loss) minus Net Earnings		
Net loss	\$ 4,310,769	\$ (1,067,296)
Less: Net income allocable to Common stock subject to possible redemption	 	 (3,239,823)
Non-Redeemable Net Income (Loss)	\$ 4,309,136	\$ (4,307,119)
Denominator: Weighted Average Non-Redeemable Common Stock		
Basic and diluted weighted average shares outstanding	6,642,759	6,621,293
Basic and diluted net income (loss) per share	\$ 0.65	\$ (0.63)

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#### **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentration of credit risk consist of a cash account in a financial institution, which, at times may exceed the federal depository insurance coverage of \$250,000. The Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

#### Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurement" ("ASC 820"), approximates the carrying amounts represented in the accompanying balance sheets, primarily due to their short-term nature, except for the Derivative Instruments (see Note 6 and 11).

#### **Recent Accounting Standards**

Management does not believe that any recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's financial statements.

#### NOTE 4. — INITIAL PUBLIC OFFERING

Pursuant to the Initial Public Offering, the Company sold20,000,000 Units at a purchase price of 10.00 per Unit. Each Unit consists of one share of common stock, and one-half of one warrant ("*Public Warrant*"). Each whole Public Warrant entitles the holder to purchase one share of common stock at an exercise price of 1.50 (see Note 8).

### NOTE 5. — PRIVATE PLACEMENT

Simultaneously with the closing of the Initial Public Offering, affiliates of the Hydra Sponsor and Matthews Lane Sponsor, HG Vora and certain members of management purchased an aggregate of 6,825,000 Private Placement Warrants at \$1.00 per Private Placement Warrant, for an aggregate purchase price of \$6,825,000. Each Private Placement Warrant entitles the holder to purchase one share of common stock at an exercise price of \$11.50. The proceeds from the Private Placement Warrants were added to the proceeds from the Initial Public Offering held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period, the proceeds of the sale of the Private Placement Warrants will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Warrants will expire worthless. There will be no redemption rights or liquidating distributions from the Trust Account with respect to the Private Placement Warrants.

The Private Placement Warrants are identical to the Public Warrants underlying the Units sold in the Initial Public Offering, except that the Private Placement Warrants and the common stock issuable upon the exercise of the Private Placement Warrants are not transferable, assignable or salable until 30 days after the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants and exercisable by such holders on the same basis as the Public Warrants.

#### NOTE 6. — RELATED PARTY TRANSACTIONS

### Founder Shares

On September 11, 2017, the Company issued an aggregate of 7,187,500 shares of common stock to the Initial Stockholders (*Founder Shares*") for an aggregate purchase price of \$25,000. On December 5, 2017, certain of the Initial Stockholders surrendered and returned to the Company, for nil consideration, an aggregate of 1,437,500 Founder Shares, which were cancelled, leaving an aggregate of 5,750,000 Founder Shares outstanding. The 5,750,000 Founder Shares included an aggregate of up to 750,000 shares subject to forfeiture by the Initial Stockholders to the extent that the underwriters' over-allotment was not exercised in full or in part, so that the Initial Stockholders would own 20% of the Company's issued and outstanding shares after the Initial Public Offering. The underwriters' election to exercise their over-allotment option expired unexercised on January 15, 2018 and, as a result, 750,000 Founder Shares were forfeited, resulting in 5,000,000 Founder Shares outstanding.

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The Initial Stockholders have agreed, subject to certain exceptions, not to transfer, assign or sell any of the Founder Shares until the earlier of(i) one year after the date of the completion of a Business Combination, or (ii) the date on which the last sales price of the Company's common stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days within any 30-trading day period commencing 150 days after a Business Combination, or earlier, in each case, if subsequent to a Business Combination, the Company completes a subsequent liquidation, merger, stock exchange, or other similar transaction which results in all of the Company's stockholders having the right to exchange their common stock for cash, securities or other property.

#### Administrative Services Agreement

The Company entered into an agreement whereby, commencing on December 1, 2017 through the earlier of the completion of a Business Combination or the Company's liquidation, the Company would pay Hydra Sponsor a monthly fee of up to \$10,000 for office space, utilities and secretarial and administrative support. For the year ended December 31, 2020 and 2019, the Company incurred \$60,000 and \$120,000, respectively, in fees for these services. Effective June 30, 2020, Hydra Sponsor agreed to stop charging the Company the monthly administrative fee and forgave the \$71,000 outstanding balance due.

# **Related Party Loans**

In order to fund working capital deficiencies or finance transaction costs in connection with a Business Combination, the Hydra Sponsor, an affiliate of the Matthews

Lane Sponsor and HG Vora (the "*Funding Parties*") loaned an aggregate of \$1,000,000 to the Company, in accordance with unsecured promissory notes issued on January 15, 2020 to the Funding Parties, pursuant to an expense advancement agreement dated December 1, 2017 which were subsequently converted by the holders into warrants on June 25, 2020. The expense advancement agreement was amended to increase the total amount of advances available to the Company under the agreement by an additional \$00,000, of which the Company drew down \$225,000 pursuant to promissory notes issued in October and November 2020 and \$75,000 remained available for drawdown as of December 31, 2020 which was drawn down on February 1, 2021. On February 23, 2021, the expense advancement agreement was further amended to increase the loan commitment amount by an additional \$160,000 which was drawn down on February 24, 2021 (see Note 12). The Funding Parties may, but are not obligated to, loan the Company additional funds from time to time or at any time, as may be required ("*Working Capital Loans*"). Under the expense advancement agreement, the Working Capital Loans would either be paid upon completion of a Business Combination, without interest, or, at the holder's discretion could be converted into warrants at a price of \$ 1.00 per warrant. The warrants would be identical to the Private Placement Warrants. In the event that a Business Combination does not close, the Company may use a portion of the proceeds held outside the Trust Account to repay the Working Capital Loans, but no proceeds held in the Trust Account would be used to repay the Working Capital Loans.

As of December 31, 2020, there was \$225,000 outstanding under the Working Capital Loans (the \$1,000,000 previously loaned by the Funding Parties having been converted into warrants on June 25, 2020). The outstanding amount was \$460,000 as of March 10, 2021 (see Note 12).

The Company assessed the provisions of the Working Capital Loans under ASC 815-15 (see Note 2). The derivative component of the obligation is initially valued and classified as a derivative liability with an offset to loss on conversion option liability. The conversion option was valued using a Modified Black Scholes Option Pricing Model, which is considered to be a Level 3 fair value measurement (see Note 11). The Modified Black Scholes Option Pricing Model's primary unobservable input utilized in determining the fair value of the conversion option is the probability of consummation of the Business Combination. The probability assigned to the consummation of the Business Combination was 85% which was determined based on the observed success rates of business combinations for special purpose acquisition companies. The Company's management evaluated the conversion option amounts outstanding as of December 31, 2020 and concluded that the amounts were immaterial.

The following table presents the change in the fair value of conversion option:

Fair value as of January 1, 2020	\$ —
Initial measurement	220,000
Change in fair value	10,000
Elimination of conversion option upon conversion of promissory note on June 25, 2020	(230,000)
Fair value as of December 31, 2020	\$ _
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### NOTE 7. — COMMITMENTS

### Forgiveness of Accounts Payable

During the year ended December 31, 2020, two of the Company's service providers forgave certain amounts due to them in connection with previously provided services. As a result, the Company recorded a forgiveness of accounts payable in the amount of \$3,298,207.

# GTWY Holdings Promissory Note

On December 5, 2019, the Company entered into the GTWY Expense Advancement Agreement, pursuant to which GTWY Holdings committed to provide \$566,288 to fund contributions to the Trust Account. The Company drew down the full amount under the GTWY Expense Advancement Agreement to fund the required Contribution to the Trust Account for the period December 6, 2019 to January 5, 2020 by issuing an unsecured promissory note that was non-interest bearing to GTWY Holdings (the "*Gateway Promissory Note*"). The Gateway Promissory Note provided for repayment out of the proceeds of the Trust Account released to the Company if the Company completes an initial Business Combination and, otherwise, out of funds held by the Company outside the Trust Account. At December 31, 2020, there was \$566,268 outstanding under the note. On January 31, 2021, the Company and GTWY Holdings entered into an amendment to the Gateway Promissory Note to permit conversion of the promissory note into warrants at a price of \$1.00 per warrant. In connection with such amendment, GTWY Holdings elected to convert the full principal balance of the Gateway Promissory Note into 566,288 warrants (see Note 10).

## **Registration Rights**

Pursuant to a registration rights agreement entered into on December 1, 2017, the holders of the Founder Shares, Private Placement Warrants (and their underlying securities), Private Placement Units (and their underlying securities) (as defined below) and any warrants that may be issued upon conversion of the Working Capital Loans (and their underlying securities) are entitled to registration rights. The holders of these securities are entitled to make up to two demands, excluding short form demands, that the Company register such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of a Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. However, the registration rights agreement provides that the Company will not permit any registration statement filed under the Securities Act to become effective until termination of the applicable lock-up period. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

#### **Underwriters** Agreement

The underwriters of the Initial Public Offering are entitled to a deferred fee of three and one-half percent §.5%) of the gross proceeds of the Initial Public Offering, or \$7,000,000. Up to \$0.05 per Unit (or up to \$1,000,000) of the deferred fee may be paid to third parties (who are members of FINRA) that assist the Company in consummating its initial Business Combination. The election to make such payments to third parties will be solely at the discretion of the Company's management team, and such third parties will be selected by the management team in their sole and absolute discretion. The deferred fee will be paid in cash upon the closing of a Business Combination from the amounts held in the Trust Account, subject to the terms of the underwriting agreement. On November 23, 2020, the underwriters agreed to waive \$250,000 of the deferred fee which had been held in the Trust Account and was to be paid upon consummation of the Business Combination, resulting in an aggregate of \$6,750,000 deferred underwriting statement of stockholders' equity.

### **Contingent Forward Purchase Contract**

On December 1, 2017, the strategic investor entered into a contingent forward purchase contract (the 'Contingent Forward Purchase Contract') with the Company to purchase, in a private placement for gross proceeds of \$62,500,000 to occur concurrently with the consummation of the Business Combination, 6,250,000 Units on substantially the same terms as the sale of Units in the Initial Public Offering at \$10.00 per Unit. In connection with previously proposed business combination transaction with GTWY Holdings, an amendment to the Contingent Forward Purchase Contract was effected on December 27, 2019 to provide that the Contingent Forward Purchase Contract would terminate as of, and contingent upon, the closing of the transaction with GTWY Holdings such that the strategic investor would instead purchase 3,000,000 units of GTWY Holdings' equity securities (with each unit consisting of one GTWY Holdings Share and one-half of one GTWY Holdings Warrant) for a purchase price of \$10.00 per unit. The Contingent Forward Purchase Contract was waived by the strategic investor in the connection with the proposed Business Combination with Ensysce.

### Service Provider Agreement

From time to time the Company has entered into and may enter into agreements with various services providers and advisors, including investment banks, to help us identify targets, negotiate terms of potential Business Combinations, consummate a Business Combination and/or provide other services. In connection with these agreements, the Company may be required to pay such service providers and advisors fees in connection with their services to the extent that certain conditions, including the closing of a potential Business Combination does not occur, the Company would not expect to be required to pay these contingent fees. There can be no assurance that the Company will complete a Business Combination.

# NOTE 8 — STOCKHOLDERS' EQUITY

**Preferred Stock** — The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.0001 per share with such designation, rights and preferences as may be determined from time to time by the Company's Board of Directors. As of December 31, 2020 and 2019, there were no shares of preferred stock issued or outstanding.

*Common Stock* — The Company is authorized to issue 100,000,000 shares of common stock with a par value of \$0.0001 per share. Holders of the Company's common stock are entitled to one vote for each share. The underwriters' election to exercise their over-allotment option expired unexercised on January 15, 2018 and, as a result,750,000 Founder Shares were forfeited. At December 31, 2020 and 2019, there were6,224,268 and 7,067,422 shares of common stock issued and outstanding, respectively, excluding0 and 16,808,829 shares of common stock subject to possible redemption, respectively.

*Warrants* — Public Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants will become exercisable on the later of (a) 30 days after the completion of a Business Combination and (b) 12 months from the closing of the Initial Public Offering; provided in each case that the Company has an effective registration statement under the Securities Act covering the shares of common stock issuable upon exercise of the Public Warrants and a current prospectus relating to them is available. The Company has agreed that as soon as practicable, but in no event later than 15 business days after the closing of a Business Combination, the Company will use its best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the Public Warrants. The Company will use its best efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the Public Warrants in accordance with the provisions of the warrant agreement. If any such registration statement has not been declared effective by the 60<sup>th</sup> business day following the closing of the Business Combination, holders of the Public Warrants shall have the right, during the period beginning on the 61<sup>st</sup> business day after the closing of the Business Combination and ending upon such registration statement being declared effective by the SEC, and during any other period when the Company shall fail to have maintained an effective registration statement covering the shares of common stock issuable upon exercise of a Public Warrants, to exercise such Public Warrants on a "cashless basis." Notwithstanding the above, if the Company's common stock issuable upon exercise of a Public Warrants, to exercise such Public Warrants to do so on a "cashless basis" in accordance with Section 18(

The Company may redeem the Public Warrants:

completion of a Business Combination or earlier upon redemption or liquidation.

- in whole and not in part;
- at a price of \$0.01 per warrant;
- at any time during the exercise period;
- upon a minimum of 30 days' prior written notice of redemption;
- if, and only if, the last sale price of the Company's common stock equals or exceeds \$18.00 per share for any 20 trading days within a 30-trading day period ending
  on the third business day prior to the date on which the Company sends the notice of redemption to the warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants.

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If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. If the Company is unable to complete a Business Combination within the Combination Period and the Company liquidates the funds held in the Trust Account, holders of warrants will not receive any of such funds with respect to their warrants, nor will they receive any distribution from the Company's assets held outside of the Trust Account with the respect to such warrants. Accordingly, the warrants may expire worthless.

# NOTE 9 — INCOME TAXES

The Company did not have any deferred tax assets or liabilities at December 31, 2020 and 2019.

The provision for income taxes consists of the following:

	Decembe	Year Ended December 31, 2020		2019
Federal:				
Current	\$	244,493	\$	556,964
Deferred				(1,764)
State and Local:				
Current		—		—
Deferred				
Change in valuation allowance				_
Income tax provision	\$	244,493	\$	555,200

As of December 31, 2020 and 2019, the Company did not have any of U.S. federal and state net operating loss carryovers available to offset future taxable income.

In assessing the realization of the deferred tax assets, management considers whether it is more likely than not that some portion of all of the deferred tax assets will not

be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all of the information available, management determined that a valuation allowance was not required for the years ended December 31, 2020 and 2019.

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	As of December	As of December 31, 2020			
	2020	2019			
Ototeta me Calena l'income tem mete	21.00/	21.00/			
Statutory federal income tax rate	21.0%	21.0%			
True-ups	(6.9)%	(1.2)%			
Change in fair value of warrant liability	(8.8)%	(58.8)%			
Business Combination expenses	0.0%	69.4%			
Income tax provision	5.3%	(108.4)%			
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For the year ended December 31, 2020, the effective tax rate differs from the statutory tax rate primarily due to the reversal of previously recorded permanent differences for transactional expenses incurred in connection with the now terminated GTWY Holdings acquisition, as well as permanent differences attributable to the change in the fair value of the warrants. For the year ended December 31, 2019, the effective tax rate differs from the statutory tax rate due to the permanent differences recorded for transactional expenses incurred with the GTWY Holdings acquisition.

The Company files income tax returns in the U.S. federal jurisdiction and is subject to examination by the various taxing authorities. The Company's tax returns for the year ended December 31, 2020 and 2019 remain open and subject to examination. The Company considers New York to be a significant state tax jurisdiction.

#### NOTE 10 — FAIR VALUE MEASUREMENTS

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually.

The fair value of the Company's financial assets and liabilities reflects management's estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

- Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs based on our assessment of the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis at December 31, 2020 and 2019, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	Level	D	ecember 31, 2020	 December 31, 2019
Assets:				
Marketable securities held in Trust Account	1	\$	12,628,170	\$ 195,312,177
Liabilities:				
Warrant Liability – Private Warrants	3		6,260,000	7,166,250

The Private Warrants are accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities on the accompanying balance sheets. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within change in fair value of warrant liabilities in the statements of operations.

The Private Warrants were valued using a Modified Black Scholes Option Pricing Model, which is considered to be a Level 3 fair value measurement. The Modified Black Scholes model's primary unobservable input utilized in determining the fair value of the Private Placement Warrants is the probability of consummation of the Business Combination. The probability assigned to the consummation of the Business Combination was determined based on the observed success rates of business combinations for special purpose acquisition companies.

The key inputs into the Black Scholes Option Pricing Model for the Private Warrants were as follows:

Input	Dec	cember 31, 2020	December 31, 2019
Risk-free interest rate		0.36%	 1.69%
Expected Term (years)		5.0	5.0
Probability of Business Combination		30.0%	90.0%
Expected volatility		19.7%	13.5%
Exercise price	\$	11.50	\$ 11.50
Stock Price	\$	12.43	\$ 10.42
Annual dividend yield		0.00%	0.00%

The following table presents the changes in the fair value of warrant liabilities:

	Private Placement
Fair value as of December 31, 2018	
	5,733,000

1,433,250
7,166,250
(906,250)
\$ 6,260,000
\$

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# NOTE 11. — SUBSEQUENT EVENTS

The Company evaluates subsequent events and transactions that occur after the balance sheet date up to the date that the financial statements were issued. Based upon this review, other than as described below and as described in Note 2, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

On January 27, 2021, the Panel granted the Company's request for continued listing of the Company's equity securities on the Nasdaq Capital Market pursuant to an extension, subject to certain milestones, through June 1, 2021 so that the Company may seek to complete an initial business combination and regain compliance with the listing rules. If the Company does not regain compliance with the Rule by the required date, Nasdaq would delist the Company's equity securities from the Nasdaq Capital Market.

On January 31, 2021, the Company entered into an Agreement and Plan of Merger (the 'Merger Agreement'), by and among the Company, Ensysce, and EB Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub"), relating to a proposed business combination transaction between the Company and Ensysce.

Pursuant to the Merger Agreement, Merger Sub will merge with and into Ensysce, with Ensysce surviving such merger as a wholly owned subsidiary of the Company and the stockholders of Ensysce becoming stockholders of the Company (the "Merger").

Ensysce's issued and outstanding share capital as of immediately prior to the Merger Effective Time will, at the closing (the '*Closing*'') of the transactions contemplated by the Merger Agreement (collectively, the "*Transaction*"), be canceled and converted into the right to receive the Company's common stock, par value \$0.0001 per share (the "*LACQ Common Stock*") calculated based on an exchange ratio of 0.06585 (the "*Exchange Ratio*").

The Transaction will be consummated subject to the deliverables and provisions as further described in the Merger Agreement.

On January 31, 2021, the underwriters of the Company's initial public offering agreed to reduce the total deferred underwriting fee that is to be paid to such underwriters upon the consummation of the Company's initial business combination to \$2,000,000, which may under certain situations be payable in the form of LACQ Common Stock.

On January 31, 2021, the Company and GTWY Holdings entered into an amendment to the Gateway Promissory Note to permit conversion of all or a portion of the promissory note into warrants at a price of \$1.00 per warrant. In connection with such amendment, GTWY Holdings elected to convert the full principal balance of the Gateway Promissory Note into 566,288 warrants.

On February 23, 2021, the Company entered into a fourth amendment to the Company's Expense Advancement Agreement with its sponsors and strategic investor to increase the total amount of advances available to the Company under the agreement by \$160,000. The promissory notes covering the prior loan balance in the aggregate amount of \$300,000 was amended and restated on February 24, 2021 in order to reflect the incremental increase of the total amount of advances available to the Company thereunder to \$460,000 and all of which increase was drawn on February 24, 2021.

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# LEISURE ACQUISITION CORP. CONDENSED CONSOLIDATED BALANCE SHEETS

	arch 31, 2021 Unaudited)	December 31, 2020		
ASSETS				
Current Assets				
Cash	\$ 18,034	\$	49,202	
Prepaid expenses	190,400		157,483	
Prepaid income taxes	 19,779		19,779	
Total Current Assets	228,213		226,464	
Deferred tax asset	61,278		—	
Cash and marketable securities held in Trust Account	 12,690,899		12,628,170	
TOTAL ASSETS	\$ 12,980,390	\$	12,854,634	
	 <u>, , , , , , , , , , , , , , , , </u>		<u>, , , , , , , , , , , , , , , ,</u>	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current Liabilities				
Accounts payable and accrued expenses	\$ 319,180	\$	260,404	
Total Current Liabilities	319,180		260,404	
	,			
Promissory note	_		566,288	
Convertible promissory notes - related party	460,000		225,000	
Warrant liability	8,307,375		6,260,000	
Deferred underwriting fee payable	2,000,000		6,750,000	
Total Liabilities	11,086,555		14,061,692	
Commitments				

#### Stockholders' Equity (Deficit)

Preferred stock, \$0.0001 par value; 1,000,000 authorized; none issued and outstanding Common stock, \$0.0001 par value; 100,000,000 shares authorized; 6,224,268 shares issued and outstanding

Additional paid-in capital	4,812,500	_
Accumulated deficit	(2,919,287)	(1,207,680)
Total Stockholders' Equity (Deficit)	1,893,835	(1,207,058)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 12,980,390	\$ 12,854,634

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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# LEISURE ACQUISITION CORP. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended March 31,				
		2021		2020	
Operating costs	\$	292,027	\$	915,183	
Loss from operations		(292,027)		(915,183)	
Other income (expense):					
Interest earned on marketable securities held in Trust Account		229		639,954	
Interest expense		_		(31,428)	
Change in fair value of conversion liability		_		(10,000)	
Change in fair value of warrant liability		(1,481,087)		2,184,000	
Other (expense) income, net		(1,480,858)		2,782,526	
(Loss) income before provision for income taxes		(1,772,885)		1,867,343	
Benefit from (provision for) income taxes		61,278		(74,625)	
Net (loss) income	\$	(1,711,607)	\$	1,792,718	
Basic and diluted weighted average shares outstanding, Common stock subject to possible redemption				15,885,267	
Basic and diluted net loss per share, Common stock subject to possible redemption	\$		\$	0.00	
Basic and diluted weighted average shares outstanding, Non-redeemable common stock		6,224,268		6,375,178	
Basic and diluted net loss per share, Non-redeemable common stock	\$	(0.27)	\$	0.28	

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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# LEISURE ACQUISITION CORP. CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

# THREE MONTHS ENDED MARCH 31, 2021

	Commo	on Stoc	k		ditional aid in	Ac	cumulated	5	Total Stockholders'
	Shares		Amount	0	Capital		Deficit		Equity
Balance – January 1, 2021	6,224,268	\$	622	\$		\$	(1,207,680)	\$	(1,207,058)
Waiver of a portion of deferred underwriting fee	—				4,750,000		—		4,750,000
Amounts returned to Trust Account for excess redemptions									
previously withdrawn	—		—		62,500		_		62,500
Net income							(1,711,607)		(1,711,607)
Balance – March 31, 2021	6,224,268	\$	622	\$	4,812,500	\$	(2,919,287)	\$	1,893,835

# THREE MONTHS ENDED MARCH 31, 2020

	Commo		Common Stock			F	Retained Earnings/ ccumulated	S	Total tockholders'
	Shares	Α	mount		Capital		Deficit)		Equity
Balance – January 1, 2020	7,067,422	\$	707	\$	5,136,000	\$	(136,706)	\$	5,000,001
Change in value of common stock subject to possible redemption	(28,849)		4		(2,275,153)		—		(2,275,157)
Net income			_		_		1,792,718		1,792,718
Balance – March 31, 2020	7,038,573	\$	703	\$	2,860,847	\$	1,656,012	\$	4,517,562

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

#### LEISURE ACQUISITION CORP. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Three Months Ended March 31,					
		2021		2020		
Cash Flows from Operating Activities:						
Net (loss) income	\$	(1,711,607)	\$	1,792,718		
Adjustments to reconcile net (loss) income to net cash used in operating activities:						
Interest earned on marketable securities held in Trust Account		(229)		(639,954)		
Change in fair value of warrant liability		1,481,087		(2,184,000)		
Deferred tax benefit		(61,278)		_		
Amortization of debt discount on convertible promissory note		—		31,428		
Change in fair value of conversion option liability		_		10,000		
Changes in operating assets and liabilities:						
Prepaid expenses		(32,917)		(42,375)		
Prepaid income taxes		—		74,625		
Accounts payable and accrued expenses		58,776		723,170		
Net cash used in operating activities		(266,168)		(234,388)		
Cash Flows from Investing Activities:						
Investment of cash in Trust Account		(62,500)		(1,698,862)		
Cash withdrawn from Trust Account for redemption of common stock		—		136,283,492		
Cash withdrawn from Trust Account for franchise taxes and income taxes				40,050		
Net cash (used in) provided by investing activities		(62,500)		134,624,680		
Cash Flows from Financing Activities:						
Proceeds from convertible promissory notes – related parties		235,000		1,000,000		
Redemption of common stock		—		(136,283,492)		
Amounts returned to Trust Account for excess redemptions previously withdrawn		62,500		_		
Net cash provided by (used in) financing activities		297,500		(135,283,492)		
Net Change in Cash		(31,168)		(893,200)		
Cash – Beginning		49,202		1,061,151		
Cash – Ending	\$	18,034	\$	167,951		
New Cook immediate and Group interactivities.						
Non-Cash investing and financing activities: Issuance of warrants in connection with conversion of promissory note	¢	5// 000	¢			
1 5	\$	566,288	\$			
Waiver of a portion of deferred underwriting fee payable	\$	4,750,000	\$			
Change in value of common stock subject to possible redemption	\$	_	\$	(349,857)		
Due to stockholders for redemption of common stock	\$			40,000,000		

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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#### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

#### 1. DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Leisure Acquisition Corp. (the "Company") is a blank check company incorporated in Delaware on September 11, 2017. The Company was formed for the purpose of acquiring, through a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, recapitalization, exchangeable share transaction or other similar business transaction, with one or more operating businesses or assets (a "Business Combination").

The Company has one subsidiary, EB Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company (see Note 6).

At March 31, 2021, the Company had not yet commenced operations. All activity through March 31, 2021 relates to the Company's formation, its initial public offering ("*Initial Public Offering*"), which is described below, identifying a target company for a Business Combination, activities in connection with the previously proposed business combination with GTWY Holdings Limited, a Canadian corporation ("*GTWY Holdings*"), which was terminated on July 16, 2020 and activities in connection with the proposed business combination with Ensysce Biosciences, Inc. ("*Ensysce*"), which is described in Note 6.

The registration statement for the Company's Initial Public Offering was declared effective on December 1, 2017. On December 5, 2017, the Company consummated the Initial Public Offering of 20,000,000 units ("Units" and, with respect to the common stock included in the Units, the 'Public Shares''), generating gross proceeds of \$200,000,000, which is described in Note 3.

Simultaneously with the closing of the Initial Public Offering, the Company consummated the sale of 6,825,000 warrants (the "*Private Placement Warrants*") at a price of \$1.00 per warrant in a private placement to Hydra LAC, LLC, an affiliate of Hydra Management, LLC (the *Hydra Sponsor*"), MLCP GLL Funding LLC, an affiliate of Matthews Lane Capital Partners, LLC (the "*Matthews Lane Sponsor*," and, together with the Hydra Sponsor, the "*Sponsors*"), HG Vora Special Opportunities Master Fund, Ltd. ("*HG Vora*") and certain members of the Company's management team, generating gross proceeds of \$6,825,000, which is described in Note 4.

Following the closing of the Initial Public Offering on December 5, 2017, an amount of \$200,000,000 (\$10.00 per Unit) from the net proceeds of the sale of the Units in the Initial Public Offering and the Private Placement Warrants was placed in a trust account (the "*Trust Account*") and invested in U.S. government securities, within the meaning set forth in Section 2(a)(16) of the Investment Company Act of 1940, as amended (the "*Investment Company Act*"), with a maturity of 180 days or less or in any open-

ended investment company that holds itself out as a money market fund selected by the Company meeting the conditions of Rule 2a-7 of the Investment Company Act, as determined by the Company, until the earlier of: (i) the consummation of a Business Combination or (ii) the distribution of the Trust Account, as described below.

Transaction costs amounted to \$11,548,735, consisting of \$4,000,000 of underwriting fees, \$7,000,000 of deferred underwriting fees and \$548,735 of Initial Public Offering costs.

The Company's management has broad discretion with respect to the specific application of the net proceeds of the Initial Public Offering and Private Placement Warrants, although substantially all of the net proceeds are intended to be applied generally toward consummating a Business Combination. The Company's initial Business Combination must be with one or more target businesses that together have a fair market value equal to at least 80% of the balance in the Trust Account (excluding deferred underwriting commissions and franchise and income taxes payable on the income earned on the Trust Account) at the time of the signing of an agreement to enter into a Business Combination. The Company will only complete a Business Combination if the post-Business Combination company owns or acquires 50% or more of the outstanding voting securities of the target or otherwise acquires a controlling interest in the target sufficient for it not to be required to register as an investment company under the Investment Company Act. There is no assurance that the Company will be able to successfully effect a Business Combination.

The Company will provide its stockholders with the opportunity to redeem all or a portion of their Public Shares upon the completion of a Business Combination either (i) in connection with a stockholder meeting called to approve the Business Combination or (ii) by means of a tender offer. The decision as to whether the Company will seek stockholder approval of a Business Combination or conduct a tender offer will be made by the Company, solely in its discretion. The stockholders will be entitled to redeem their shares for a pro rata portion of the amount then on deposit in the Trust Account (\$10.00 per share, plus any deposits made to the Trust Account in connection with extension payments and any pro rata interest earned on the funds held in the Trust Account and not previously released to the Company to pay franchise and income taxes). The per share amount to be distributed to stockholders who redeem their shares will not be reduced by the deferred underwriting commissions the Company will pay to the underwriters (see Note 6).

The Company will proceed with a Business Combination if the Company has net tangible assets of at least \$,000,001 upon consummation of a Business Combination and, if the Company seeks stockholder approval, a majority of the outstanding shares voted are voted in favor of the Business Combination. If a stockholder vote is not required by law and the Company does not decide to hold a stockholder vote for business or other legal reasons, the Company will, pursuant to its Second Amended and Restated Certificate of Incorporation, conduct the redemptions pursuant to the tender offer rules of the Securities and Exchange Commission ("SEC"), and file tender offer documents with the SEC prior to completing a Business Combination. If, however, a stockholder approval of the transaction is required by law, or the Company decides to obtain stockholder approval for business or other legal reasons, the Company will offer to redeem shares in conjunction with a proxy solicitation pursuant to the proxy rules and not pursuant to the tender offer rules. If the Company seeks stockholder approval in connection with a Business Combination, the Sponsors and the Company's other initial stockholders (collectively, the "*Initial Stockholders*") have agreed to vote their Founder Shares (as defined in Note 5) and any Public Shares held by them in favor of approving a Business Combination. Additionally, each public stockholder may elect to redeem their Public Shares irrespective of whether they vote for or against the proposed transaction.

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### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

Notwithstanding the foregoing, the Company's Second Amended and Restated Certificate of Incorporation provides that a public stockholder, together with any affiliate of such stockholder or any other person with whom such stockholder is acting in concert or as a "group" (as defined under Section 13 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")), will be restricted from redeeming its shares with respect to an aggregate of 20% or more of the common stock sold in the Initial Public Offering.

The Company has until June 30, 2021 to consummate a Business Combination (the 'Combination Period'). If the Company is unable to complete a Business Combination within the Combination Period, the Company will (i) cease all operations except for the purpose of winding up, (ii) as promptly as reasonably possible but no more than ten business days thereafter, redeem 100% of the outstanding Public Shares, at a per-share price, payable in cash, equal to the aggregate amount then on deposit in the Trust Account, including interest earned and not previously released to pay franchise and income taxes (less up to \$75,000 of interest to pay dissolution expenses), divided by the number of then outstanding Public Shares, which redemption will completely extinguish public stockholders' rights as stockholders (including the right to receive further liquidation distributions, if any), subject to applicable law, and (iii) as promptly as reasonably possible following such redemption, subject to the approval of the remaining stockholders and the Company's board of directors, proceed to commence a voluntary liquidation and thereby a formal dissolution of the Company, subject in each case to its obligations to provide for claims of creditors and the requirements of applicable law. The underwriters have agreed to waive their rights to the deferred underwriting will be included with the funds held in the Trust Account that will be available to fund the redemption of the Company's Public Shares. In the event, such amounts will be included with the per share value of the assets remaining available for distribution (including Trust Account assets) will be less than the \$10.00 per Unit in the Initial Public Offering.

On November 26, 2019, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from December 5, 2019 to April 5, 2020 (the "*Initial Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of \$11,583,473 (or approximately \$10.31 per share) was released from the Company's Trust Account to pay such stockholders.

The Company agreed to contribute (the "*Contribution*") \$0.03 for each share of the Company's common stock that was not redeemed in connection with the extension for each of the four monthly periods covered by the extension (commencing on December 6, 2019 through the Initial Extension Date), subject to certain conditions.

On each of December 5, 2019, January 3, 2020, February 4, 2020 and March 4, 2020, the Company made a Contribution of \$0.03 for each of the Public Shares outstanding, for an aggregate Contribution of \$2,265,151, which amounts were deposited into the Trust Account.

On December 5, 2019, the Company entered into an expense advancement agreement with GTWY Holdings (the 'GTWY Expense Advance Agreement'), pursuant to which GTWY Holdings committed to provide \$566,288 to fund contributions to the Trust Account. The Company drew down the full amount under the GTWY Expense Advance Agreement to fund the required Contribution to the Trust Account for the period December 6, 2019 to January 5, 2020 by issuing an unsecured promissory note to GTWY Holdings. The note was converted into warrants on January 31, 2021 (see Note 6).

On January 15, 2020, the Company drew down \$1,000,000 under the expense advancement agreement with the Company's Sponsors and strategic investor dated December 1, 2017 in exchange for issuing unsecured promissory notes to fund its working capital requirements and to fund required Contributions to the Trust Account. The holders had the option to convert the promissory notes into warrants at a price of \$1.00 per warrant subject to the same terms and conditions as private placement warrants. The notes were converted into warrants on June 25, 2020 (see Note 5).

On March 26, 2020, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from April 5, 2020 to June 30, 2020 (the "*Second Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of 16,837,678 shares of the Company's common stock. As a result, an aggregate of \$176,283,492 (or approximately \$10.47 per share) was released from the Company's Trust Account to pay such stockholders. Of the amount paid to redeeming stockholders, \$136,283,492 was paid as of March 31, 2020 and the balance of \$40,000,000 was paid on April 1, 2020.

On June 26, 2020, the Company held a special meeting pursuant to which the Company's stockholders approved extending the Combination Period from June 30, 2020 to December 1, 2020 (the *"Third Extension Date"*). In connection with the approval of the extension, stockholders elected to redeem an aggregate of 776,290 shares of the Company's common stock. As a result, an aggregate of \$8,099,292 (or approximately \$10.43 per share) was released from the Company's Trust Account to pay such stockholders.

### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

On November 24, 2020, the Company's stockholders approved extending the Combination Period from December 1, 2020 to June 30, 2021 (the *Fourth Extension Date*"). In connection with the approval of the extension, stockholders elected to redeem an aggregate of \$393,380 (or approximately \$10.34 per share) was released from the Company's Trust Account to pay such stockholders.

The Initial Stockholders have agreed to (i) waive their redemption rights with respect to their Founder Shares in connection with the completion of a Business Combination, (ii) to waive their rights to liquidating distributions from the Trust Account with respect to their Founder Shares if the Company fails to complete a Business Combination within the Combination Period and (iii) not to propose an amendment to the Company's Second Amended and Restated Certificate of Incorporation that would affect the substance or timing of the Company's obligation to redeem 100% of its Public Shares if the Company does not complete a Business Combination, unless the Company provides the public stockholders with the opportunity to redeem their shares in conjunction with any such amendment.

In order to protect the amounts held in the Trust Account, the Sponsors have agreed to be liable to the Company if and to the extent any claims by a vendor for services rendered or products sold to the Company, or a prospective target business with which the Company has discussed entering into a transaction agreement, reduce the amount of funds in the Trust Account to below the lesser of (i) \$10.00 per Public Share or (ii) such lesser amount per share held in the Trust Account as of the date of the liquidation of the Trust Account due to reductions in the value of the trust assets. This liability will not apply with respect to any claims by a third party who executed a waiver of any right, title, interest or claim of any kind in or to any monies held in the Trust Account or to any claims under the Company's indemnity of the underwriters of the Initial Public Offering against certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "*Securities Act*"). Moreover, in the event that an executed waiver is deemed to be unenforceable against a third party, the Sponsors will not be responsible to the extent of any liability for such third-party claims. The Company will seek to reduce the possibility that the Sponsors will have to indemnify the Trust Account due to claims of creditors by endeavoring to have all vendors, service providers, prospective target businesses or other entities with which the Company does business, execute agreements with the Company waiving any right, title, interest or claim of any kind in or to monies held in the Trust Account.

# Nasdaq Notifications

On November 30, 2020, the Company received a notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC stating that the Company was not in compliance with Listing Rule IM-5101-2 (the "*Rule*"), which requires that a special purpose acquisition company complete one or more business combinations within 36 months of the effectiveness of the registration statement filed in connection with its initial public offering. Since the Company's registration statement became effective on December 1, 2017, it was required to complete an initial business combination by no later than December 1, 2020. The Rule also provides that failure to comply with this requirement will result in the Listing Qualifications Department issuing a Staff Delisting Determination under Rule 5810 to delist the Company's securities. In addition, the Nasdaq Notice states that the Company was not in compliance with Nasdaq's minimum publicly held shares requirement under Listing Rule 5550(a)(4), which requires a listed company's primary equity security to maintain a minimum of 500,000 publicly held shares.

The Listing Qualifications Department advised the Company that its securities would be subject to delisting unless the Company timely requested a hearing before an independent Hearings Panel (the "*Panel*"). Following a hearing before the Panel, the Panel granted the Company an extension, through June 1, 2021, to complete an initial business combination and thereby evidence compliance with all criteria for initial listing on Nasdaq. The notice stated that June 1, 2021 constituted the full extent of the Panel's discretion in this matter.

The Company continues to work towards completion of the proposed business combination with Ensysce; however, the merger has not yet been consummated. As a result, on June 1, 2021, Nasdaq notified the Company that trading in the Company's securities on Nasdaq would be suspended effective with the open of the market on June 3, 2021 (the *"Suspension Notice"*). The Company's securities became eligible to trade on the OTC Markets system beginning on June 3, 2021. Although trading, if any, will occur in the over-the-counter market beginning June 3, 2021, the Company will remain technically listed on Nasdaq pending the expiration of all Nasdaq review and appeal processes. The Company believes completion of the merger will enable it to evidence Nasdaq listing compliance by June 30, 2021; however, there can be no assurance that the Company's proposed merger with Ensysce will be completed or that the Company's securities will trade on Nasdaq upon completion of the merger.

In addition, and prior to the issuance of Suspension Notice, on May 25, 2021, the Company received formal notice from the Staff indicating that the Company's failure to timely file its Form 10-Q with the SEC, as required by Nasdaq Listing Rule 5250(c)(1) (the "*Filing Requirement*"), could serve as a separate basis for suspension and delisting of the Company's securities from Nasdaq. The Company was granted the opportunity to submit a plan to regain compliance with the Filing Requirement for the Panel's review by no later than June 1, 2021 and, notwithstanding the Suspension Notice, submitted that plan and filed the Form 10-Q in accordance with that plan.

The Company was unable to complete the merger with Ensysce or to timely file the Form 10-Q with the SEC due to the additional time required by the Company to determine and otherwise address the appropriate accounting treatment for the Company's warrants, as a result of the SEC statement released on April 12, 2021, entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "SEC Statement"). The SEC Statement provided guidance to all SPAC-related companies regarding the appropriate accounting for and reporting of warrants in their financial statements.

See "Risk Factors — If the Nasdaq delists our Common Stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, this could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions."

### **Risks and Uncertainties**

Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's financial position, results of its operations and/or search for a target company, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Liquidity and Going Concern

As of March 31, 2021, the Company had \$18,034 in its operating bank accounts, \$12,690,899 in securities held in the Trust Account to be used for a Business Combination or to repurchase or redeem its common stock in connection therewith and working capital deficit of \$163,896, which excludes \$72,929 of prepaid income and franchise taxes.

As of March 31, 2021, the Company there was no remaining amounts available for drawdown under the Company's expense advancement agreement with the Company's Sponsors and HG Vora (see "*Related Party Loans*" in Note 5).

The Company will need to raise additional capital through loans or additional investments from its Sponsors, HG Vora, stockholders, officers, directors, or third parties. The Company's Sponsors and HG Vora may, but are not obligated to, loan the Company funds, from time to time or at any time, in whatever amount they deem reasonable in their sole discretion, to meet the Company's working capital needs. Accordingly, the Company may not be able to obtain additional financing. If the Company is unable to raise additional capital, it may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations, suspending the pursuit of a potential transaction, and reducing overhead expenses. The Company cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all. These conditions raise substantial doubt about the Company's ability to continue as a going concern through June 30, 2021, the date that the Company will be required to cease all operations, except for the purpose of winding up, if a Business Combination is not consummated. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X of the SEC. Certain information or footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a comprehensive presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K/A for the year ended December 31, 2020, as filed with the SEC on June 7, 2021, which contains the audited financial statements and notes thereto. The interim results for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any future interim periods.

# **Emerging Growth Company**

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "*JOBS Act*"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company, which is neither an emerging growth company nor an emerging growth company and which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

### **Principles of Consolidation**

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

# Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future events. Accordingly, the actual results could differ significantly from the Company's estimates.

### **Cash and Cash Equivalents**

The Company considers all short-term investments with an original maturity of three months or less, when purchased, to be cash equivalents. The Company did not have any cash equivalents as of March 31, 2021 and December 31, 2020.

#### Marketable Securities Held in Trust Account

At March 31, 2021 and December 31, 2020, the assets held in the Trust Account were substantially held in a money market fund that invests primarily in U.S. Treasury Bills. During the three months ended March 31, 2021, the Company did not make any withdrawals of interest income from the Trust Account.

### **Derivative Instruments**

The Company accounts for debt and equity issuances as either equity-classified or liability-classified instruments based on an assessment of the instruments specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("*FASB*") Accounting Standards Codification ("*ASC*") 480, Distinguishing Liabilities from Equity ("*ASC 480*") and ASC 815, Derivatives and Hedging ("*ASC 815*"). The assessment considers whether the instruments are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own common shares and whether the holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time

of issuance of the instruments and as of each subsequent quarterly period end date while the instruments are outstanding.

For issued or modified instruments that meet all of the criteria for equity classification, the instruments are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified instruments that do not meet all the criteria for equity classification, the instruments are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the instruments are recognized as a non-cash change in the fair value of warrant liability on the condensed consolidated statements of operations.

#### **Income Taxes**

The Company complies with the accounting and reporting requirements of Accounting Standards Codification ("*ASC*") Topic 740 "Income Taxes," which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed for differences between the financial statement and tax bases of assets and liabilities that will result in future taxable or deductible amounts, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

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### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

ASC Topic 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of March 31, 2021 and December 31, 2020. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The effective tax rate of 3% and 4% differs from the statutory tax rate of21% for the three months ended March 31, 2021 and 2021 primarily due to the effect of the permanent differences attributable to the change in the fair value of the warrants.

The Company may be subject to potential examination by federal, state and city taxing authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with federal, state and city tax laws. The Company's management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

#### Net Loss Per Common Share

Net income (loss) per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, excluding shares of common stock subject to forfeiture. The Company has not considered the effect of the warrants sold in the Initial Public Offering and private placement to purchase an aggregate of 18,391,289 shares in the calculation of diluted loss per share, since the inclusion of such warrants would be anti-dilutive.

The Company's statement of operations includes a presentation of income (loss) per share for common shares subject to possible redemption in a manner similar to the two-class method of income (loss) per share. Net income (loss) per common share, basic and diluted, for Common stock subject to possible redemption is calculated by dividing the proportionate share of income or loss on marketable securities held by the Trust Account, net of applicable franchise and income taxes, by the weighted average number of Common stock subject to possible redemption outstanding since original issuance.

Net loss per share, basic and diluted, for non-redeemable common stock is calculated by dividing the net income (loss), adjusted for income or loss on marketable securities attributable to Common stock subject to possible redemption, by the weighted average number of non-redeemable common stock outstanding for the period.

Non-redeemable common stock includes Founder Shares and non-redeemable shares of common stock as these shares do not have any redemption features. Non-redeemable common stock participates in the income or loss on marketable securities based on non-redeemable shares' proportionate interest.

The following table reflects the calculation of basic and diluted net income (loss) per common share (in dollars, except per share amounts):

	For three months ended March 31,				
		2021	_	2020	
Common stock subject to possible redemption					
Numerator: Earnings attributable to Common stock subject to possible redemption					
Interest earned on marketable securities held in Trust Account	\$	—	\$	—	
Less: interest available to be withdrawn for payment of taxes					
Net income	\$	_	\$	_	
Denominator: Weighted Average Common stock subject to possible redemption					
Basic and diluted weighted average shares outstanding		_		15,885,267	
Basic and diluted net income per share	\$	_	\$	0.00	
Non-Redeemable Common Stock					
Numerator: Net (Loss) Income minus Net Earnings					
Net (loss) income	\$	(1,711,607)	\$	1,792,718	
Less: Net income attributable to Common stock subject to possible redemption		_			
Non-redeemable net (loss) income	\$	(1,711,607)	\$	1,792,718	
Denominator: Weighted Average Non-redeemable common stock					
Basic and diluted weighted average shares outstanding		6,224,268		6,375,178	
Basic and diluted net (loss) income per share	\$	(0.27)	\$	0.28	
		· · · · · ·			

LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited) Financial instruments that potentially subject the Company to concentration of credit risk consist of a cash account in a financial institution, which, at times may exceed the federal depository insurance coverage of \$250,000. The Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

### Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurement" ("ASC 820"), approximates the carrying amounts represented in the accompanying condensed consolidated balance sheets, primarily due to their short-term nature, except for the Private Placement Warrants, the working capital warrants issued on conversion of its convertible promissory note and the warrants issued on conversion of the amounts outstanding under the Gateway Promissory Note (*collectively, the "Private Warrants*").

# **Recent Accounting Standards**

In August 2020, the Financial Accounting Standards Board ("*FASB*") issued Accounting Standards Update ("*ASU*") 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) ("*ASU 2020-06*") to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2022 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company adopted ASU 2020-06 effective January 1, 2021. The adoption of ASU 2020-06 did not have an impact on the Company's financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting standards, if currently adopted, would have a material effect on the Company's condensed consolidated financial statements.

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# LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

# **3. INITIAL PUBLIC OFFERING**

Pursuant to the Initial Public Offering, the Company sold20,000,000 Units at a purchase price of \$10.00 per Unit. Each Unit consists of one share of common stock, and one-half of one warrant ("*Public Warrant*"). Each whole Public Warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.50 (see Note 8).

### 4. PRIVATE PLACEMENT

Simultaneously with the closing of the Initial Public Offering, affiliates of the Hydra Sponsor and Matthews Lane Sponsor, HG Vora and certain members of management purchased an aggregate of 6,825,000 Private Placement Warrants at \$1.00 per Private Placement Warrant, for an aggregate purchase price of \$6,825,000. Each Private Placement Warrant entitles the holder to purchase one share of common stock at an exercise price of \$11.50. The proceeds from the Private Placement Warrants were added to the proceeds from the Initial Public Offering held in the Trust Account. If the Company does not complete a Business Combination within the Combination Period, the proceeds of the sale of the Private Placement Warrants will be used to fund the redemption of the Public Shares (subject to the requirements of applicable law) and the Private Placement Warrants will expire worthless. There will be no redemption rights or liquidating distributions from the Trust Account with respect to the Private Placement Warrants.

The Private Placement Warrants are identical to the Public Warrants underlying the Units sold in the Initial Public Offering, except that the Private Placement Warrants and the common stock issuable upon the exercise of the Private Placement Warrants are not transferable, assignable or salable until 30 days after the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

# 5. RELATED PARTY TRANSACTIONS

### **Founder Shares**

On September 11, 2017, the Company issued an aggregate of 7,187,500 shares of common stock to the Initial Stockholders (*Founder Shares*") for an aggregate purchase price of \$25,000. On December 5, 2017, certain of the Initial Stockholders surrendered and returned to the Company, for nil consideration, an aggregate of 1,437,500 Founder Shares, which were cancelled, leaving an aggregate of 5,750,000 Founder Shares outstanding. The 5,750,000 Founder Shares included an aggregate of up to 750,000 shares subject to forfeiture by the Initial Stockholders to the extent that the underwriters' over-allotment was not exercised in full or in part, so that the Initial Stockholders would own 20% of the Company's issued and outstanding shares after the Initial Public Offering. The underwriters' election to exercise their over-allotment option expired unexercised on January 15, 2018 and, as a result, 750,000 Founder Shares were forfeited, resulting in 5,000,000 Founder Shares outstanding.

The Initial Stockholders have agreed, subject to certain exceptions, not to transfer, assign or sell any of the Founder Shares until the earlier of(i) one year after the date of the completion of a Business Combination, or (ii) the date on which the last sales price of the Company's common stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations) for any 20 trading days within any 30-trading day period commencing 150 days after a Business Combination, or earlier, in each case, if subsequent to a Business Combination, the Company completes a subsequent liquidation, merger, stock exchange, or other similar transaction which results in all of the Company's stockholders having the right to exchange their common stock for cash, securities or other property.

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LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited) The Company entered into an agreement whereby, commencing on December 1, 2017 through the earlier of the completion of a Business Combination or the Company's liquidation, the Company would pay Hydra Sponsor a monthly fee of up to \$10,000 for office space, utilities and secretarial and administrative support. For the three months ended March 31, 2020, the Company incurred \$30,000 in fees for these services. Effective June 30, 2020, Hydra Sponsor agreed to stop charging the Company the monthly administrative fee and forgave the \$71,000 outstanding balance due.

### **Related Party Loans**

In order to fund working capital deficiencies or finance transaction costs in connection with a Business Combination, the Hydra Sponsor, an affiliate of the Matthews Lane Sponsor and HG Vora (the "*Funding Parties*") loaned an aggregate of \$1,000,000 to the Company, in accordance with unsecured promissory notes issued on January 15, 2020 to the Funding Parties, pursuant to an expense advancement agreement dated December 1, 2017 which were subsequently converted by the holders into warrants on June 25, 2020. The expense advancement agreement was amended to increase the total amount of advances available to the Company under the agreement by an additional \$300,000, of which the Company drew down \$225,000 pursuant to promissory notes issued in October and November 2020 and \$75,000 was drawn down on February 1, 2021. On February 23, 2021, the expense advancement agreement was further amended to increase the loan commitment amount by an additional \$160,000 which was drawn down on February 24, 2021. The Funding Parties may, but are not obligated to, loan the Company additional finds from time to time or at any time, as may be required ("*Working Capital Loans*"). Under the expense advancement agreement, the Working Capital Loans would either be paid upon completion of a Business Combination, without interest, or, at the holder's discretion could be converted into warrants at a price of \$1.00 per warrant. The warrants would be identical to the Private Placement Warrants. In the event that a Business Combination does not close, the Company may use a portion of the proceeds held outside the Trust Account to repay the Working Capital Loans.

As of March 31, 2021, there was \$460,000 outstanding under the Working Capital Loans.

### 6. COMMITMENTS

# **GTWY Holdings Promissory Note**

On December 5, 2019, the Company entered into the GTWY Expense Advancement Agreement, pursuant to which GTWY Holdings committed to provide \$566,288 to fund contributions to the Trust Account. The Company drew down the full amount under the GTWY Expense Advancement Agreement to fund the required Contribution to the Trust Account for the period December 6, 2019 to January 5, 2020 by issuing an unsecured promissory note that was not interest-bearing to GTWY Holdings (the "*Gateway Promissory Note*"). The Gateway Promissory Note provided for repayment out of the proceeds of the Trust Account released to the Company if the Company completes an initial Business Combination and, otherwise, out of funds held by the Company outside the Trust Account. On January 31, 2021, the Company and GTWY Holdings entered into an amendment to the Gateway Promissory Note to permit conversion of the promissory note into warrants at a price of \$1.00 per warrant. In connection with such amendment, GTWY Holdings elected to convert the full principal balance of the Gateway Promissory Note into 566,288 warrants.

#### **Registration Rights**

Pursuant to a registration rights agreement entered into on December 1, 2017, the holders of the Founder Shares, Private Placement Warrants (and their underlying securities), Private Placement Units (and their underlying securities) (as defined below) and any warrants that may be issued upon conversion of the Working Capital Loans (and their underlying securities) are entitled to registration rights. The holders of these securities are entitled to make up to two demands, excluding short form demands, that the Company register such securities. In addition, the holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of a Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. However, the registration rights agreement provides that the Company will not permit any registration statement filed under the Securities Act to become effective until termination of the applicable lock-up period. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

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### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

### **Underwriters** Agreement

The underwriters of the Initial Public Offering are entitled to a deferred fee of three and one-half percent §.5%) of the gross proceeds of the Initial Public Offering, or \$7,000,000. Up to \$0.05 per Unit (or up to \$1,000,000) of the deferred fee may be paid to third parties (who are members of FINRA) that assist the Company in consummating its initial Business Combination. The election to make such payments to third parties will be solely at the discretion of the Company's management team, and such third parties will be selected by the management team in their sole and absolute discretion. The deferred fee will be paid in cash upon the closing of a Business Combination from the amounts held in the Trust Account, subject to the terms of the underwriting agreement. On November 23, 2020, the underwriters agreed to waive \$250,000 of the deferred fee which had been held in the Trust Account and was to be paid upon consummation of the Business Combination, resulting in an aggregate of \$6,750,000 of the deferred underwriting to be paid upon consummation, resulting in an aggregate of \$2,000,000 deferred underwriting fee payable as of March 31, 2021.

### **Contingent Forward Purchase Contract**

On December 1, 2017, the strategic investor entered into a contingent forward purchase contract (the 'Contingent Forward Purchase Contract') with the Company to purchase, in a private placement for gross proceeds of \$62,500,000 to occur concurrently with the consummation of the Business Combination, 6,250,000 Units on substantially the same terms as the sale of Units in the Initial Public Offering at \$10.00 per Unit. In connection with previously proposed business combination transaction with GTWY Holdings, an amendment to the Contingent Forward Purchase Contract was effected on December 27, 2019 to provide that the Contingent Forward Purchase Contract would terminate as of, and contingent upon, the closing of the transaction with GTWY Holdings such that the strategic investor would instead purchase 3,000,000 units of GTWY Holdings' equity securities (with each unit consisting of one GTWY Holdings Share and one-half of one GTWY Holdings Warrant) for a purchase price of \$10.00 per unit. The Contingent Forward Purchase Contract was waived by the strategic investor in the connection with the proposed Business Combination with Ensysce.

### Service Provider Agreement

From time to time the Company has entered into and may enter into agreements with various services providers and advisors, including investment banks, to help us identify targets, negotiate terms of potential Business Combinations, consummate a Business Combination and/or provide other services. In connection with these agreements, the Company may be required to pay such service providers and advisors fees in connection with their services to the extent that certain conditions, including the closing of a potential Business Combination does not occur, the Company would not expect to be required to pay these contingent fees. There can be no assurance that the Company will complete a Business Combination.

### Merger Agreement

On January 31, 2021, the Company entered into an Agreement and Plan of Merger (the 'Merger Agreement'), by and among the Company, Ensysce, and EB Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub"), relating to a proposed business combination transaction between the Company

and Ensysce.

Pursuant to the Merger Agreement, Merger Sub will merge with and into Ensysce, with Ensysce surviving such merger as a wholly owned subsidiary of the Company and the stockholders of Ensysce becoming stockholders of the Company (the "Merger").

Ensysce's issued and outstanding share capital as of immediately prior to the Merger Effective Time will, at the closing (the 'Closing') of the transactions contemplated by the Merger Agreement (collectively, the "Transaction"), be canceled and converted into the right to receive the Company's common stock, par value \$.0001 per share (the "LACQ Common Stock") calculated based on an exchange ratio of 0.06585 (the 'Exchange Ratio").

The Transaction will be consummated subject to the deliverables and provisions as further described in the Merger Agreement.

#### Warrant Surrender Agreement

On January 31, 2021, in connection with entering into the Merger Agreement, the Company entered into a Warrant Surrender Agreement, by and among Company and the Sponsors, pursuant to which each of the Sponsors agreed to irrevocably forfeit and surrender 250,000 Private Placement Warrants immediately prior to, and contingent upon, the Closing of the Transaction.

## 7. STOCKHOLDERS' EQUITY

*Preferred Stock* — The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of \$0.0001 per share with such designation, rights and preferences as may be determined from time to time by the Company's Board of Directors. As of March 31, 2021 and December 31, 2020, there were no shares of preferred stock issued or outstanding.

*Common Stock* — The Company is authorized to issue 100,000,000 shares of common stock with a par value of \$0.0001 per share. Holders of the Company's common stock are entitled to one vote for each share. The underwriters' election to exercise their over-allotment option expired unexercised on January 15, 2018 and, as a result,750,000 Founder Shares were forfeited. At March 31, 2021 and December 31, 2020, there were6,224,268 shares of common stock issued and outstanding.

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## LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

## 8. WARRANTS

Public Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants will become exercisable on the later of (a) 30 days after the completion of a Business Combination and (b) 12 months from the closing of the Initial Public Offering; provided in each case that the Company has an effective registration statement under the Securities Act covering the shares of common stock issuable upon exercise of the Public Warrants and a current prospectus relating to them is available. The Company has agreed that as soon as practicable, but in no event later than 15 business days after the closing of a Business Combination, the Company will use its best efforts to file with the SEC a registration statement for the registration, under the Securities Act, of the shares of common stock issuable upon exercise of the Public Warrants. The Company will use its best efforts to cause the same to become effective and to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the Public Warrants in accordance with the provisions of the warrant agreement. If any such registration statement has not been declared effective by the 60<sup>th</sup> business day following the closing of the Business Combination, holders of the Public Warrants shall have the right, during the period beginning on the 61<sup>st</sup> business day after the closing of the Business Combination and ending upon such registration statement being declared effective by the SEC, and during any other period when the Company shall fail to have maintained an effective registration statement covering the shares of common stock issuable upon exercise of the Public Warrants, to exercise such Public Warrants on a "cashless basis." Notwithstanding the above, if the Company's common stock is at the time of any exercise of a Public Warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, the Company may, at its option, require holders of Public Warrants who exercise their warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event the Company so elects, the Company will not be required to file or maintain in effect a registration statement, but will be required to use its best efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. The Public Warrants will expire five years after the completion of a Business Combination or earlier upon redemption or liquidation.

The Company may redeem the Public Warrants:

- in whole and not in part;
- at a price of \$0.01 per warrant;
- at any time during the exercise period;
- upon a minimum of 30 days' prior written notice of redemption;
- if, and only if, the last sale price of the Company's common stock equals or exceeds \$18.00 per share for any 20 trading days within a 30-trading day period ending
  on the third business day prior to the date on which the Company sends the notice of redemption to the warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. If the Company is unable to complete a Business Combination within the Combination Period and the Company liquidates the funds held in the Trust Account, holders of warrants will not receive any of such funds with respect to their warrants, nor will they receive any distribution from the Company's assets held outside of the Trust Account with the respect to such warrants. Accordingly, the warrants may expire worthless.

## 9. FAIR VALUE MEASUREMENTS

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and nonfinancial assets and liabilities that are re-measured and reported at fair value at least annually.

The fair value of the Company's financial assets and liabilities reflects management's estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

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#### LEISURE ACQUISITION CORP. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2021 (Unaudited)

Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on our assessment of the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about the Company's assets that are measured at fair value on a recurring basis at March 31, 2021 and December 31, 2020, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	Level	Ma	rch 31, 2021	De	cember 31, 2020
Assets:					
Cash and marketable securities held in Trust Account	1	\$	12,690,899	\$	12,628,170
Liabilities:					
Warrant Liability – Private Warrants	3		8,307,375		6,260,000

The Private Warrants are accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities on the accompanying balance sheets. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within change in fair value of warrant liabilities in the statements of operations.

The Private Warrants were valued using a Modified Black Scholes Option Pricing Model, which is considered to be a Level 3 fair value measurement. The Modified Black Scholes model's primary unobservable input utilized in determining the fair value of the Private Warrants is the probability of consummation of the Business Combination. The probability assigned to the consummation of the Business Combination was determined based on the observed success rates of business combinations for special purpose acquisition companies.

The key inputs into the Black Scholes Option Pricing Model for the Private Warrants were as follows:

Input	March	31, 2021	December	31, 2020
Risk-free interest rate		0.92%		0.36%
Expected Term (years)		5.0		5.0
Probability of Business Combination		30.0%		30.0%
Expected volatility		19.6%		19.7%
Exercise price	\$	11.50	\$	11.50
Stock Price	\$	13.08	\$	12.43
Annual dividend yield		0.00%		0.00%

The following table presents the changes in the fair value of warrant liabilities:

Fair value as of December 31, 2020	\$ 6,260,000
Change in fair value	 2,047,375
Fair value as of March 31, 2021	\$ 8,307,375

## **10. SUBSEQUENT EVENTS**

The Company evaluates subsequent events and transactions that occur after the balance sheet date up to the date that the condensed consolidated financial statements were issued. Based upon this review, other than as described below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the condensed consolidated financial statements.

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#### **Report Of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

#### **ENSYSCE BIOSCIENCES, INC.**

#### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of **Ensysce Biosciences**, **Inc**. ("*Company*") as of December 31, 2020 and 2019, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "*financial statements*"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

#### **Going Concern Uncertainty**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company does not have revenue generating activities and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 2 to the consolidated

financial statements. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("*PCAOB*") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2017.

/s/ Mayer Hoffman McCann P.C.

San Diego, California March 15, 2021

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#### Ensysce Biosciences, Inc. Consolidated Balance Sheets As of December 31, 2020 and 2019

		2020	2019
Assets			
Current assets:			
Cash and cash equivalents	\$	194,214	\$ 341,536
Unbilled receivable		-	173,552
Right-of-use asset		23,538	-
Prepaid expenses and other current assets		130,124	103,502
Total current assets		347,876	 618,590
Property and equipment, net		151	351
Other assets		3,780	 5,000
Total assets	\$	351,807	\$ 623,941
Liabilities and stockholders' deficit			
Current liabilities:			
Accounts payable	\$	1,724,598	\$ 540,778
Accrued expenses and other liabilities		344,792	1,491,660
Lease liability		25,500	-
Notes payable and accrued interest		4,245,082	2,621,407
Embedded derivative on convertible notes		670,262	 2,646,347
Total current liabilities		7,010,234	7,300,192
Total liabilities		7,010,234	 7,300,192
Commitments and contingencies (Note 6)			 
Stockholders' deficit			
Preferred stock, \$0.000025 par value, 50,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and 2019		-	-
Common stock, \$0.000025 par value, 500,000,000 shares authorized; 239,465,160 shares issued and outstanding at			
December 31, 2020 and 2019		5,987	5,987
Additional paid-in capital		49,511,927	49,333,248
Accumulated deficit		(55,958,716)	 (56,015,486)
Total Ensysce Biosciences, Inc. stockholders' deficit		(6,440,802)	(6,676,251)
Noncontrolling interest in stockholders' deficit		(217,625)	 -
Total stockholders' deficit	-	(6,658,427)	(6,676,251)
Total liabilities and stockholders' deficit	\$	351,807	\$ 623,941
			 ,

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

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#### Ensysce Biosciences, Inc. Consolidated Statements of Operations For the Years Ended December 31, 2020 and 2019

	 Years Ended	Decemb	oer 31,
	 2020		2019
Federal grants	\$ 3,931,209	\$	1,763,961
Operating expenses:			
Research and development	4,389,579		3,402,301

General and administrative	1,154,917	6,929,904
Total operating expenses	 5,544,496	 10,332,205
Loss from operations	(1,613,287)	(8,568,244)
Other income (expense):		
Change in fair value of derivative liability	2,447,908	(575,087)
Interest expense	(995,496)	(958,949)
Total other income (expense), net	1,452,412	(1,534,036)
Net loss	\$ (160,875)	\$ (10,102,280)
Net loss attributable to noncontrolling interests	\$ (217,645)	\$ -
Net income (loss) attributable to common stockholders	\$ 56,770	\$ (10,102,280)
Net income (loss) per basic share:		
Net income (loss) per share attributable to common stockholders, basic	\$ 0.00	\$ (0.04)
Weighted average common shares outstanding, basic	 239,465,160	 239,465,160
Net income (loss) per diluted share:		
Net income (loss) per share attributable to common stockholders, diluted	\$ 0.00	\$ (0.04)
Weighted average common shares outstanding, diluted	 250,682,575	 239,465,160

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

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## Ensysce Biosciences, Inc. Consolidated Statements of Changes in Stockholders' Deficit For the Years Ended December 31, 2020 and 2019

				Stock	holo	lers' Deficit			
	Common	Stoc	k	Additional					
	Number of Shares	A	mount	Paid-In Capital		Accumulated Deficit	N	oncontrolling interest	Total
Balance on December 31, 2018	239,465,160	\$	5,987	\$ 43,287,315	\$	(45,913,206)	\$	-	\$ (2,619,904)
Issuance of common stock warrants	-		-	10,500		-		-	10,500
Stock-based compensation	-		-	6,035,433		-		-	6,035,433
Net loss			-		_	(10,102,280)	_	-	(10,102,280)
Balance on December 31, 2019	239,465,160	\$	5,987	\$ 49,333,248	\$	(56,015,486)	\$	-	\$ (6,676,251)
Stock-based compensation	-		-	178,679		-		-	178,679
Contribution from noncontrolling interest	-		-	-		-		20	20
Net income (loss)			-		_	56,770		(217,645)	(160,875)
Balance on December 31, 2020	239,465,160	\$	5,987	\$ 49,511,927	\$	(55,958,716)	\$	(217,625)	<u>\$ (6,658,427)</u>

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

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## Ensysce Biosciences, Inc. Consolidated Statements of Cash Flows For the Years Ended December 31, 2020 and 2019

		Years Ended Decen	nber 31,
	2	2020	2019
Cash flows from operating activities:			
Net loss	\$	(160,875) \$	(10,102,280)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation		201	201
Accrued interest		381,886	292,260
Accretion of discounts on promissory notes		613,610	666,689
Change in fair value of embedded derivative		(2,447,908)	575,087
Stock-based compensation		178,679	6,035,433
Lease cost		1,962	
Changes in operating assets and liabilities:			
Accounts receivable		173,552	(173,552)
Prepaid expenses and other assets		(25,401)	70,332
Accounts payable		1,183,820	372,928
Accrued expenses and other liabilities		(1,146,868)	1,327,639
Net cash used in operating activities		(1,247,342)	(935,263)
Cash flows from financing activities:			
Proceeds from issuance of promissory notes		700,000	400,000
Proceeds from issuance of promissory notes to related party		400,000	100,000
Contribution from noncontrolling interest		20	-

Net cash provided by financing activities	 1,100,020	 500,000
Decrease in cash and cash equivalents	(147,322)	(435,263)
Cash and cash equivalents beginning of period	341,536	776,799
Cash and cash equivalents end of period	\$ 194,214	\$ 341,536
Supplemental cash flow information:		
Income tax payments	\$ 1,600	\$ 1,600
Supplemental disclosure of non-cash investing and financing activities:		
Adoption of ASC 842	\$ 25,500	\$ -
Fair value of embedded derivative at issuance	\$ 471,823	\$ 414,188

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

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### NOTE 1 - ORGANIZATION AND PRINCIPAL ACTIVITIES

Ensysce Biosciences, Inc. ("*Ensysce*"), along with its subsidiary, Covistat Inc. ("*Covistat*") and its wholly owned subsidiary EBI Operating, Inc. (collectively, the "*Company*"), is engaged in the development of small and large molecule drug delivery platforms targeting pain and cancer markets. The primary focus of the Company is its small molecule program developing abuse and overdose resistant pain technology with a clinical stage program being the abuse resistant, TAAP (Trypsin Activated Abuse Protection) opioid product candidate, PF614. In addition, the Company is developing its MPAR<sup>TM</sup> (Multi-Pill Abuse Resistant) technology for overdose protection which will be applied to the PF614 program. In 2019, the Company commenced development work applying its TAAP and MPAR technology to a methadone prodrug for use in the treatment of Opioid Use Disorder (OUD). The Company has also developed a delivery platform for large biomolecules utilizing single walled carbon nanotubes (SWCNT) to produce intravenously delivered immunology and gene therapy products.

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

In March 2020, the World Health Organization declared the outbreak of a respiratory disease caused by a new coronavirus as a "pandemic." First identified in late 2019 and known now as COVID-19, the outbreak has impacted millions of individuals worldwide. In response, many countries have implemented measures to combat the outbreak which have impacted global business operations. As of the date of issuance of the consolidated financial statements, the Company's operations have not been significantly impacted; however, the Company continues to monitor the situation. No impairments were recorded as of the balance sheet date as no triggering events or changes in circumstances had occurred as of year-end; however, due to significant uncertainty surrounding the situation, management's judgment regarding this could change in the future. In addition, while the Company's results of operations, cash flows and financial condition could be negatively impacted, the extent of the impact cannot be reasonably estimated at this time.

In June 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, Covistat, Inc., a Delaware corporation. Pursuant to the articles of incorporation, Covistat was authorized to issue 1,000,000 shares of common stock, \$0.001 par value per share, and 100,000 shares of preferred stock, \$0.001 par value per share. Ensysce is a 79.2% shareholder in Covistat, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively.

## NOTE 2 - BASIS OF PRESENTATION

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP") and include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

#### **Going Concern**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any product revenue and has not achieved profitable operations and is not expected to do so in 2021. The Company has experienced net losses since inception, had net cash outflows used in operating activities of \$1.2 million for the year ended December 31, 2020, and had a working capital deficit of \$6.7 million and an accumulated deficit of \$56.0 million at December 31, 2020. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. Product development activities, clinical and preclinical testing, and commercialization of the Company's product candidates are necessary to develop the Company's products and will require significant additional financing. Cash on hand as of March 2021 is not expected to be sufficient to meet the cash flow needs to continue these product development activities throughout 2021 without additional capital. Management estimates additional funding will be required over the next 12 months to continue development of drug candidates. There can be no assurance the Company will be able to obtain such funds. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

In December 2020, the Company executed a share subscription facility with an investment group. Under the agreement, the investor agreed to provide the Company with a share subscription facility of up to \$60.0 million for a 36-month term following the public listing of the Company's common stock. The Company will control the timing and maximum amount of drawdown under this facility and has no minimum drawdown obligation. The investor will pay, in cash, a per-share amount equal to 90% of the average daily closing price of the Company's stock during the 30 consecutive trading days prior to the issuance of a draw notice, which shall not exceed 400% of the average trading volume for the 30 trading days immediately preceding the draw down date. Concurrent with a public listing of the Company's shares, the Company will issue warrants to the investor to purchase outstanding common stock of Ensysce. The number of warrants issued will be equal to 4% of the common shares outstanding on a fully diluted basis as of the public listing date. The Company must pay a commitment fee to the investor of \$1.2 million with \$800,000 due on the first anniversary of the public listing date. The commitment fee can be paid from the proceeds of a draw against the facility or in freely tradable common stock of the Company. Additionally, in January 2021, the Company executed a definitive merger agreement with Leisure Acquisition Corp, a special purpose acquisition company ("*SPAC*") to effect a public listing of its stock. The agreement with the SPAC has not resulted in the Company's shares being publicly listed; the consummation of the merger is contingent on customary filings and shareholder approval. Refer to Note 12 for additional details.

While the Company believes that, with adequate financial resources, it will be able to ultimately generate revenues from products and services, and further develop and launch

its product portfolio, the Company's current cash position is not sufficient to support its plans. While the Company believes in the viability of its strategy to ultimately realize revenues and in its ability to raise additional funds, management cannot be certain that additional funding will be available on acceptable terms, or at all. The Company's ability to continue as a going concern is dependent upon its ability to obtain adequate financing beyond the limited funding it has received during the year ended December 31, 2020, primarily from a related party, and achieve profitable operations. As a result, these plans do not alleviate substantial doubt about the Company's ability to continue as a going concern for a period of 12 months following the date these financial statements were issued.

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

## NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## Immaterial Correction of Error

In February 2021, the Company concluded that due to an error in the measurement of the fair value of embedded derivatives as of December 31, 2019, the 2019 balance sheet would be adjusted. The change resulted in an increase in the fair value of the embedded derivatives of approximately \$269,000 with a corresponding increase in the change in fair value of derivative liabilities presented in the consolidated statement of operations.

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

#### Reclassification

The Company reclassified \$11,331 of accrued and unpaid interest on convertible debt from notes payable to accrued expenses and other liabilities in order to consistently present its consolidated financial statements. The reclassification did not impact net income.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### Use of Estimates and Assumptions

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

#### Cash and Cash Equivalents

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

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

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

#### Earnings per Share

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

	Years Ended	Decemt	oer 31,
	 2020		2019
Numerator:			
Net income (loss) attributable to common stockholders	\$ 56,770	\$	(10,102,280)
Denominator:			
Weighted average shares outstanding, basic	239,465,160		239,465,160
Weighted average dilutive stock options	11,217,415		-
Weighted average shares outstanding, diluted	250,682,575		239,465,160
Net income (loss) per share attributable to common stockholders, basic	\$ 0.00	\$	(0.04)
Net income (loss) per share attributable to common stockholders, diluted	0.00		(0.04)

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

	Years Ended D	ecember 31,
	2020	2019
Stock options	55,281,877	78,976,701
Warrants	300,000	236,986
Total	55,581,877	79,213,687

Property and equipment include office and laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives offive to six years. Depreciation expense of approximately \$201 and \$201 was recognized for the years ended December 31, 2020 and 2019, respectively, and is classified in general and administrative expense in the accompanying consolidated statements of operations.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. There were no such losses for the years ended December 31, 2020 and December 31, 2019.

#### **Derivative Financial Instruments**

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

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

During the years ended December 31, 2020 and 2019, the Company entered into a series of notes that were determined to have embedded derivative instruments in the form of a contingent put option. The notes are recognized at the value of proceeds received after allocating issuance proceeds to the bifurcated contingent put option. The notes are subsequently measured at amortized cost using the effective interest method to accrete interest over their term to bring the notes' initial carrying value to their principal balance at maturity. The bifurcated put option is initially measured at fair value and subsequently measured at fair value with changes in fair value recognized as a component of other expenses in the consolidated statements of operations (see Note 7). The notes and the contingent put option are classified as either long-term or short-term liabilities based on the maturity date of the related loan.

#### Federal Grants

In September 2018, the National Institutes of Health (*"NIH*") through the National Institute on Drug Abuse awarded the Company a research and development grant related to the development of its MPAR overdose prevention technology (the *"MPAR Grant*"). The total approved budget for the two-year period was approximately \$.4 million (\$3.2 million and \$2.2 million in years 1 and 2 respectively) of which the Company must contribute \$1.1 million in the first year of the grant. In August 2019, the grant was amended such that the approved budget for the two-year period decreased to approximately \$5.1 million (\$2.1 million and \$3.0 million in years 1 and 2, respectively).

In September 2019, the NIH/National Institute on Drug Abuse awarded the Company a second research and development grant related to the development of its *TAAP/MPAR* abuse deterrent technology (the "TAAP/MPAR Grant"). The total approved budget for the two-year period was approximately \$5.4 million.

The Company concluded the government grants are not within the scope of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), as government entities do not meet the definition of a "customer" as defined by ASC 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded the government grants do not meet the definition of a contribution and is a non-reciprocal transaction, therefore, ASC 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity, and the grant is with a governmental agency. Revenues from the grants are based upon internal costs incurred that are specifically covered by the grants, plus an additional rate that provides funding for overhead expenses. Revenue is recognized when the Company incurs costs related to the grants. The Company believes this policy is consistent with the overarching premise in ASC 606, applied by analogy, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in ASC 606. The Company believes the recognition of revenue as costs are incurred and amounts become due is analogous to the concept of transfer of control of a service over time under ASC 606.

Revenue recognized under the MPAR Grant was approximately \$3,037,234 and \$1,706,508 during the years ended December 31, 2020 and 2019, respectively. Revenue recognized under the TAAP/MPAR Grant was approximately \$893,975 and \$57,453 during the years ended December 31, 2020 and 2019, respectively.

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

## **Research and Development Costs**

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

## General and Administrative Expenses

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

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### Fair Value Measurement

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

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

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

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

ASC 820 requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value, and defines fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. As of December 31, 2020 and 2019, the recorded values of cash and cash equivalents, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

The carrying value of outstanding notes payable approximates the estimated aggregate fair value as the embedded contingent put option is recognized at fair value and classified with the debt host. The put option allows certain notes payable to be converted into common stock, contingent upon completion of an equity financing transaction with gross proceeds above certain thresholds. The fair value estimate of the embedded put option is based on the probability-weighted discounted value of the put feature and represents a Level 3 measurement. Significant assumptions used to determine the fair value of the put feature include the estimated probability of exercise of the put option and the discount rate used to calculate fair value. The estimated probability of exercise is based on management's expectation for future equity financing transactions. The discount rate is based on the weighted average effective yield of notes payable previously issued by the Company, adjusted for changes in market yields of healthcare sector CCC-rated debt. As of December 31, 2020, assumptions included a probability of exercise of the put option of 10% and a discount rate of 42.9%. As of December 31, 2019, assumptions included a probability of exercise of the put option reflects greater expectation for an initial public offering or reverse merger transaction, which would not trigger the put option. Beginning in late 2020, the Company held discussions with various public companies and SPACs about potential mergers to effect a public listing of the Company's stock and executed the GEM Agreement to provide a source of funding following such public listing of the Company's stock.

The following table presents assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheets on a recurring basis:

		Decembe	er 31, 2020	
	Total	Level 1	Level 2	Level 3
Contingent put option	\$ 670,262	\$ -	\$	\$ 670,262
Total	\$ 670,262	\$ -	\$	\$ 670,262
		Decembe	er 31, 2019	
	Total	December Level 1	er 31, 2019 Level 2	Level 3
Contingent put option	Total \$ 2,646,347		/	Level 3 \$ 2,646,347

The following table summarizes the change in fair value of the Company's Level 3 contingent put options:

		December 31,				
		2020		2019		
Beginning fair value	\$	2,646,347	\$	1,657,072		
Issuance		471,823		414,188		
Change in fair value		(2,447,908)		575,087		
Ending fair value	<u>\$</u>	670,262	\$	2,646,347		

See Note 7 for further details on the embedded contingent put option.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### Stock-based Compensation

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

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the years ended December 31, 2020 and 2019, stock-based compensation costs are recorded in general and administrative expenses in the consolidated statements of operations.

#### Income Taxes

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

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

#### **Recently Adopted Accounting Pronouncements**

In August 2018, the Financial Accounting Standards Board (the "FASB") issued ASU 2018-13, Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to

the Disclosure Requirements for Fair Value Measurement, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. The Company adopted ASU 2018-13 on January 1, 2020 with no material impact to the consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), and has since issued amendments thereto, related to the accounting for leases (collectively referred to as "ASC 842"). ASC 842 establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the consolidated balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statement of operations. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. Entities have the option to continue to apply historical accounting under Topic 840, including its disclosure requirements, in comparative periods presented in the year of adoption. An entity that elects this option will recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption instead of the earliest period presented. The Company adopted ASU 2016-02 on January 1, 2020 with no material impact to the consolidated financial statements.

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

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes ("*ASU 2019-12*"), which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 31, 2021 and interim periods within that year. Early adoption is permitted. The Company is evaluating the impact of ASU 2019-12 on the consolidated financial statements.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

## NOTE 4 - PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

		As of Dec	ember 31,	
	2	2020		2019
Prepaid research and development	\$	112,966	\$	68,815
Prepaid insurance		17,158		32,187
Prepaid rent		-		2,500
Total prepaid expenses and other current assets	\$	130,124	\$	103,502

## NOTE 5 – ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consisted of the following:

		As of December 31,				
	2020		2019			
Accrued research and development	\$	72,906	\$	1,141,727		
Deferred grant revenue		159,047		279,808		
Accrued scientific advisory board fees		60,032		58,794		
Other accrued liabilities		52,807		11,331		
Total accrued expenses and other liabilities	\$	344,792	\$	1,491,660		

## NOTE 6 - COMMITMENTS AND CONTINGENCIES

## Litigation

As of December 31, 2020 and 2019, there were no pending legal proceedings against the Company that are expected to have a material adverse effect on cash flows, financial condition or results of operations. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

Lease

In August 2020, the Company entered into an agreement to lease office space. The lease commencement date wasOctober 1, 2020 and the lease will terminate on October 31, 2021 with no option to renew. As of December 31, 2020, the future lease payments totaled \$5,500.

The Company recognized total rent expense of \$36,645 and \$32,593 in the years ended December 31, 2020 and 2019, respectively.

## NOTE 7 - NOTES PAYABLE

The following table provides a summary of the Company's outstanding debt as of December 31, 2020:

			Unamortized debt					
	Pri	ncipal balance	Ac	crued interest		discount	Net	t debt balance
2015 convertible notes	\$	100,000	\$	28,671	\$	-	\$	128,671
2018 convertible notes		3,500,000		727,905		(783,124)		3,444,781
2020 promissory notes		100,000		1,694		-		101,694
2020 convertible notes		700,000		29,726		(159,790)		569,936
Total	\$	4,400,000	\$	787,996	\$	(942,914)	\$	4,245,082

The following table provides a summary of the Company's outstanding debt as of December 31, 2019:

			Unamortized debt					
	Prin	cipal balance	Ace	crued interest		discount	Ne	et debt balance
2015 convertible notes	\$	100,000	\$	23,658	\$	-	\$	123,658
2018 convertible notes		3,200,000		382,452		(1,084,703)		2,497,749
Total	\$	3,300,000	\$	406,110	\$	(1,084,703)	\$	2,621,407

#### 2015 Convertible Notes Payable

During 2015, the Company issued certain convertible promissory notes in the aggregate principal amount of \$73,000. During 2017 and 2018, all but \$100,000 were converted into common shares of Ensysce. The remaining convertible promissory note bears interest at 5% per annum, is due on demand (principal and interest) and is mandatorily convertible at a variable price per share equal to 80% of the price received in certain future equity transactions.

#### 2018 Convertible Notes Payable

Between January 2018 and December 2020, the Company received financing totaling \$\$,500,000 under a series of unsecured promissory notes with a stockholder and board member (\$2,500,000) and an unrelated party (\$1,000,000). The promissory notes mature 24 months from the date of issuance and bear interest at the rate of 10% per annum. The promissory notes, together with all interest as accrued, can be converted into shares of Ensysce's common stock at the option of the noteholder, at 50% of the price paid per share for equity securities by the investors in a subsequent equity financing of no less than \$5,000,000 gross proceeds (the "contingent put option"). The contingent put option is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3).

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Additionally, if there is an initial public offering or reverse merger that results in Ensysce becoming publicly listed, the promissory notes automatically convert to equity at the lower of \$0.25 per share or the then-current Enterprise Value per share (the *"automatic conversion option"*). Enterprise Value per share is defined as market capitalization, debt and preferred stock less cash and cash equivalents divided by the common stock of Ensysce on the measurement date, not to exceed \$55 million. The Company assessed whether the automatic conversion option should be accounted for separately from the debt host and concluded that as the common shares of Ensysce are currently not publicly traded and thus are not considered readily convertible to cash, the automatic conversion option cannot be net settled. Further, the conversion price of the promissory notes exceeded the per share fair value of Ensysce's common stock on each issuance date and, consequently, no beneficial conversion feature exists.

The promissory notes also include a change in control call option whereby, upon the close of a sale of Ensysce, other than an initial public offering, Ensysce has the right to prepay the promissory notes at 200% of the principal outstanding plus all accrued and unpaid interest. This call option is required to be bifurcated because it is considered to not be clearly and closely related to the debt host. However, the Company has concluded that as of each balance sheet date presented, the exercise of this call option is not probable and thus the call option has a de minimis value. The Company will reassess the probability of the Company exercising this call option at each reporting period during the term of these promissory notes.

In June 2020, the board resolved to extend the maturity of all 2018 convertible notes payable issued in 2018 by one year. The Company did not incur legal fees or other additional costs to effect the modification. The modification met the criteria to be classified as a troubled debt restructuring under ASC 470-50. The effective interest rate was recalculated to reflect the modified expected term of the 2018 convertible notes and no gain or loss was recognized.

#### 2020 Promissory Notes Payable

During the year ended December 31, 2020, the Company received financing totaling \$100,000 under a series of unsecured promissory notes with the CEO and a board member. The promissory notes bear interest at a rate of 10% per annum and mature December 31, 2021 or upon certain financing transactions, whichever is earlier.

#### 2020 Convertible Notes Payable

During the year ended December 31, 2020, Covistat received financing totaling \$700,000 under a series of unsecured promissory notes with unrelated parties. The notes mature in July 2022 and bear interest at a rate of 10% per annum. The notes cannot be prepaid without the prior consent of the holder. The notes, together with all accrued and unpaid interest, are automatically convertible upon an initial public offering of Covistat shares or a private sale of a single class of Covistat's equity securities with gross proceeds of at least \$2.0 million within a 12-month period. The notes are convertible at the option of the holder at maturity. With respect to an automatic conversion, the conversion price will be the lesser of (a) 80% of the per-share price of the equity securities sold or (b) the price equal to \$10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. With respect to an optional conversion price will be the price equal to \$10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. The conversion is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3).

During the year ended December 31, 2020, interest expense for all notes payable was recognized in the amounts of \$81,886 and \$613,610 related to the face value interest and the amortization of the discount due to the embedded derivative instrument, respectively. During the year ended December 31, 2019, interest expense was recognized in the amounts of \$292,260 and \$666,689 related to the face value interest and the amortization of the debt discount due to the embedded derivative instrument, respectively. The

remaining debt discount is expected to be amortized over 1.2 years at an effective interest rate of 55.4%, which represents the weighted average remaining term of the notes and the weighted average effective interest rate, respectively.

## NOTE 8 - STOCKHOLDERS' EQUITY

In February 2018, the Company amended and restated its articles of incorporation to increase the authorized shares of common stock to500,000,000 shares and authorized the issuance of 50,000,000 shares of preferred stock. Pursuant to the Company's amended and restated articles of incorporation, as of December 31, 2020, the Company was authorized to issue 500,000,000 shares of common stock with a par value of \$0.000025 per share and 50,000,000 shares of preferred stock, par value \$0.000025. As of December 31, 2020 and 2019, there were no shares of preferred stock issued and outstanding.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### **Common Stock**

As of December 31, 2020 and 2019, the Company had a total of 239,465,160 shares of common stock issued and outstanding.

#### Warrants

In February 2013, the Company issued 200,000 warrants to purchase common stock. The warrants have a ten-year life and have an exercise price of \$0.41 per share. As of December 31, 2020 and 2019, the warrants remained outstanding.

In August 2019, the Company issued 100,000 warrants in connection with the issuance of convertible debt. The warrants have a ten-year life and have an exercise price of \$0.20. As of December 31, 2020 and 2019, the warrants remained outstanding. The warrants were measured using a Black-Scholes model with the following inputs:

	 2019 warrants
Stock price	\$ 0.17
Exercise price	\$ 0.20
Expected term (years)	10.00
Volatility	59.9%
Risk free rate	1.9%

#### **NOTE 9 - STOCK-BASED COMPENSATION**

In 2016, the Company adopted the Ensysce Biosciences, Inc. 2016 Stock Incentive Plan (the '2016 Plan'). The 2016 Plan, as amended in 2019, allows for the issuance of up to 100,000,000 shares of the Company's common stock pursuant to the grant of non-statutory stock options, incentive stock options and other equity awards. Grants pursuant to the 2016 Plan may be made to the Company's employees, directors, and consultants. As of December 31, 2020 and 2019, options outstanding under the 2016 Plan totaled 61,265,500 and 78,265,500, respectively. In February 2019, the Board and stockholders authorized an increase in the shares reserved under the 2016 Plan from75,000,000 to 100,000,000.

In March 2019, the Company adopted the 2019 Directors Plan (the "2019 Plan"), which was amended in August 2020. The 2019 Plan as amended allows for the issuance of up to 2,500,000 shares of the Company's common stock pursuant to the grant of non-statutory stock options. As of December 31, 2020 and 2019, options outstanding under the 2019 Plan totaled 2,300,000 and 300,000, respectively.

In addition to the 2016 Plan and the 2019 Plan, as of December 31, 2020 and 2019, options outstanding under two legacy equity incentive plans (the *Legacy Plans*") totaled 8,247,669 and 8,293,204, respectively. No additional equity awards may be made under the Legacy Plans and the outstanding options will expire if unexercised by certain dates through August 2024.

#### **Option** Activity

During the year ended December 31, 2019, the Company granted fully vested stock options to purchase an aggregate of \$5,300,000 shares of common stock, including an option granted to the Company's Chief Executive Officer to purchase 10,100,000 shares of common stock and options granted to directors and consultants to purchase an aggregate of \$5,200,000 shares of common stock.

During the year ended December 31, 2020, the Company granted stock options to purchase an aggregate of 2,000,000 shares of common stock to members of the board of directors. The options vest over three years and have an exercise price of \$0.22 per share.

The Company recognized within general and administrative expense stock-based compensation expense of approximately \$178,679 and \$6,035,433 for the years ended December 31, 2020 and 2019, respectively. During the years ended December 31, 2020 and 2019, there was no stock-based compensation allocated to research and development expense.

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes the Company's stock option activities for the years ended December 31, 2020 and 2019:

			Weighted a			
	Options	Ez	xercise price	Remaining contractual life	In	trinsic value
Outstanding at December 31, 2018	43,544,606	\$	0.13	7.3	\$	2,209,192
Granted	45,300,000	\$	0.17	9.2		
Expired / Forfeited	(1,985,902)	\$	0.03		\$	285,269
Outstanding at December 31, 2019	86,858,704	\$	0.15	8.0	\$	1,923,924
Granted	2,000,000	\$	0.22	9.3		
Expired / Forfeited	(17,045,535)	\$	0.16		\$	106,541

Outstanding at December 31, 2020	71,813,169	\$ 0.15	6.8	\$ 1,817,383
Exercisable at December 31, 2020	67,479,826	\$ 0.15	6.7	\$ 1,700,715
Vested and expected to vest	71,813,169	\$ 0.15	6.8	\$ 1,817,383

#### **Option Valuation**

The fair value of each stock option granted has been determined using the Black-Scholes option-pricing model. The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows:

	For the years en	ded December 31,
	2020	2019
Expected dividend yield	0.00%	0.00%
Expected stock-price volatility	124.0%	105.0%
Risk-free interest rate	0.27% - 1.52%	2.21% - 2.56%
Stock price	\$0.17	\$0.17
Expected term (years)	5.8	5.0

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

The weighted-average grant date fair value of options granted during the years ended December 31, 2020 and 2019 was \$1.4 and \$0.13, respectively.

As of December 31, 2020 and 2019 the Company had an aggregate of \$159,453 and \$48,438 of unrecognized share-based compensation cost, respectively, which is expected to be recognized over the weighted average period of 2.38 years.

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 10 - INCOME TAXES

As of December 31, 2020, the Company had net operating loss carry forwards that may be available to reduce future years' taxable income.

Income (loss) before provision for income taxes consisted of the following:

	 Year ending December 31,           2020         2019           (159,275)         \$ (10,100,680)		er 31,
	2020		2019
United States	\$ (159,275)	\$	(10,100,680)

The federal and state income tax provision (benefit), included in general and administrative expenses in the consolidated statements of operations, is summarized as follows:

		Year ending I	ear ending December 31, 20 2019	r 31,
	2	020		2019
Current state provision	\$	1,600	\$	1,600

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The Company's deferred tax assets were comprised of the following as of December 31, 2020 and 2019:

	 As of Dec	ember 3	31,
	2020		2019
Deferred tax assets:		_	
Net operating loss tax carryforwards	\$ 23,332,247	\$	22,826,050
Tax credits	2,663,350		2,547,986
Fixed assets and intangibles	63,047		79,453
Other	20,248		200,261
Stock-based compensation	 1,798,263		2,316,380
Total deferred tax assets	27,877,155		27,970,130
Deferred tax liabilities:			
Convertible notes: embedded derivatives	 (81,603)		-
Valuation allowance	(27,795,552)		(27,970,130)
Net deferred tax assets	\$ -	\$	-

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance. Further, an uncertain tax position exists insofar as some portion of qualified research and development expenses could be disallowed under tax audits. As a result, the Company applies a 25% reserve on all research and development credits generated.

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#### ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The Company's ability to utilize its net operating losses may be limited under Section 382 and 383 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Although the Company not undergone a Section 382 analysis, it is possible that the utilization of the net operating losses, could be substantially limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, the Company may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

Net operating losses and tax credit carryforwards as of December 31, 2020 are as follows:

	 Amount	Expiration years
Net operating losses, federal (Post December 31, 2017)	\$ 4,220,846	Indefinite
Net operating losses, federal (Pre January 1, 2018)	84,007,935	2024-2037
Net operating losses, state	68,792,637	2028-2040
Tax credits, federal	2,344,011	2028-2040
Tax credits, state	1,528,444	Indefinite

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	Year ending Dece	mber 31,
	2020	2019
Statutory rate	21.0%	21.0%
State tax	-30.7%	6.4%
Stock based compensation	0.0%	-0.1%
Change in valuation allowance	17.0%	-27.3%
Other permanent items	-0.3%	0.0%
Nondeductible interest expense	-7.0%	0.0%
Total	0.0%	0.0%

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities. The Company is not currently under audit by the Internal Revenue Service or other similar state and local authorities. All tax years remain open to examination by major taxing jurisdictions to which the Company is subject.

On December 22, 2017, the 2017 Tax Cut and Jobs Act (the Act) was enacted into law and the new legislation contains several key tax provisions, including a one-time mandatory transition tax on accumulated foreign earnings and a reduction of the corporate income tax rate to 21% effective January 1, 2018, among others. The Company was required to recognize the effect of the tax law changes in the period of enactment, such as determining the estimated transition tax, re-measuring our U.S. deferred tax assets and liabilities at a 21% rate as well as reassessing the net realizability of our deferred tax assets and liabilities. The one-time transition tax does not generate a tax liability as the deemed distribution is offset by current year taxable losses. The amount related to the re-measurement of the deferred tax balance was a reduction of approximately \$9.8 million. Due to the corresponding valuation allowance fully offsetting deferred taxes, there was no impact on the consolidated statement of operations.

## NOTE 11 - RELATED PARTIES

During the year ended December 31, 2019, the Company issued stock options to the Chief Executive Officer, a stockholder of the Company. A total of 10,100,000 fully vested options were granted with an exercise price of 0.17 per share. During the year ended December 31, 2020, the Company paid cash compensation of 229,890 to the Chief Executive Officer through a separate operating company with which the Chief Executive Officer is affiliated. As of December 31, 2020, the Company owed \$12,989 in accounts payable to the separate operating company.

In March 2019, the Company issued 100,000 stock options with an exercise price of \$0.17 per share with immediate vesting to each of the two non-employee members of the Board of Directors, both of whom are stockholders of the Company.

The Company issued a series of convertible notes to the Chairman of the Board which total \$2.5 million and \$2.2 million as of December 31, 2020 and 2019, respectively as described in Note 7.

During the year ended December 31, 2020, the Company issued promissory notes to two members of the Board of Directors, including the Chief Executive Officer, which total \$100,000 as described in Note 7.

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## ENSYSCE BIOSCIENCES, INC. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 12 - SUBSEQUENT EVENTS

The Company evaluated subsequent events requiring recording or disclosure in the consolidated financial statements for the year ended December 31, 2020 and concluded that no events have occurred that would require recognition or disclosure in the consolidated financial statements except as described below:

#### **Financing** Activities

In January 2021, the Company issued a convertible promissory note for proceeds of \$0,000. The note contains the same terms as the 2018 convertible notes discussed in Note 7.

#### Merger

In January 2021, the Company entered into a definitive merger agreement with a SPAC. In connection with the merger, outstanding shares of Ensysce (including shares

resulting from the conversion of Ensysce's convertible debt prior to closing) will be converted in the business combination into the right to receive shares of the SPAC at an exchange ratio of 0.06585. In addition, Ensysce's existing options and warrants will be exchanged for equivalent securities in the SPAC on their existing terms (with standard adjustments to exercise price and underlying shares, consistent with the foregoing exchange ratio).

The proposed transaction has been unanimously approved by the boards of directors of both the Company and the SPAC, and is expected to close in the second quarter of 2021, subject to approval by the SPAC's shareholders, required regulatory approvals, and other customary closing conditions. Upon closing, the SPAC intends to change its name to Ensysce Biosciences, Inc. and remain on the Nasdaq Capital Market, listed under the new ticker symbol ENSC. Management is not in control of the timely filing of all regulatory requirements or the shareholders' approval of the merger, therefore the consummation of the merger with the SPAC and subsequent ability to draw on the share subscription facility are not within management's control.

The contemplated merger with the SPAC will trigger conversion of the 2015 convertible notes and the 2018 convertible notes but will not trigger conversion of the 2020 convertible notes. The 2020 promissory notes are expected to be repaid from the proceeds of the merger with the SPAC or subsequent financing.

In January 2021, the Company terminated an agreement with a strategic advisor. Under terms of the termination agreement, the strategic advisor accepted500,000 private placement warrants to purchase the SPAC's common stock and 500,000 shares of the SPAC's common stock. The securities will be issued upon the Company's consummation of a business combination with the SPAC; if such a business combination is not consummated for any reason, the arrangement will be nullified and the strategic advisor would be eligible to receive a transaction fee if the Company completes a transaction within one year of termination of the agreement.

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#### Ensysce Biosciences, Inc. Unaudited Consolidated Balance Sheets

		March 31, 2021 (Unaudited) (Restated)		December 31, 2020
Assets				
Current assets:				
Cash and cash equivalents	\$	289,927	\$	194,214
Right-of-use asset		16,476		23,538
Prepaid expenses and other current assets		78,880		130,124
Deferred transaction costs		797,902		-
Total current assets		1,183,185		347,876
Property and equipment, net		100		151
Other assets		3,780		3,780
Total assets	\$	1,187,065	\$	351,807
Liabilities and stockholders' deficit	<u> </u>			
Current liabilities:				
Accounts payable	\$	2,229,389	\$	1,724,598
Accrued expenses and other liabilities		614,542		344,792
Lease liability		17,848		25,500
Notes payable and accrued interest		4,526,552		4,245,082
Embedded derivative on convertible notes		709,583		670,262
Total current liabilities		8.097.914		7,010,234
Long-term liabilities:		- , ,-		.,,-
Notes payable, net of current portion		349,272		-
Derivative liabilities, net of current portion		3,316		-
Total liabilities	-	8,450,502		7,010,234
Commitments and contingencies (Note 6)			_	.,,.
Stockholders' deficit				
Preferred stock, \$0.000025 par value, 50,000,000 shares authorized, no shares issued and outstanding at March 31, 2021 (unaudited) and December 31, 2020		-		-
Common stock, \$0.000025 par value, 500,000,000 shares authorized; 243,790,541 and 239,465,160 shares issued and outstanding at March 31, 2021 (unaudited) and December 31, 2020, respectively		6.095		5,987
Additional paid-in capital		49,818,501		49,511,927
Accumulated deficit		(56,866,447)		(55,958,716)
Total Ensysce Biosciences, Inc. stockholders' deficit		(7,041,851)		(6,440,802)
Noncontrolling interests in stockholders' deficit		(221,586)		(217,625)
Total stockholders' deficit		(7,263,437)		(6,658,427)
Total liabilities and stockholders' deficit	\$	1,187,065	\$	351,807
	¢	1,107,005	φ	551,007

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

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#### Ensysce Biosciences, Inc. Unaudited Consolidated Statements of Operations

		Three Months <b>B</b>	Inded March	h 31,
		2021		2020
	(Re	estated)		
deral grants	\$	250,576	\$	862,400
Operating expenses:				
Research and development		284,378		838,970
General and administrative				
		490,471		277,693
Total operating expenses		774,849		1,116,663

Loss from operations	(524,273)	(254,263)
Other income (expense):		
Change in fair value of derivative liability	(39,585)	(439,334)
Interest expense	(347,834)	(329,650)
Total other income (expense), net	(387,419)	(768,984)
Net loss	\$ (911,692)	\$ (1,023,247)
Net loss attributable to noncontrolling interests	\$ (3,961)	\$ -
Net loss attributable to common stockholders	\$ (907,731)	\$ (1,023,247)
Net loss per share, basic and diluted:		
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.00)	\$ (0.00)
Weighted average common shares outstanding, basic and diluted	 240,421,807	 239,465,160

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

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## Ensysce Biosciences, Inc. Unaudited Consolidated Statements of Changes in Stockholders' Deficit

	Stockholders' Deficit						
	Common Stock						
	Number of Shares	A	mount	Additional Paid-In Capital	Accumulated Deficit	Noncontrolling interests	Total
Balance on December 31, 2019	239,465,160	\$	5,987	\$ 49,333,248	\$ (56,015,486)	s -	\$ (6,676,251)
Stock-based compensation	-		-	32,486	-	-	32,486
Net loss	-		-	-	(1,023,247)	-	(1,023,247)
Balance on March 31, 2020	239,465,160	\$	5,987	\$ 49,365,734	\$ (57,038,733)	\$ -	\$(7,667,012)
Balance on December 31, 2020	239,465,160	\$	5,987	\$49,511,927	\$ (55,958,716)	\$ (217,625)	\$ (6,658,427)
Exercise of stock options	4,325,381		108	262,754	-	-	262,862
Stock-based compensation	-		-	43,820	-	-	43,820
Net loss			-		(907,731)	(3,961)	(911,692)
Balance on March 31, 2021 (restated)	243,790,541	\$	6,095	\$ 49,818,501	\$ (56,866,447)	\$ (221,586)	\$(7,263,437)

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

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## Ensysce Biosciences, Inc. Unaudited Consolidated Statements of Cash Flows

		Three Months Ended March 31,		
		2021		2020
	(F	(Restated)		
Cash flows from operating activities:				
Net loss	\$	(911,692)	\$	(1,023,247)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		51		50
Accrued interest		173,422		83,438
Accretion of discounts on promissory notes		174,413		246,211
Change in fair value of embedded derivative		39,586		439,334
Stock-based compensation		43,820		32,486
Lease cost		(589)		-
Changes in operating assets and liabilities:				
Unbilled receivable		-		34,243
Prepaid expenses and other assets		51,244		(294,993)
Accounts payable		(92,184)		148,943
Accrued expenses and other liabilities		4,780		30,117
Net cash used in operating activities		(517,149)		(303,418)
Cash flows from financing activities:				
Proceeds from issuance of promissory notes		50,000		-
Proceeds from issuance of promissory notes to related parties		300,000		200,000
Proceeds from exercise of stock options		262,862		-
Net cash provided by financing activities		612,862		200,000
Increase (decrease) in cash and cash equivalents		95,713	_	(103,418)
Cash and cash equivalents beginning of period		194,214		341,536
Cash and cash equivalents end of period	\$	289,927	\$	238,118
Supplemental cash flow information:				
Income tax payments	\$	1,600	\$	1,600
Supplemental disclosure of non-cash investing and financing activities:				
Fair value of embedded derivative at issuance	\$	3,052	\$	181,541

Deferred transaction costs in accounts payable	\$ 596,975	\$	-
Deferred transaction costs in accrued expenses and other liabilities	\$ 200,927	\$	-
Deterred transaction costs in accrued expenses and other natinities	\$ 200,927	э	

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

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#### NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Ensysce Biosciences, Inc. ("*Ensysce*"), along with its subsidiary, Covistat Inc. ("*Covistat*") and its wholly owned subsidiary EBI Operating, Inc. (collectively, the "*Company*"), is engaged in the development of small and large molecule drug delivery platforms targeting pain and cancer markets. The primary focus of the Company is its small molecule program developing abuse and overdose resistant pain technology with a clinical stage program being the abuse resistant, TAAP (Trypsin Activated Abuse Protection) opioid product candidate, PF614. In addition, the Company is developing its MPAR<sup>TM</sup> (Multi-Pill Abuse Resistant) technology for overdose protection which will be applied to the PF614 program. In 2019, the Company commenced development work applying its TAAP and MPAR technology to a methadone prodrug for use in the treatment of Opioid Use Disorder (OUD). The Company has also developed a delivery platform for large biomolecules utilizing single walled carbon nanotubes (SWCNT) to produce intravenously delivered immunology and gene therapy products.

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

In March 2020, the World Health Organization declared the outbreak of a respiratory disease caused by a new coronavirus as a "pandemic." First identified in late 2019 and known now as COVID-19, the outbreak has impacted millions of individuals worldwide. In response, many countries have implemented measures to combat the outbreak which have impacted global business operations. As of the date of issuance of the consolidated financial statements, the Company's operations have not been significantly impacted; however, the Company continues to monitor the situation. No impairments were recorded as of the balance sheet date as no triggering events or changes in circumstances had occurred as of year-end; however, due to significant uncertainty surrounding the situation, management's judgment regarding this could change in the future. In addition, while the Company's results of operations, cash flows and financial condition could be negatively impacted, the extent of the impact cannot be reasonably estimated at this time.

In June 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, Covistat, Inc., a Delaware corporation. Pursuant to the articles of incorporation, Covistat was authorized to issue 1,000,000 shares of common stock, \$0.001 par value per share, and 100,000 shares of preferred stock, \$0.001 par value per share. Ensysce is a 79.2% shareholder in Covistat, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively.

In January 2021, the Company entered into a definitive merger agreement with a special purpose acquisition company (*SPAC*<sup>\*</sup>). In connection with the merger, outstanding shares of Ensysce (including shares resulting from the conversion of Ensysce's convertible debt prior to closing) will be converted in the business combination into the right to receive shares of the SPAC at an exchange ratio of 0.06585. In addition, Ensysce's existing options and warrants will be exchanged for equivalent securities in the SPAC on their existing terms (with standard adjustments to exercise price and underlying shares, consistent with the foregoing exchange ratio).

The proposed transaction has been unanimously approved by the boards of directors of both the Company and the SPAC, and is expected to close in the second quarter of 2021, subject to approval by the SPAC's shareholders, required regulatory approvals, and other customary closing conditions. Upon closing, the SPAC intends to change its name to Ensysce Biosciences, Inc. and remain on the Nasdaq Capital Market, listed under the new ticker symbol ENSC.

The contemplated merger with the SPAC will trigger conversion of the 2015 convertible notes, the 2018 convertible notes, and the 2021 convertible note but will not trigger conversion of the 2020 promissory notes and 2021 promissory notes are expected to be repaid from the proceeds of the merger with the SPAC or subsequent financing. Refer to Note 7 for details.

As of March 31, 2021, the Company had recorded \$0.8 million of deferred transaction costs, consisting of legal and accounting fees directly related to the merger. The deferred transaction costs will be offset against additional paid-in capital upon completion of the merger. In the event the merger is not completed, any deferred transaction costs will be immediately charged to general and administrative expenses.

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## NOTE 2 - BASIS OF PRESENTATION

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP") and include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

In the opinion of management, all adjustments considered necessary for a fair presentation have been included in the accompanying condensed financial statements. Operating results for the three months ended March 31, 2021, are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. For further information, refer to the audited consolidated financial statements and notes for the year ended December 31, 2020.

The unaudited consolidated financial statements herein have been prepared by the Company pursuant to the rules and regulations of the United States Securities Exchange Commission ("SEC"). The accompanying interim unaudited consolidated financial statements have been prepared under the presumption that users of the interim financial information have either read or have access to the audited consolidated financial statements for the latest year ended December 31, 2020.

#### **Going Concern**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any product revenue and has not achieved profitable operations and is not expected to do so in 2021. The Company has experienced net losses since inception, and had a working capital deficit of \$7.2 million and an accumulated deficit of \$56.9 million at March 31, 2021. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. Product development activities, clinical and preclinical testing, and commercialization of the Company's product candidates are necessary to develop the Company's products and will require significant additional financing. Cash on hand as of May 2021 is not expected to be sufficient to meet the cash flow needs over the next 12 months following the issuance of these consolidated financial statements. Management estimates additional funding will be required to continue development of drug candidates. There can be no assurance the Company will be able to obtain such funds. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern.

In December 2020, the Company executed a share subscription facility with an investment group. Under the agreement, the investor agreed to provide the Company with a share subscription facility of up to \$60.0 million for a 36-month term following the public listing of the Company's common stock. The Company will control the timing and maximum amount of drawdown under this facility and has no minimum drawdown obligation. The investor will pay, in cash, a per-share amount equal to 90% of the average daily closing price of the Company's stock during the 30 consecutive trading days prior to the issuance of a draw notice, which shall not exceed 400% of the average trading volume for the 30 trading days immediately preceding the draw down date. Concurrent with a public listing of the Company's shares, the Company will issue warrants to the

investor to purchase outstanding common stock of Ensysce. The number of warrants issued will be equal to 4% of the common shares outstanding on a fully diluted basis as of the public listing date. The Company must pay a commitment fee to the investor of \$1.2 million with \$800,000 due on the first anniversary of the public listing date and \$400,000 due on the 18-month anniversary of the public listing date. The commitment fee can be paid from the proceeds of a draw against the facility or in freely tradable common stock of the Company. As noted above, in January 2021, the Company executed a definitive merger agreement with a SPAC to effect a public listing of its stock. The agreement with the SPAC has not resulted in the Company's shares being publicly listed; the consummation of the merger is contingent on customary regulatory filings and shareholder approval and is expected to occur in the second quarter of 2021. Management is not in control of the timely filing of all regulatory requirements or the shareholders' approval of the merger, therefore the consummation of the merger with the SPAC and subsequent ability to draw on the share subscription facility are not within management's control.

While the Company believes that, with adequate financial resources, it will be able to ultimately generate revenues from products and services, and further develop and launch its product portfolio, the Company's current cash position is not sufficient to support its plans. While the Company believes in the viability of its strategy to ultimately realize revenues and in its ability to raise additional funds, management cannot be certain that additional funding will be available on acceptable terms, or at all. The Company's ability to continue as a going concern is dependent upon its ability to obtain adequate financing and achieve profitable operations. As a result, these plans do not alleviate substantial doubt about the Company's ability to continue as a going concern for a period of 12 months following the date these financial statements were issued.

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

## NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Correction of Error**

In July 2021, the Company concluded that due to an error in the calculation of accrued research and development expenses as of March 31, 2021, the unaudited consolidated financial statements would be adjusted. The adjustment resulted in a \$240,000 decrease in research and development expenses, net loss and accumulated deficit, with a corresponding decrease in accrued expenses and other liabilities presented in the March 31, 2021 unaudited consolidated financial statements. The adjustment had no impact on earnings per share. There was no impact on fiscal periods other than the three months ended March 31, 2021.

## Use of Estimates and Assumptions

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

#### Cash and Cash Equivalents

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

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

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

#### Property and Equipment

Property and equipment include office and laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives offive to six years. Depreciation expense of \$51 and \$50 was recognized for the three months ended March 31, 2021 and 2020, respectively, and is classified in general and administrative expense in the accompanying consolidated statements of operations.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. There were no such losses for the three months ended March 31, 2021 and 2020.

#### **Derivative Financial Instruments**

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

Between January 2018 and January 2021, the Company entered into a series of notes that were determined to have embedded derivative instruments in the form of a contingent put option. The notes are recognized at the value of proceeds received after allocating issuance proceeds to the bifurcated contingent put option. The notes are subsequently measured at amortized cost using the effective interest method to accrete interest over their term to bring the notes' initial carrying value to their principal balance at maturity. The bifurcated put option is initially measured at fair value and subsequently measured at fair value with changes in fair value recognized as a component of other expenses in the consolidated statements of operations (see Note 7). The notes and the contingent put option are classified as either long-term or short-term liabilities based on the maturity date of the related loan.

## Fair Value Measurement

ASC 820, Fair Value Measurements, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at

the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

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

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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

ASC 820 requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value, and defines fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. As of March 31, 2021 and December 31, 2020, the recorded values of cash and cash equivalents, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

The carrying value of outstanding notes payable approximates the estimated aggregate fair value as the embedded contingent put option is recognized at fair value and classified with the debt host. The put option allows certain notes payable to be converted into common stock, contingent upon completion of an equity financing transaction with gross proceeds above certain thresholds. The fair value estimate of the embedded put option is based on the probability-weighted discounted value of the put feature and represents a Level 3 measurement. Significant assumptions used to determine the fair value of the put feature include the estimated probability of exercise of the put option and the discount rate used to calculate fair value. The estimated probability of exercise is based on management's expectation for future equity financing transactions. The discount rate is based on the weighted average effective yield of notes payable previously issued by the Company, adjusted for changes in market yields of healthcare sector CCC-rated debt. As of March 31, 2021, assumptions included a probability of exercise of the put option of 10% and a discount rate of 42.9%.

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The following table presents assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheets on a recurring basis:

		Mar	ch 31, 2021			
	Total	Level 1	Level 2		Level 3	
Contingent put option	\$ 712,899	\$	- \$	- \$	712,899	
Total	\$ 712,899	\$	- \$	\$	712,899	
		December 31, 2020				
		Decem	iber 31, 2020			
	Total	Decem	ber 31, 2020 Level 2		Level 3	
Contingent put option	<b>Total</b> \$ 670,262		,	- \$	Level 3 670,262	

The following table summarizes the change in fair value of the Company's Level 3 contingent put options:

	March 31, 2021	December 31, 2020		
Beginning fair value	\$ 670,262	\$	2,646,347	
Issuance	3,052		471,823	
Change in fair value	 39,585		(2,447,908)	
Ending fair value	\$ 712,899	\$	670,262	

See Note 7 for further details on the embedded contingent put option.

#### Federal Grants

In September 2018, the National Institutes of Health (*"NIH*") through the National Institute on Drug Abuse awarded the Company a research and development grant related to the development of its MPAR overdose prevention technology (the *"MPAR Grant*"). The total approved budget for the two-year period was approximately \$.4 million (\$3.2 million and \$2.2 million in years 1 and 2 respectively) of which the Company must contribute \$1.1 million in the first year of the grant. In August 2019, the grant was amended such that the approved budget for the two-year period decreased to approximately \$5.1 million (\$2.1 million and \$3.0 million in years 1 and 2, respectively).

In September 2019, the NIH/National Institute on Drug Abuse awarded the Company a second research and development grant related to the development of its TAAP/MPAR abuse deterrent technology (the "*TAAP/MPAR Grant*"). The total approved budget for the two-year period was approximately \$.4 million.

The Company concluded the government grants are not within the scope of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), as government entities do not meet the definition of a "customer" as defined by ASC 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded the government grants do not meet the definition of a contribution and is a non-reciprocal transaction, therefore, ASC 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity, and the grant is with a governmental agency. Revenues from the grants are based upon internal costs related to the grants. The Company believes this policy is consistent with the overarching premise in ASC 606, applied by analogy, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in ASC 606. The Company believes the recognition of revenue as costs are incurred and amounts become due is analogous to the concept of transfer of control of a service over time under ASC 606.

Revenue recognized under the MPAR Grant was approximately \$73,726 and \$691,131 during the three months ended March 31, 2021 and 2020, respectively. Revenue recognized under the TAAP/MPAR Grant was approximately \$176,850 and \$171,269 during the three months ended March 31, 2021 and 2020, respectively.

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

## **Research and Development Costs**

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

#### General and Administrative Expenses

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

#### Stock-based Compensation

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

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the three months ended March 31, 2021 and 2020, stock-based compensation costs are recorded in general and administrative expenses in the consolidated statements of operations.

#### Income Taxes

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

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

#### Net Loss per Share

The basic net loss per share is calculated by dividing the Company's net loss attributable to common stockholders by the weighted average number of common shares outstanding during the year. The diluted net loss per share is calculated by dividing the Company's net loss attributable to common stockholders by the diluted weighted average number of common shares outstanding during the year. The following weighted average shares have been excluded from the calculations of diluted weighted average common shares outstanding because they would have been anti-dilutive:

	Three Months Ended	l March 31,
	2021	2020
Stock options	70,069,228	87,603,148
Warrants	300,000	300,000
Total	70,369,228	87,903,148



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

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes ("*ASU 2019-12*"), which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 31, 2021 and interim periods within that year. Early adoption is permitted. The Company is evaluating the impact of ASU 2019-12 on the consolidated financial statements.

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

## NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	March 31, 2021	D	ecember 31, 2020
Prepaid research and development	\$ 51,065	\$	112,966
Prepaid insurance	22,508		17,158
Prepaid rent	2,550		-

Other prepaid expenses	_	2,757	 -
Total prepaid expenses and other current assets	\$	78,880	\$ 130,124
	=		

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## NOTE 5 - ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consisted of the following:

	 March 31, 2021		December 31, 2020	
Professional fees	\$ 315,830	\$	13,755	
Deferred grant revenue	100,215		159,047	
Accrued research and development	57,655		72,906	
Accrued scientific advisory board fees	60,032		60,032	
Other accrued liabilities	 80,810		39,052	
Total accrued expenses and other liabilities	\$ 614,542	\$	344,792	

#### NOTE 6 - COMMITMENTS AND CONTINGENCIES Litization

As of March 31, 2021 and December 31, 2020, there were no pending legal proceedings against the Company that are expected to have a material adverse effect on cash flows, financial condition or results of operations. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

#### Lease

During the three months ended March 31, 2020, the Company leased office space on a month-to-month basis.

In August 2020, the Company entered into an agreement to lease office space. The lease commencement date wasOctober 1, 2020 and the lease will terminate October 31, 2021 with no option to renew. As of March 31, 2021, the future lease payments totaled \$7,850.

The Company recognized total rent expense of \$12,379 and \$9,727 in the three months ended March 31, 2021 and 2020, respectively.

## NOTE 7 - NOTES PAYABLE

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

	Principal balance	Accrued interest	Unamortized discount		t debt balance
2015 convertible notes	\$ 100,000	\$ 29,904	1 \$	- \$	129,904
2018 convertible notes	3,500,000	814,208	3 (63	30,852)	3,683,356
2020 promissory notes	100,000	4,194	1	-	104,194
2020 convertible notes	700,000	46,986	5 (13	37,888)	609,098
2021 promissory notes	300,000	1,250	)	-	301,250
2021 convertible notes	50,000	835	5	(2,813)	48,022
Total	\$ 4,750,000	\$ 897,377	7 \$ (77	71,553) \$	4,875,824
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The following table provides a summary of the Company's outstanding debt as of December 31, 2020:

					Unan	nortized debt		
	Princ	ipal balance	Accr	ued interest		discount	Net	debt balance
2015 convertible notes	\$	100,000	\$	28,671	\$	-	\$	128,671
2018 convertible notes		3,500,000		727,905		(783,124)		3,444,781
2020 promissory notes		100,000		1,694		-		101,694
2020 convertible notes		700,000		29,726		(159,790)		569,936
Total	\$	4,400,000	\$	787,996	\$	(942,914)	\$	4,245,082

During the three months ended March 31, 2021, interest expense for all notes payable was recognized in the amounts of \$09,381 and \$174,412 related to the face value interest and the amounts of the discount due to the embedded derivative instrument, respectively. During the three months ended March 31, 2020, interest expense was recognized in the amounts of \$83,438 and \$246,211 related to the face value interest and the amortization of the debt discount due to the embedded derivative instrument, respectively. The remaining debt discount is expected to be amortized over 1.1 years at an effective interest rate of 50.7%, which represents the weighted average remaining term of the notes and the weighted average effective interest rate, respectively.

#### 2015 Convertible Notes Payable

During 2015, the Company issued certain convertible promissory notes in the aggregate principal amount of \$73,000. During 2017 and 2018, all but \$100,000 were converted into common shares of Ensysce. The remaining convertible promissory note bears interest at 5% per annum, is due on demand (principal and interest) and is mandatorily convertible at a variable price per share equal to 80% of the price received in certain future equity transactions.

#### 2018 Convertible Notes Payable

Between January 2018 and December 2020, the Company received financing totaling \$\$,500,000 under a series of unsecured promissory notes with a stockholder and board member (\$2,500,000) and an unrelated party (\$1,000,000). The promissory notes mature 24 months from the date of issuance and bear interest at the rate of 0% per annum.

The promissory notes, together with all interest as accrued, can be converted into shares of Ensysce's common stock at the option of the noteholder, at 50% of the price paid per share for equity securities by the investors in a subsequent equity financing of no less than \$5,000,000 gross proceeds (the "contingent put option"). The contingent put option is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3).

Additionally, if there is an initial public offering or reverse merger that results in Ensysce becoming publicly listed, the promissory notes automatically convert to equity at the lower of \$0.25 per share or the then-current Enterprise Value per share (the "automatic conversion option"). Enterprise Value per Share is defined as market capitalization, debt and preferred stock less cash and cash equivalents divided by the common stock of Ensysce on the measurement date, not to exceed \$55 million. The Company assessed whether the automatic conversion option should be accounted for separately from the debt host and concluded that as the common shares of Ensysce are currently not publicly traded and thus are not considered readily convertible to cash, the automatic conversion option cannot be net settled. Further, the conversion price of the promissory notes exceeded the per share fair value of Ensysce's common stock on each issuance date and, consequently, no beneficial conversion feature exists.

The promissory notes also include a change in control call option whereby, upon the close of a sale of Ensysce, other than an initial public offering, Ensysce has the right to prepay the promissory notes at 200% of the principal outstanding plus all accrued and unpaid interest. This call option is required to be bifurcated because it is considered to not be clearly and closely related to the debt host. However, the Company has concluded that as of each balance sheet date presented, the exercise of this call option is not probable and thus the call option has a de minimis value. The Company will reassess the probability of the Company exercising this call option at each reporting period during the term of these promissory notes.

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In June 2020, the board resolved to extend the maturity of all 2018 convertible notes payable issued in 2018 by one year. The Company did not incur legal fees or other additional costs to effect the modification. The modification met the criteria to be classified as a troubled debt restructuring under ASC 470-50. The effective interest rate was recalculated to reflect the modified expected term of the notes and no gain or loss was recognized.

## 2020 Promissory Notes Payable

During the year ended December 31, 2020, the Company received financing totaling \$100,000 under a series of unsecured promissory notes with the Chief Executive Officer and a board member. The promissory notes bear interest at a rate of 10% per annum and mature December 31, 2021 or upon certain financing transactions, whichever is earlier.

## 2020 Convertible Notes Payable

During the year ended December 31, 2020, Covistat received financing totaling \$700,000 under a series of unsecured promissory notes with unrelated parties. The notes mature in July 2022 and bear interest at a rate of 10% per annum. The notes cannot be prepaid without the prior consent of the holder. The notes, together with all accrued and unpaid interest, are automatically convertible upon an initial public offering of Covistat shares or a private sale of a single class of Covistat's equity securities with gross proceeds of at least \$2.0 million within a 12-month period. The notes are convertible at the option of the holder at maturity. With respect to an automatic conversion, the conversion price will be the lesser of (a) 80% of the per-share price of the equity securities sold or (b) the price equal to \$10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. With respect to an optional conversion price will be the price equal to \$10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. With respect to an optional conversion price will be the price equal to \$10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. We recorded in earnings (see Note 3).

#### 2021 Convertible Note Payable

In January 2021, the Company received financing totaling \$50,000 under an unsecured convertible note. The convertible note bears interest at a rate of 10% per annum and matures January 28, 2023. The promissory note, together with accrued interest, would be automatically converted into shares of Ensysce's common stock a80% of the price paid per share for equity securities by investors in an IPO or equity financing of no less than \$10.0 million gross proceeds. The conversion feature is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3).

#### 2021 Promissory Notes Payable

In March 2021, the Company received financing totaling \$300,000 under unsecured promissory notes issued to related parties including the Chief Executive Officer and the Chairman of the Board. The notes mature on the earlier of June 30, 2022 or the Company's receipt of gross proceeds of at least \$2.0 million from the sale of common or preferred stock and bear interest at a rate of 10% per annum.

## NOTE 8 - STOCKHOLDERS' EQUITY

In February 2018, the Company amended and restated its articles of incorporation to increase the authorized shares of common stock to500,000,000 shares and authorized the issuance of 50,000,000 shares of preferred stock. Pursuant to the Company's amended and restated articles of incorporation, as of March 31, 2021, the Company was authorized to issue 500,000,000 shares of common stock with a par value of \$0.00025 per share and 50,000,000 shares of preferred stock, par value \$0.000025. As of March 31, 2021 and December 31, 2020, there were no shares of preferred stock issued and outstanding.

In January 2021, the Company terminated an agreement with a strategic advisor. Under the terms of the termination agreement, the strategic advisor accepted500,000 private placement warrants to purchase the SPAC's common stock and 500,000 shares of the SPAC's common stock. The securities will be issued upon the Company's consummation of a business combination with the SPAC; if such a business combination is not consummated for any reason, the arrangement will be nullified and the strategic advisor would be eligible to receive a transaction fee if the Company completes a transaction within one year of the termination of the agreement.

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#### **Common Stock**

As of March 31, 2021 and December 31, 2020 the Company had a total of 243, 790, 541 and 239, 465, 160 shares of common stock issued and outstanding, respectively.

## Warrants

In February 2013, the Company issued 200,000 warrants to purchase common stock. The warrants have a ten-year life and have an exercise price of \$0.41 per share. As of March 31, 2021 and December 31, 2020, the warrants remained outstanding.

In August 2019, the Company issued 100,000 warrants in connection with the issuance of convertible debt. The warrants have a ten-year life and have an exercise price of \$0.20. As of March 31, 2021 and December 31, 2020, the warrants remained outstanding.

## NOTE 9 - STOCK-BASED COMPENSATION

In 2016, the Company adopted the Ensysce Biosciences, Inc. 2016 Stock Incentive Plan (the "2016 Plan"). In February 2019, the Board and stockholders authorized an increase

in the shares reserved under the 2016 Plan from 75,000,000 to 100,000,000. The 2016 Plan, as amended, allows for the issuance of non-statutory stock options, incentive stock options and other equity awards. Grants pursuant to the 2016 Plan may be made to the Company's employees, directors, and consultants.

In March 2019, the Company adopted the 2019 Directors Plan, which was amended in August 2020. The 2019 Directors Plan, as amended, allows for the issuance of up to 2,500,000 shares of the Company's common stock pursuant to the grant of non-statutory stock options.

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

As of March 31, 2021 and December 31, 2020, the options outstanding under each plan were as follows:

	March 31,	December 31,
	2021	2020
Legacy Plans	4,022,288	8,247,669
2016 Plan	61,265,500	61,265,500
2019 Directors Plan	2,200,000	2,300,000
Total options outstanding	67,487,788	71,813,169

#### **Option** Activity

During the three months ended March 31, 2020, the Company granted stock options to purchase an aggregate of1,000,000 shares of common stock to a member of the board of directors. The options vest over three years and have an exercise price of \$0.22 per share.

The Company recognized within general and administrative expense stock-based compensation expense of \$43,820 and \$32,486 for the three months ended March 31, 2021 and 2020, respectively. During the three months ended March 31, 2021 and 2020, there was no stock-based compensation allocated to research and development expense.

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The following table summarizes the Company's stock option activity the three months ended March 31, 2021:

	_	Weighted average			
Options	E	xercise price	Remaining contractual life	Int	rinsic value
71,813,169	\$	0.15	6.8	\$	1,817,383
-	\$	-		\$	-
(4,325,381)	\$	0.06		\$	472,453
-	\$	-		\$	-
67,487,788	\$	0.16	7.0	\$	1,344,930
65,543,350	\$	0.16	6.9	\$	1,328,263
67,487,788	\$	0.16	7.0	\$	1,344,930
	71,813,169 (4,325,381) 67,487,788 65,543,350	71,813,169 \$ - \$ (4,325,381) \$ - \$ <u>67,487,788</u> \$ <u>65,543,350</u> \$	Options         Exercise price           71,813,169         \$         0.15           -         \$         -           (4,325,381)         \$         0.06           -         \$         -           (4,325,381)         \$         0.06           -         \$         -           (67,487,788)         \$         0.16           65,543,350         \$         0.16	Options         Exercise price         Remaining contractual life           71,813,169         \$ 0.15         6.8           -         \$ -         -           (4,325,381)         \$ 0.06         -           -         \$ -         -           67,487,788         \$ 0.16         7.0           65,543,350         \$ 0.16         6.9	Options         Exercise price         Remaining contractual life         Int           71,813,169         \$         0.15         6.8         \$           -         \$         -         \$         \$         \$           (4,325,381)         \$         0.06         \$         \$           -         \$         -         \$         \$           -         \$         -         \$         \$           67,487,788         \$         0.16         6.9         \$

#### **Option Valuation**

The fair value of each stock option granted has been determined using the Black-Scholes option-pricing model. The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows:

	Three mon	ths ended
	March 3	1, 2021
Stock price	\$	0.17
Exercise price	\$	0.22
Expected stock price volatility		124.0%
Expected term (years)		5.8
Risk-free interest rate		1.52%
Expected dividend yield		0%

• Expected stock-price volatility. The expected volatility is derived from the historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.

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

The weighted-average grant date fair value of options granted during the three months ended March 31, 2020 was \$0.15. There were no options granted during the three months ended March 31, 2021.

As of March 31, 2021, the Company had an aggregate of \$115,633 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 2.1 years.

#### Shares Reserved for Future Issuance

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

6	March 31, 2021
Stock options outstanding	67,487,788
Stock options available for future grant under 2016 Plan	38,734,500
Stock options available for future grant under 2019 Directors Plan	200,000

Warrants outstanding	300,000
Total shares of common stock reserved for future issuance	106,722,288

## NOTE 10 - RELATED PARTIES

During the three months ended March 31, 2021 and 2020, the Company paid cash compensation of \$3,146 and \$12,989, respectively, to the Chief Executive Officer through a separate operating company with which the Chief Executive Officer is affiliated. As of March 31, 2021 and December 31, 2020, the Company owed \$3,584 and \$12,989, respectively, in accounts payable to the separate operating company.

The Company issued a series of convertible notes to the Chairman of the Board as described in Note 7, which totaled \$.5 million as of March 31, 2021 and December 31, 2020.

As of March 31, 2021 and December 31, 2020, the Company had promissory notes outstanding to three members of the board of directors, including the Chief Executive Officer and Chairman of the Board, which totaled \$400,000 and \$100,000, respectively, as described in Note 7.

#### NOTE 11 - SUBSEQUENT EVENTS

The Company evaluated subsequent events requiring recording or disclosure in the unaudited consolidated financial statements for the three months ended March 31, 2021 through the date the financial statements were issued and concluded that no events have occurred that would require recognition or disclosure in the consolidated financial statements except as described below:

In May 2021, the Company issued a promissory note to a member of the Board of Directors for proceeds of \$0,000. The note contains the same terms as the 2021 promissory notes discussed in Note 7.

On June 30, 2021, the Company completed a merger with a SPAC in accordance with the terms of the definitive merger agreement entered into in January 2021. The Company received \$7.8 million in cash proceeds from the merger. The closing of the merger triggered conversion of the convertible notes payable. The promissory notes payable were repaid in July 2021 from the cash proceeds of the merger.

On July 2, 2021, the Company issued 1,106,108 warrants to an investor pursuant to the share subscription facility described in Note 2. The warrants have athree-year contractual term and an exercise price of \$10.01. In addition, the Company became obligated to pay a commitment fee of \$1,200,000 as described in Note 2.

On July 12, 2021, following the Company's business combination with a SPAC, the Company's former financial advisor filed an action against the Company and its Chief Executive Officer alleging that the common stock and warrants issued to the former advisor in satisfaction of its advisory fee should have been registered and immediately tradeable. On August 3, 2021, the parties entered into a settlement agreement whereby the former advisor would have their common stock and the common stock underlying their warrants registered on the Company's Form S-1 registration statement. In addition, the warrants would be modified to allow for cashless exercise and to reduce the exercise price from \$11.50/share to \$10.00/share. In consideration for this, both parties agreed to release the other from any past, present or future claims. In addition, the former advisor agreed to immediately stay the proceedings and inform the Superior Court of a conditional settlement and to dismiss the lawsuit with prejudice five days following the effectiveness of a registration statement on Form S-1.

On July 22, 2021, the Company engaged consultants to perform certain public and investor relations services in consideration for 500,000 warrants, 50,000 shares of common stock, and 200,000 restricted stock units. The restricted stock units vest over one year with 50% of the vesting contingent upon certain market conditions.

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following is a statement of estimated expenses payable by the registrant in connection with the offering described in this registration statement. All amounts are estimates except the SEC registration fee.

SEC expenses	\$ 28,489
Accounting fees and expenses	[•]
Legal fees and expenses	[•]
Miscellaneous	 [•]
Total <sup>(1)</sup>	\$ [•]

(1) Discounts, concessions, commissions and similar selling expenses attributable to the sale of shares of common stock covered by this prospectus will be borne by the selling securityholders. We will pay all expenses (other than discounts, concessions, commissions and similar selling expenses) relating to the registration of the shares with the Securities and Exchange Commission, as estimated in the table above.

#### Item 14. 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, 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 is or was a director, 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 c

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.

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The registrant intends to enter 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 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

- LACQ issued an aggregate of 1,000,001 private warrants exercisable for 1,000,001 shares of common stock to Hydra Management, LLC ("Hydra"), Matthews Lane
  Capital Partners LLC ("MLCP" and together with Hydra, the "Sponsors"), and HG Vora Capital Management LLC on behalf of one or more funds or accounts managed
  by it (the "Strategic Investor") in connection with their conversion of promissory notes covering \$1,000,000 of loans to LACQ under an Expense Advancement
  Agreement, as amended, among LACQ, the Sponsors and the Strategic Investor (the "Expense Advancement Agreement").
- On January 31, 2021, LACQ issued 566,288 warrants exercisable for up to 566,288 shares of common stock to Gateway Holdings Limited in exchange for previously
  outstanding loans under the Expense Advancement Agreement dated December 5, 2019 between LACQ and Gateway Holdings Limited, as amended (the "GTWY
  Expense Advancement Agreement").
- On June 7, 2021, LACQ entered into exchange agreements with each of the holders of (i) LACQ's warrants issued by LACQ to the Sponsors and the Strategic Investor (the "Private Placement Warrants") and (ii) other private warrants held by the Sponsors, the Strategic Investor, certain members of former LACQ management and unaffiliated parties. Pursuant to the exchange agreements, each of these holders exchanged their warrants for new private warrants. In connection with this exchange, an aggregate of 8,391,289 Private Placement Warrants and other private warrants were exchanged for new private warrants in a transaction exempt from registration under the Act pursuant to Section 3(a)(9) of the Act.
- On June 7, 2021, we issued 500,000 warrants exercisable for up to 500,000 shares of common stock to DelMorgan Group LLC (the "DelMorgan") under the terms of the Email Agreement, dated January 31, 2021, among us and DelMorgan, as amended by the First Amendment to the Email Agreement, dated June 7, 2021 (the "Email Agreement").
- On June 30, 2021, we issued warrants to the Sponsors and the Strategic Investor to purchase 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants in exchange for outstanding loans under the Expense Advancement Agreement.
- On June 30, 2021, we issued 1,106,108 warrants with a 36-month term to purchase 1,106,108 shares of our common stock at a strike price per share equal to \$10.01, to GEM Yield Bahamas Limited ("GYBL").
- On June 30, 2021, we issued 125,000 shares of common stock to the underwriters in LACQ's initial public offering to satisfy deferred underwriting fees payable to such underwriters.
- On July 22, 2021, we entered into agreements with consultants to issue up to 1,500,000 shares of common stock in the form of non-transferable warrants with a five-year term to purchase 1,000,000 shares of common stock at a strike price per share equal to \$6.28 and up to 500,000 shares of common stock based on certain service and market price conditions.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise set forth above, we believe each of these transactions was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) as transactions by an issuer not involving any public offering or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

#### Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

No.	Description of Exhibit
2.1†	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
3.1	Third Amended and Restated Certificate of Incorporation of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.1 filed with Enscysce Biosciences,
3.2	Inc.'s Current Report on Form 8-K on July 7, 2021). Amended and Restated Bylaws of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.2 filed with Ensysce's Biosciences, Inc.'s Current Report on
4.1	Form 8-K on July 7, 2021). Warrant Agreement, dated December 1, 2017, between the Leisure Acquisition Corp. and Continental Stock Transfer & Trust Company (incorporated by
4.2	reference to Exhibit 4.1 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on December 5, 2017). Common Stock Purchase Warrant in the amount of 100,000 shares of common stock of Ensysce Biosciences, Inc. dated as of August 13, 2019 (incorporated by
4.3	reference to Exhibit 4.5 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021). 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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.4	Warrant Certificate issued to Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 4.7 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.5	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
5.1*	Opinion of Troutman Pepper Hamilton Sanders LLP
10.1	Registration Rights Agreement, dated December 1, 2017, among Leisure Acquisition Corp. and certain securityholders (incorporated by reference to Exhibit 10.2
10.2	filed with the Company's Current Report on Form 8-K on December 5, 2017). Warrant Purchase Agreement, dated December 1, 2017, between Leisure Acquisition Corp. and certain security holders (incorporated by reference to Exhibit 10.3).
10.3(a)	filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on December 5, 2017). Administrative Services Agreement, dated December 1, 2017, between Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by reference to
10.3(b)	Exhibit 10.4 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on December 5, 2017). Amendment to the Administrative Services Agreement, dated August 7, 2020 between Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by
10.3(a)	reference to Exhibit 10.1 filed with Leisure Acquisition Corp.'s Quarterly Report on Form 10-Q on November 9, 2020). Expense Advancement Agreement, dated December 1, 2017, between Leisure Acquisition Corp., HG Vora Special Opportunities Master Fund, Ltd., Hydra Management, LLC and Matthews Lane Capital Partners LLC (incorporated by reference to Exhibit 10.5 filed with Leisure Acquisition Corp.'s Current Report on
10.4(b)	Form 8-K on December 5, 2017). Amendment to Expense Advancement Agreement, dated June 29, 2020 (incorporated by reference to Exhibit 10.2 filed with Leisure Acquisition Corp.'s Current
10.4(0)	Antendment to Expense Advancement Agreement, dated June 29, 2020 (incorporated by reference to Exmott 10.2 med with Leisure Acquisition Corp.'s Current Report on Form 8-K on June 30, 2020).
10.4(c)	Amendment No. 2 to Expense Advancement Agreement, dated October 26, 2020 (incorporated by reference to Exhibit 10.1 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on October 29, 2020).
10.4(d)	Amendment No. 3 to Expense Advancement Agreement, dated November 30, 2020 (incorporated by reference to Exhibit 10.2 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on November 30, 2020).
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10.4(e)	Amendment No. 4 to Expense Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with Leisure Advancement) (incorporated by reference to Exhibit 10.2 filed with 10.2 file	cquisition Corp.'s
	Current Report on Form 8-K on February 25, 2021).	· ·

- 10.4(f) Form of Amended and Restated Promissory Note relating to Expense Advancement Agreement (incorporated by reference to Exhibit 10.1 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on February 25, 2021).
- 10.5(a) Letter Agreement, dated December 1, 2017, among the Leisure Acquisition Corp., its officers, directors and securityholders (incorporated by reference to Exhibit 10.6 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on December 5, 2017).
- 10.5(b) Amendment to Letter Agreement, dated December 5, 2019 (incorporated by reference to Exhibit 10.6(b) filed with Leisure Acquisition Corp.'s Annual Report on Form 10-K on March 10, 2020).
- 10.6 Contingent Forward Purchase Contract, dated December 1, 2017, between Leisure Acquisition Corp. and HG Vora Special Opportunities Master Fund, Ltd (incorporated by reference to Exhibit 10.7 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on December 5, 2017).
- 10.7 Form of Director and Officer Indemnity Agreement (incorporated by reference to Exhibit 10.8 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
- 10.8 Securities Subscription Agreement, dated September 11, 2017, between the Registrant and HG Vora Special Opportunities Master Fund, Ltd (incorporated by reference to Exhibit 10.4 filed with the Company's Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
   10.9 Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by reference to
- Exhibit 10.5 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
   Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by reference to Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by reference to Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by reference to Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by Securities Subscription Agreement, dated Securities Subscrities Subscription Agreement, dated Securities Subscription Agr
- 10.10 Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by reference to Exhibit 10.6 filed with the Leisure Acquisition Corp.'s Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
- 10.11(a) Expense Advance Agreement, dated December 5, 2019, between Leisure Acquisition Corp. and GTWY Holdings Limited (incorporated by reference to Exhibit 10.12 filed with Leisure Acquisition Corp.'s Annual Report on Form 10-K on March 10, 2020).
- 10.11(b) Amendment to GTWY Holdings Limited Promissory Note, dated January 31, 2021 (incorporated by reference to Exhibit 10.3 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on February 2, 2021).
- 10.11(c) Letter Agreement, dated June 7, 2021, between Leisure Acquisition Corp. and Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 10.12(c) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
   10.11(c) Letter Agreement, dated June 7, 2021, between Leisure Acquisition Corp. and Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 10.12(c) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.11(d) Exchange Agreement, dated June 7, 2021, between Leisure Acquisition Corp. and Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 10.12(d) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
   10.12
- 10.12 Fee Waiver Letter, dated November 23, 2020 (incorporated by reference to Exhibit 10.3 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on November 30, 2020).
- 10.13 Fee Waiver Letter, dated January 31, 2021 (incorporated by reference to Exhibit 10.2 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on February 2, 2021).
- 10.14 Warrant Surrender Agreement, among MLCP GLL Funding LLC, Hydra LAC, LLC, and Leisure Acquisition Corp., dated January 31, 2021 (incorporated by reference to Exhibit 10.1 filed with Leisure Acquisition Corp.'s Current Report on Form 8-K on February 2, 2021).
- 10.15 Form of Lock-up Agreement executed by each of the Ensysce's directors and executive officers (incorporated by reference to Exhibit 10.16 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).

10.16 Unsecured 10% Convertible Promissory Notes issued by the Company to Bob Gower in the aggregate amount of \$2,500,000 on the following dates for the following amounts: May 4, 2018 in the amount of \$600,000, September 14, 2018 in the amount of \$1,000,000, December 31, 2018 in the amount of \$500,000, October 17, 2019 in the amount of \$100,000, January 23, 2020 in the amount of \$100,000, March 9, 2020 in the amount of \$100,000, and April 15, 2020 in the amount of \$100,000, each as amended (incorporated by reference to Exhibit 10.17 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).

- 10.17 Unsecured 10% Convertible Promissory Notes issued by the Company to Paul Vezolles in the aggregate amount of \$1,000,000 on the following dates for the following amounts: May 11, 2018 in the amount of \$200,000, July 6, 2018 in the amount of \$200,000, September 7, 2018 in the amount of \$200,000, and August 13, 2019 in the amount of \$400,000, each as amended (incorporated by reference to Exhibit 10.18 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.18 Consulting Arrangement of the Company for Lynn Kirkpatrick reflected in the Action by Unanimous Written Consent by the Compensation Committee of the Company dated January 15, 2016 (incorporated by reference to Exhibit 10.20 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.19 Agreement and Plan of Merger by and among the Signature Therapeutics, Inc., Signature Acquisition Corp. and the Company dated December 28, 2015 (incorporated by reference to Exhibit 10.21 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.20 Promissory Note in the amount of \$50,000 to Dr. Lynn Kirkpatrick on August 3, 2020 (incorporated by reference to Exhibit 10.22 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- Promissory Note in the amount of \$50,000 to Andrew Benton on August 3, 2020 (incorporated by reference to Exhibit 10.23 filed with Leisure Acquisition 10.21 Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.22 Employment Offer Letter to Richard Wright dated July 31, 2017 (incorporated by reference to Exhibit 10.24 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- Consulting Agreement between the Company and Geoff Birkett effective as of July 8, 2018 (incorporated by reference to Exhibit 10.25 filed with Leisure 10.23 Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.24 Employment Agreement between the Company and David Humphrey dated February 11, 2021 (incorporated by reference to Exhibit 10.26 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- Amendment to Offer Letter between the Company and David Humphrey dated February 23, 2021 (incorporated by reference to Exhibit 10.27 filed with the 10.25 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.26 2021 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.28 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.27 Share Purchase Agreement between the Company, GEM Global Yield LLC SCS and GEM Yield Bahamas Limited dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date and form of Warrant to Purchase Common Shares of Ensysce Biosciences, Inc. issued by the Company to GEM Yield Bahamas Limited (incorporated by reference to Exhibit 10.29 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.28† Technology Transfer Agreement by and among the Company, Covistat, Inc., Mucokinetica, Ltd., Roderick Hall and Peter Cole dated August 5, 2020 (incorporated by reference to Exhibit 10.30 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.29† Consulting Agreement between Roderick Hall and Covistat, Inc. dated August 5, 2020 (incorporated by reference to Exhibit 10.31 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).

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- 10.30† Consulting Agreement between Peter Cole and Covistat, Inc. dated August 5, 2020 (incorporated by reference to Exhibit 10.32 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.31 Promissory Note in the amount of \$100,000 to Dr. Lynn Kirkpatrick on March 16, 2021 (incorporated by reference to Exhibit 10.33 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.32 Promissory Note in the amount of \$200,000 to Bob Gower on March 16, 2021 (incorporated by reference to Exhibit 10.34 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.33 Manufacturing Agreement between Recro Gaineville LLC and the Company dated September 11, 2019 (incorporated by reference to Exhibit 10.35 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.34(a) Form of Exchange Agreement between Leisure Acquisition Corp. and the holders of Private Placement Warrants (incorporated by reference to Exhibit 10.36(a)) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.34(b) Form of Exchange Agreement to be entered into by the Company with each of the Sponsors and the Strategic Investor (incorporated by reference to Exhibit 10.36(b) filed with the Company's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.35 10.0% Convertible Promissory Note issued by the Company to Feliciano Global Enterprises Inc. on January 28, 2021 (incorporated by reference to Exhibit 10.37 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
- 10.36(a) Email Agreement, dated January 31, 2021, between the Company and DelMorgan Group LLC (incorporated by reference to Exhibit 10.38(a) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).

- Engagement Agreement with David L. Kovacs (a portion of Appendix B to the exhibit has been omitted).
- 10.38\* Engagement Agreement with Mercury FundingCo, LLC (a portion of Appendix B to the exhibit has been omitted).
- 21.1\* List of Subsidiaries
- 23.1\* Consent of Troutman Pepper Hamilton Sanders LLP (included in Exhibit 5.1)
- 23.2\* Consent of Marcum LLP
- 23.3\* Consent of Mayer Hoffman McCann P.C.
- 24.1\* Power of Attorney (included on signature page to this registration statement)
- (101)Interactive Data File

- 101.SCH ++Inline XBRL Taxonomy Extension Schema Document
- 101.CAL ++Inline XBRL Taxonomy Extension Calculation Document
- 101.LAB ++Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE ++Inline XBRL Taxonomy Extension Presentation Linkbase Document
- ++Inline XBRL Taxonomy Extension Definition Linkbase Document 101.DEF

First Amendment to the Email Agreement, dated June 7, 2021, between the Company and DelMorgan Group LLC (incorporated by reference to Exhibit 10.38(b) 10.36(b) filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021). 10.37\*

<sup>++</sup>Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)

- † 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.
- ++ Pursuant to Rule 406T of Regulation S-T, this interactive data file is deemed not "filed" or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, is deemed not "filed" for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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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 Registration Fee" 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.
- (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) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, in a primary offering of securities of the 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 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 registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the registrant or used or referred to by the registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the registrant or its securities provided by or on behalf of the registrant to the purchaser.
- (5) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (6) That, prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the registrant undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.
- (8) That every prospectus (i) that is filed pursuant to the immediately preceding paragraph, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment has become effective, and 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.
- (9) Insofar as indemnification for liabilities arising under the Securities Act 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 SEC, such indemnification is against public policy as expressed in the Securities 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 Securities 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, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, State of California, on August 6, 2021.

**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-infact, 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, 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 attorney-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 August 6, 2021.

	Name	Title
By:	/s/ Dr. Lynn Kirkpatrick Dr. Lynn Kirkpatrick	President, Chief Executive Officer and Director (Principal Executive Officer)
By:	/s/ David Humphrey David Humphrey	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)
By:	/s/ Andrew Benton Andrew Benton	Director
By:	/s/ William Chang William Chang	Director
By:	/s/ Bob Gower Bob Gower	Director and Chairman of the Board
By:	/s/ Adam Levin Adam Levin	Director
By:	/s/ Steve Martin Steve Martin	Director
By:	/s/ Curtis Rosebraugh Curtis Rosebraugh	Director
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#### troutman.com

August 6, 2021

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

Ladies and Gentlemen:



Exhibit 5.1

We are acting as counsel to Ensysce Biosciences, Inc., a Delaware corporation (the "<u>Company</u>"), in connection with the registration statement on Form S-1 (the "<u>Registration</u> <u>Statement</u>"), filed with the Securities and Exchange Commission (the '<u>SEC</u>"), including a related prospectus included in the Registration Statement (the "<u>Prospectus</u>"), on August 6, 2021, relating to the registration under the Securities Act of 1933, as amended (the "<u>Act</u>"), of (a) the issuance of shares of common stock, \$0.0001 par value per share (the "<u>Common Stock</u>"), of the Company upon the exercise of warrants issued by the Company, and (b) the resale of Common Stock and warrants issued by the Company held by certain stockholders and holders of outstanding warrants of the Company, as follows:

- the issuance of up to 10,000,000 shares (the "<u>Public Warrant Shares</u>") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "<u>Public Warrants</u>") by the holders thereof;
- (ii) the issuance of up to 6,325,000 shares (the "<u>Private Placement Warrant Shares</u>") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "<u>Private Placement Warrants</u>") by the holders thereof;
- (iii) the issuance of up to 1,106,108 shares (the "<u>GEM Warrant Shares</u>") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "<u>GEM Agreement Warrants</u>") by the holder thereof;
- (iv) the issuance of up to 1,000,001 shares (the "Expense Advancement Agreement Warrant Shares") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "Expense Advancement Agreement Warrants") by the holders thereof;
- (v) the issuance of up to 566,288 shares (the "<u>GTWY Expense Advancement Agreement Warrant Shares</u>") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "<u>GTWY Expense Advancement Agreement Warrants</u>") by the holders thereof;
- (vi) the issuance of up to 510,001 shares (the "Expense Advancement Agreement Loan Warrant Shares") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "Expense Advancement Agreement Loan Warrants") by the holders thereof;
- (vii) the issuance of up to 1,000,000 shares (the <u>'Consultant Warrant Shares</u>'') of Common Stock issuable upon the exercise of currently outstanding warrants to purchase Common Stock (the <u>'Consultant Warrants</u>'') by the holders thereof;
- (viii) the issuance of up to 500,000 shares (the "Email Agreement Warrant Shares," and together with the Public Warrant Shares, Private Placement Warrant Shares, GEM Warrant Shares, Expense Advancement Agreement Warrant Shares, the GTWY Expense Advancement Agreement Warrant Shares and the Expense Advancement Agreement Loan Warrant Shares, the "Warrant Shares") of Common Stock issuable upon exercise of certain currently outstanding warrants to purchase Common Stock (the "Email Agreement Warrants," and together with the Public Warrants, Private Placement Warrants, GEM Agreement Warrants, Expense Advancement Agreement Warrants, and together with the Public Warrants, Private Placement Warrants, GEM Agreement Warrants, Expense Advancement Agreement Warrants, and Expense Advancement Agreement Warrants, the Consultant Warrants, and Expense Advancement Agreement Warrants, the "Warrants") by the holder thereof as identified in the Registration Statement;

Ensysce Biosciences, Inc. August 6, 2021 Page 2 troutman<sup>7</sup> pepper

- (ix) the resale of up to 125,000 shares (the "Deferred Underwriting Fee Shares") of Common Stock issued in satisfaction of certain deferred underwriting fees;
- (x) the resale of up to 500,000 shares (the "Email Agreement Shares") of Common Stock issued to the stockholder identified in the Registration Statement;
- (xi) the resale of up to 5,000,000 shares (the "Sponsors Shares") of Common Stock by certain stockholders of the Company identified in the Registration Statement;
- (xii) the resale of up to an aggregate of 500,000 shares of common stock (the "Consultant Shares") issuable to certain consultants named in the Registration Statement (the "consultants"); and
- (xiii) the resale of up to 21,007,398 Warrant Shares which includes the (i) Public Warrant Shares, (ii) Private Placement Warrant Shares, (iii) GEM Warrant Shares, (iv) Expense Advancement Agreement Warrant Shares, (v) GTWY Expense Advancement Agreement Warrant Shares, (vi) Expense Advancement Agreement Warrant Shares, (vii) Email Agreement Warrant Shares, and (viii) Consultant Warrant Shares.

The Public Warrants were issued pursuant to a warrant agreement dated December 1, 2017 (the 'Public Warrant Agreement'). The Private Placement Warrants were originally issued pursuant to a Warrant Agreement dated as of December 1, 2017. On June 7, 2021, each of the holders of the Private Placement Warrants exchanged their warrants for new private warrants which were on the same terms as the Private Placement Warrants, except that they were not issued under the Private Placement Warrant Agreement and were non-transferrable except to permitted transferes (the "Private Placement Warrant Agreement"). The Email Agreement Warrants and Email Agreement Shares were issued pursuant to the Email Agreement dated January 31, 2021, as amended by the First Amendment to the Email Agreement, dated June 7, 2021 (the "Email Agreement"). The Expense Advancement Agreement Warrants and the Expense Advancement Agreement Loan Warrants were issued in exchange for outstanding loans under the Expense Advancement Warrants exchanged their warrants for new private warrants which were on the same terms as the Expense Advancement Agreement"). On June 7, 2021, the holders of the Expense Advancement Agreement Warrants exchanged their warrants for new private warrants which were on the same terms as the Expense Advancement Agreement Warrants except that they were non-transferable except to permitted transferees. The GTWY Expense Advancement Agreement Warrants were issued pursuant to an unsecured promissory note issued to

GTWY Holdings Limited, a Canadian corporation, on December 5, 2019, as amended on January 31, 2021 (the "<u>GTWY Promissory Note</u>"), which permitted conversion of all or a portion of the GTWY Promissory Note into warrants of the Company. On June 7, 2021, each of the holders of the GTWY Expense Advancement Agreement Warrants exchanged their warrants for new private warrants which were on the same terms as the GTWY Expense Advancement Agreement Warrants except that they were non-transferable except to permitted transferees. The GEM Agreement Warrants were issued to GEM Yield Bahamas Limited ("<u>GYBL</u>") under the terms of the Share Purchase Agreement between the Company, GEM Global Yield LLC SCS ("<u>GEM Global</u>") and GYBL, dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the "<u>GEM Agreement</u>"). The Consultant Warrants and Consultant Shares are issuable pursuant to certain agreements with the consultants dated as of July 22, 2021 (the "<u>Consultant Warrant and Share Agreements</u>").

Ensysce Biosciences, Inc. August 6, 2021 Page 3



This opinion is being furnished in accordance with the requirements of Item 16 of Form S-1 and Item 601(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 (the "<u>Certificate of Incorporation</u>") and the amended and restated bylaws of the Company, each as amended and/or restated to date, (iii) the Email Agreement, (iv) the Expense Advancement Agreement, (v) the GTWY Promissory Note, (vi) the Public Warrant Agreement, (viii) the Private Placement Warrant Agreement, (viii) the GEM Agreement, (ix) the Consultant Warrant and Share Agreements, and (x) 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 Warrants and 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 antidilution adjustments to outstanding securities of the Company may cause the number of shares issuable upon 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.

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 herein 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). With regard to 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.

Ensysce Biosciences, Inc. August 6, 2021 Page 4

## troutman<sup>1</sup> pepper

- 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 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 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 Warrant Shares have been duly authorized and, when issued and paid for upon exercise of the Warrants in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable;
- 2. The Warrants constitute valid and legally binding obligations of the Company;
- 3. The Sponsors Shares, Email Agreement Shares and Deferred Underwriting Fee Shares are validly issued, fully paid and nonassessable; and
- 4. The Consultant Shares, when issued in accordance with the terms of the Consultant Warrant and Share Agreements, will be validly issued, fully paid and nonassessable.

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 5.1 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 Commission promulgated thereunder.

Very truly yours,

/s/ Troutman Pepper Hamilton Sanders LLP

Troutman Pepper Hamilton Sanders LLP

# [Certain bracketed information in Appendix B to this Exhibit has been excluded because it is both not material and is the type that the registrant treats as private or confidential]

Mr. David J. Kovacs

CONFIDENTIAL DRAFT July 22, 2021

Dr. Lynn Kirkpatrick, Chief Executive Officer, Ensysce Biosciences, Inc.

Re: Ensysce Biosciences, Inc.

Dear Dr. Kirkpatrick:

1. Engagement; Services. This letter (the "Agreement") confirms the engagement of David J. Kovacs ("Consultant") by Ensysce Biosciences, Inc. (the "Company") to provide certain consulting services, effective as of the date indicated above (the "Effective Date").

- (a) Services to be provided by Consultant will include those set forth on Appendix A.
- (b) Consultant shall have the title, Vice President Public Policy.

(b) Consultant services will not include acting as a broker-dealer as defined under the Securities and Exchange Act of 1934 (the '<u>1934 Act</u>'). Consultant will not act as an Agent for the Company in the performance of his duties under this Agreement. Consultant will not perform any function in his execution of this Agreement that could be deemed as effecting a transaction in securities of the Company. Consultant will not participate in any meetings, discussions, or any other course of dealing between the Company and any existing or prospective investor following their introduction, beyond that of establishing the relationship between the parties.

2. Fees. Consultant will be paid:

(a) <u>Securities</u>: Subject to the terms and conditions of this Agreement, Common Stock and Warrants (together, "Securities") shall be issued in accordance with the schedule set forth on <u>Appendix B</u>. The Securities shall be registered on a registration statement filed and declared effective with the Securities and Exchange Commission as soon as reasonably practicable.

(b) Expenses: Consultant will be reimbursed for all expenses as described in the Additional Terms section of this Agreement.

3. <u>Term</u>. One year from execution, unless notice of termination is provided by the Company no less than 10 days before the applicable Notice Date as set forth on <u>Appendix B</u> (each, a Notice Period); and following one year as provided in <u>Appendix B</u>. Terminable at any time by Company with 30 days' notice (or immediately in the event of material breach). For the avoidance of doubt, Company's Board of Directors has the sole discretion to decide whether to continue the agreement as provided on <u>Appendix B</u>. No expiration or termination of this Agreement shall affect (a) the confidentiality and indemnification provisions set forth in Section 3, 4 and 5 of the attached Additional Terms and Conditions, or (b) Consultant's right to receive, and the Company's obligation to pay, any and all fees due (if any, as applicable).

4. <u>Third-Party Beneficiaries</u>. The parties agree and understand that there are no third-party beneficiaries to this Agreement. Accordingly, no third party shall have any right to pursue or enforce any right or remedy hereunder; to assert a claim against Consultant; or to assert reliance in any manner on Consultant's advice or work product.

5. Confidentiality and Non-Disparagement. Except as required to be publicly disclosed, Consultant and any associated personnel, consultants, advisors, professionals or other affiliates (collectively "Consultant Representatives") agree to treat confidentially and to maintain in strict confidence the existence and terms of this Agreement. In the event that Consultant or Consultant Representatives become legally compelled to disclose any Confidential Information (as defined in the Non-Disclosure Agreement signed by the Parties), it will provide Company with reasonable notice so that Company may seek a protective order or other appropriate remedy or waive compliance with the provisions of the Agreement. In the event that such protective order or other remedy is not obtained, or that Company waives compliance with the provisions of the Agreement, Consultant or Consultant Representatives will furnish only that portion of the Agreement that it is advised by opinion of counsel (reasonably acceptable to Company) is legally required and will endeavor to obtain assurance that confidential treatment will be accorded the remainder of the Agreement. Consultant and its Representatives further agree that they will not engage in any disparagement of the Company or any of its personnel, Board, consultants, advisors, professionals or other affiliates (collectively "Company Representatives") in any written, oral or broadcast form in any medium whatsoever. Consultant and its Representatives acknowledge that money damages may be both incalculable and an insufficient remedy for any breach of this Section 5, and that any such breach would cause the Company and/or Company Representatives irreparable harm. Accordingly, Consultant agrees that in the event of any breach or threatened breach hereof by Consultant or by its Representatives of this Section 5, (i) the Company shall become entitled, in addition to any other available remedies at law, without the requirement to mitigate damages or take any other action, to equitable relief, including injunctive relief and specific performance without the posting of any bond or other security, and (ii) that the Company shall become entitled to terminate this Agreement and cease making any payments pursuant to Section 2(b) hereof that have not yet been paid, and (iii) depending upon the severity of the breach, Consultant shall, upon any such termination of this Agreement pursuant to this Section 5, forfeit to the Company within five business days following the date of such termination up to the full amount of any and all Securities paid by Company to Consultant or its Representatives pursuant to Section 2 hereof.

6. <u>Additional Terms</u>. The attached Additional Terms and Conditions are incorporated in their entirety into this Agreement to contain material provisions of this Agreement.

7. <u>Multiple Originals</u>. This Agreement may be signed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed and delivered by facsimile or email of a pdf counterpart signature.

By:	/s/ David J. Kovacs	By:	/s/ Lynn Kirkpatrick
	David J. Kovacs		Lynn Kirkpatrick, CEO
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## DAVID J. KOVACS ADDITIONAL TERMS AND CONDITIONS OF ENGAGEMENT

The following are additional terms and conditions that are incorporated in their entirety into the Agreement between the undersigned parties and constitute material additional terms of the Agreement. The term "Company" refers to Ensysce Biosciences, Inc. and its predecessors, assigns, successors and affiliates.

- 1. <u>Scope of Services</u>. Consultant does not perform audit, accounting compilation, legal, asset appraisal, tax preparation or tax advisory services and shall not provide such services hereunder. Consultant will provide no assurance of future financial performance or results and takes no responsibility for the achievability of any results. Consultant acknowledges he is not licensed as a broker-dealer with the SEC, FINRA or any state securities commission, and will not perform or be entitled to be compensated for any services for which such licensure would be required under applicable federal or state securities laws.
- 2. <u>Reimbursement of Expenses</u>. Consultant will be reimbursed for all documented out-of-pocket expenses, at cost, reasonably incurred following receipt of the prior written approval of the Company in connection with its services hereunder, including, but not limited to, travel (coach class, unless unavailable or for flights of four or more hours), messengers, and legal fees and disbursements of its legal counsel.
- 3. Indemnification. Consultant shall be indemnified and held harmless against any losses, claims, damages or liabilities, joint or several, to which Consultant directly or indirectly may become subject in connection with or arising out of Consultant performance of the services which are the subject of, and within the agreed-upon scope of, the Agreement, except to the extent any such loss, claim, damage, liability or expense is found by a court of competent jurisdiction in a judgment that has become final (in that it is no longer subject to appeal or review) to have resulted from the indemnified person's bad faith, willful misconduct or gross negligence. Consultant shall promptly be reimbursed for expenses incurred hereunder, subject to any such final judgment, and the assertion by the Company that it may have defenses to this indemnification shall not be grounds for refusal to pay or advance expenses hereunder, subject to Consultant executing an undertaking satisfactory to the Company to repay the Company if it is later determined by a court of competent jurisdiction in a judgment that has become final (in that it is no longer subject to appeal or review) that Consultant was not entitled to be indemnified for such expenses. The reimbursement and indemnity obligations and conditions set forth in this paragraph shall extend upon the same terms and conditions to the members, shareholders, directors, officers, partners, employees, contractors, agents and controlling persons (if any) of Consultant and shall be binding upon and inure to the benefit of any successors, assigns, heirs and personal representative of the Company, Consultant and any such persons. The foregoing provisions shall survive any termination of the Agreement.

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- 4. Information. The Company will furnish Consultant with such information as Consultant may reasonably request for the purpose of carrying out the engagement hereunder. Consultant may rely, without independent verification, on the accuracy and completeness of all information that is publicly available and of all information furnished to it by or on behalf of the Company. Except as required by applicable law, Consultant shall keep confidential all non-public information provided to it by the Company and its representative and affiliates, and Consultant shall not disclose such information to any third party, other than such of its employees and authorized advisors as Consultant determines to have a need to know such information, all of whom shall be advised by Consultant of the confidentiality of such information. The Company understands and agrees that Consultant will not be responsible for the accuracy or completeness of such information, and shall not be liable for any inaccuracies or omissions therein. Any advice (whether written or oral) rendered by Consultant pursuant to this Agreement is intended solely for use by the officers and directors of the Company (solely in their capacity as such), and such advice may not be relied upon by any other person or entity or used for any other purpose. The terms of this Agreement may not be disclosed without Consultant's written consent. For the avoidance of doubt, (a) Consultant shall only make representations concerning the Company's products that are provided in information furnished by the Company, and further subject to any limitations on such information as may be imposed by any regulatory body including the FDA and SEC as advised by the Company and (b) Consultant agrees to comply with all applicable laws in the performance of its services pursuant to this Agreement.
- 5. <u>Personnel</u>. Consultant will be directly engaged in this project and may collaborate with David Tanzer and certain other personnel. Consultant reserves the right to include additional personnel to work in the project upon consultation with the Company.
- 6. <u>Miscellaneous</u>. This Agreement shall be binding upon the parties hereto and their respective successors, heirs and assigns and any successor, heir or assign of any substantial portion of such parties' respective businesses and/or assets. Nothing in this Agreement, express or implied, is intended to confer or does confer on any person or entity, other than the parties hereto, the Indemnified Parties and each of their respective successors, heirs and assigns, any rights or remedies (directly or indirectly as a third-party beneficiary or otherwise) under or by reason of this Agreement or as a result of the services to be rendered by Broker hereunder.

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The parties understand that Consultant is being engaged hereunder as an independent contractor to provide the services described above solely to the Company, and that Consultant is not acting as a general agent or fiduciary of the Company, the security holders or creditors of the Company or any other person or entity in connection with this engagement, and the Company agrees that it shall not make, and hereby waives, any claim based on an assertion of such an agency or fiduciary relationship. Any duties arising by reason of this Agreement or as a result of the services to be rendered by Consultant hereunder will be owed solely to the Company.

The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect pursuant to the terms hereof.

The Company understands that Consultant is not undertaking to provide any legal, regulatory, accounting, insurance, tax or other similar professional advice.

This Agreement is the complete and exclusive statement of the entire understanding of the parties regarding the subject matter hereof, and supersedes all previous agreements or understandings regarding the same, whether written or oral.

This Agreement may not be amended, and no portion hereof may be waived, except in a writing duly executed by the parties.

This Agreement has been reviewed by the signatories hereto and their counsel. There shall be no construction of any provision against Company because it had drafted the Agreement. Consultant and the parties waive any statute or rule of law to such effect.

Each of Consultant and the Company has all requisite power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly and validly authorized by all necessary action on the part of the Company and Consultant and has been duly executed and delivered by the Company and Consultant and constitutes a legal, valid and binding agreement of the Company and Consultant, enforceable in accordance with its terms.

This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which will constitute one and the same instrument. Such counterparts may be delivered by one party to the other by facsimile or other electronic transmission, and such counterparts shall be valid for all purposes.

CONFLICTS OF LAWS. EACH OF CONSULTANT AND THE COMPANY (ON ITS OWN BEHALF AND, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ON BEHALF OF ITS EQUITY HOLDERS) IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED UPON CONTRACT, TORT OR OTHERWISE) RELATED TO OR ARISING OUT OF THE ENGAGEMENT OF BROKER PURSUANT TO, OR THE PERFORMANCE BY BROKER OF THE SERVICES CONTEMPLATED BY, THIS AGREEMENT.

Please confirm that the foregoing terms are in accordance with your understanding by signing and returning a copy of this Letter Agreement.

Sincerely,

#### **ENSYSCE BIOSCIENCES, INC.**

By: /s/ Lynn Kirkpatrick

Lynn Kirkpatrick Chief Executive Officer

Accepted and agreed to as of the date first written above.

DAVID J. KOVACS

By: /s/ David J. Kovacs David J. Kovacs

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## <u>Appendix A – Services</u>

#### **Purpose**

- · Support successful and timely achievement of Company's media objectives, which Consultant understands to include
  - o Assist in creating retail and/or institutional demand sufficient to provide liquidity to large holders of Company stock
  - o Assist in discussions concerning cash funding for short-term liquidity requirements
  - $\circ \quad \text{Assist in discussions concerning longer-term funding}$
  - o Assist with developing media and messaging strategy to promote the Company's image
  - As requested, provide strategic advice to assist with the Company's regulatory and commercialization strategies
- As appropriate, and at the request of the Company, assist in supporting other strategic, regulatory, and other objectives, including making appropriate introductions.

## Scope of Work

- Support ongoing investor strategy by reviewing the Company's financial information and prospects, its investor presentation and its communications strategy. This work
  may include
  - Assist the Company in its effort to identify and introduce potential investors to the Company, including hedge funds, family offices and other investors with deep biotech investing experience, it being agreed that no part of Consultant's compensation is tied to securing such funding
  - If desired by the Company, assist in securing the services, on advantageous terms, of a leading investment bank with deep biotech experience
- Support the Company in strategic discussions with investors/companies/other parties, including with Global Emerging Markets (GEM), as required.
- Provide introductions and contacts that advance the development of PF614, PF614-MPAR<sup>™</sup> and nafamostat for opioid, ADHD and other applications. This could include media, industry, regulatory and medical resources as requested by the Company and that Consultants can facilitate.
- Consultants agree to devote such time and efforts as are required to achieve the purposes set forth above.

## Appendix B

#### Compensation Schedule

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Subject to the provisions of Section 3 "Term" of the Agreement, and subject to the conditions set forth below, registered common stock in the form of restricted stock units and/or non-transferable warrants exercisable for common stock for five years. The restricted stock units for [ ] this Agreement shall be granted on the Effective Date and subject to the vesting provisions set forth below. If the renewal term occurs, then an additional grant of restricted stock units shall occur preceding the renewal term.

- At the Effective Date of the Consulting Agreement:
  - 500,000 warrants at FMV (Fair Market Value) will be issued, and
  - [ ] shares of common stock will be issued, and
  - [ ] restricted stock units will be granted, subject to vesting as follows:
- At the date [ ]months following the Effective Date (Notice Date is [ ]months following the Effective Date):
  - [ ] restricted stock units will vest, and
  - [ ] restricted stock units will vest only if the following condition has been satisfied: over the [ ] consecutive trading days the average stock price exceeds \$[ ]/share.
  - At the date [ ]months following the Effective Date (Notice Date is [ ]months following the Effective Date):
    - [ ] restricted stock units will vest, and
    - [] restricted stock units will vest only if the following condition has been satisfied: over the []] consecutive trading days the average stock price exceeds \$[]/share.
- At the date [ ] months following the Effective Date (Notice Date is [ ] months following the Effective Date):

• [ ] restricted stock units will vest, and

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[ ] restricted stock units will vest only if the following condition has been satisfied: over the [ price exceeds \$[ ]/share.

Renewal [ ]: Following grant of additional restricted stock units after completion of the initial [ ] month term of the agreement, [ ] restricted stock units to vest [ ] for a period of [ ] months, for each [ ] that the average stock price exceeds \$[ ]/share, or at the discretion of the Board if lower, but in the range of \$[ ]/share, and provided that the Consultants continue to provide services to the Company in accordance with the Consultant's past practice. Company agrees that if the Company has not previously terminated this Agreement and all prior restricted stock units have vested, it may not terminate during this [ ]-month period except in the event of material breach of this Agreement.

Effect of Termination. The Company will not be obligated to issue shares to the extent their issuance date would occur after the Company elects to terminate the engagement except for any shares previously earned. The Parties to determine the most tax efficient method for issuance of the shares but Consultant responsible for its own tax liabilities. The consideration above is the full and complete consideration under any and all circumstances.

Registration of stock to be granted: the shares to be granted hereunder are not currently registered, but the Company affirmatively undertakes to register them as soon as reasonably practicable.

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## [Certain bracketed information in Appendix B to this Exhibit has been excluded because it is both not material and is the type that the registrant treats as private or confidential]

Mercury FundingCo, LLC (Mr. David Tanzer, Managing Member)

CONFIDENTIAL DRAFT July 22, 2021

Dr. Lynn Kirkpatrick, Chief Executive Officer, Ensysce Biosciences, Inc.

Re: Ensysce Biosciences, Inc.

Dear Dr. Kirkpatrick:

1. <u>Engagement</u>; Services. This letter (the "<u>Agreement</u>") confirms the engagement of Mercury FundingCo, LLC ("Consultant") by Ensysce Biosciences, Inc. (the "<u>Company</u>") to provide certain consulting services, effective as of the date indicated above (the '<u>Effective Date</u>").

- (a) Services to be provided by Consultant will include those set forth on Appendix A.
- (b) Consultant shall have the title, Vice President Strategic Development

(b) Consultant services will not include acting as a broker-dealer as defined under the Securities and Exchange Act of 1934 (the '<u>1934 Act</u>'). Consultant will not act as an Agent for the Company in the performance of his duties under this Agreement. Consultant will not perform any function in his execution of this Agreement that could be deemed as effecting a transaction in securities of the Company. Consultant will not participate in any meetings, discussions, or any other course of dealing between the Company and any existing or prospective investor following their introduction, beyond that of establishing the relationship between the parties.

2. Fees. Consultant will be paid:

(a) <u>Securities</u>: Subject to the terms and conditions of this Agreement, Common Stock and Warrants (together, "Securities") shall be issued in accordance with the schedule set forth on <u>Appendix B</u>. The Securities shall be registered on a registration statement filed and declared effective with the Securities and Exchange Commission as soon as reasonably practicable.

(b) Expenses: Consultant will be reimbursed for all expenses as described in the Additional Terms section of this Agreement.

3. <u>Term</u>. One year from execution, unless notice of termination is provided by the Company no less than 10 days before the applicable Notice Date as set forth on <u>Appendix B</u> (each, a Notice Period); and following one year as provided in <u>Appendix B</u>. Terminable at any time by Company with 30 days' notice (or immediately in the event of material breach). For the avoidance of doubt, Company's Board of Directors has the sole discretion to decide whether to continue the agreement as provided on <u>Appendix B</u>. No expiration or termination of this Agreement shall affect (a) the confidentiality and indemnification provisions set forth in Section 3, 4 and 5 of the attached Additional Terms and Conditions, or (b) Consultant's right to receive, and the Company's obligation to pay, any and all fees due (if any, as applicable).

4. <u>Third-Party Beneficiaries</u>. The parties agree and understand that there are no third-party beneficiaries to this Agreement. Accordingly, no third party shall have any right to pursue or enforce any right or remedy hereunder; to assert a claim against Consultant; or to assert reliance in any manner on Consultant's advice or work product.

5. Confidentiality and Non-Disparagement. Except as required to be publicly disclosed, Consultant and any associated personnel, consultants, advisors, professionals or other affiliates (collectively "Consultant Representatives") agree to treat confidentially and to maintain in strict confidence the existence and terms of this Agreement. In the event that Consultant or Consultant Representatives become legally compelled to disclose any Confidential Information (as defined in the Non-Disclosure Agreement signed by the Parties), it will provide Company with reasonable notice so that Company may seek a protective order or other appropriate remedy or waive compliance with the provisions of the Agreement. In the event that such protective order or other remedy is not obtained, or that Company waives compliance with the provisions of the Agreement, Consultant or Consultant Representatives will furnish only that portion of the Agreement that it is advised by opinion of counsel (reasonably acceptable to Company) is legally required and will endeavor to obtain assurance that confidential treatment will be accorded the remainder of the Agreement. Consultant and its Representatives further agree that they will not engage in any disparagement of the Company or any of its personnel, Board, consultants, advisors, professionals or other affiliates (collectively "Company Representatives") in any written, oral or broadcast form in any medium whatsoever. Consultant and its Representatives acknowledge that money damages may be both incalculable and an insufficient remedy for any breach of this Section 5, and that any such breach would cause the Company and/or Company Representatives irreparable harm. Accordingly, Consultant agrees that in the event of any breach or threatened breach hereof by Consultant or by its Representatives of this Section 5, (i) the Company shall become entitled, in addition to any other available remedies at law, without the requirement to mitigate damages or take any other action, to equitable relief, including injunctive relief and specific performance without the posting of any bond or other security, and (ii) that the Company shall become entitled to terminate this Agreement and cease making any payments pursuant to Section 2(b) hereof that have not yet been paid, and (iii) depending upon the severity of the breach, Consultant shall, upon any such termination of this Agreement pursuant to this Section 5, forfeit to the Company within five business days following the date of such termination up to the full amount of any and all Securities paid by Company to Consultant or its Representatives pursuant to Section 2 hereof.

6. <u>Additional Terms</u>. The attached Additional Terms and Conditions are incorporated in their entirety into this Agreement to contain material provisions of this Agreement.

7. <u>Multiple Originals</u>. This Agreement may be signed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed and delivered by facsimile or email of a pdf counterpart signature.

By:	/s/ David Tanzer	By:	/s/ Lynn Kirkpatrick
	David Tanzer		Lynn Kirkpatrick, CEO
	Mercury FundingCo, LLC		
	Managing Member		
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## MERCURY FUNDINGCO ADDITIONAL TERMS AND CONDITIONS OF ENGAGEMENT

The following are additional terms and conditions that are incorporated in their entirety into the Agreement between the undersigned parties and constitute material additional terms of the Agreement. The term "Company" refers to Ensysce Biosciences, Inc. and its predecessors, assigns, successors and affiliates.

- 1. <u>Scope of Services</u>. Consultant does not perform audit, accounting compilation, legal, asset appraisal, tax preparation or tax advisory services and shall not provide such services hereunder. Consultant will provide no assurance of future financial performance or results and takes no responsibility for the achievability of any results. Consultant acknowledges he is not licensed as a broker-dealer with the SEC, FINRA or any state securities commission, and will not perform or be entitled to be compensated for any services for which such licensure would be required under applicable federal or state securities laws.
- 2. <u>Reimbursement of Expenses</u>. Consultant will be reimbursed for all documented out-of-pocket expenses, at cost, reasonably incurred following receipt of the prior written approval of the Company in connection with its services hereunder, including, but not limited to, travel (coach class, unless unavailable or for flights of four or more hours), messengers, and legal fees and disbursements of its legal counsel.
- 3. Indemnification. Consultant shall be indemnified and held harmless against any losses, claims, damages or liabilities, joint or several, to which Consultant directly or indirectly may become subject in connection with or arising out of Consultant performance of the services which are the subject of, and within the agreed-upon scope of, the Agreement, except to the extent any such loss, claim, damage, liability or expense is found by a court of competent jurisdiction in a judgment that has become final (in that it is no longer subject to appeal or review) to have resulted from the indemnified person's bad faith, willful misconduct or gross negligence. Consultant shall promptly be reimbursed for expenses incurred hereunder, subject to any such final judgment, and the assertion by the Company that it may have defenses to this indemnification shall not be grounds for refusal to pay or advance expenses hereunder, subject to Consultant executing an undertaking satisfactory to the Company to repay the Company if it is later determined by a court of competent jurisdiction in a judgment that has become final (in that it is no longer subject to appeal or review) that Consultant was not entitled to be indemnified for such expenses. The reimbursement and indemnity obligations and conditions set forth in this paragraph shall extend upon the same terms and conditions to the members, shareholders, directors, officers, partners, employees, contractors, agents and controlling persons (if any) of Consultant and shall be binding upon and inure to the benefit of any successors, assigns, heirs and personal representative of the Company, Consultant and any such persons. The foregoing provisions shall survive any termination of the Agreement.

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- 4. Information. The Company will furnish Consultant with such information as Consultant may reasonably request for the purpose of carrying out the engagement hereunder. Consultant may rely, without independent verification, on the accuracy and completeness of all information that is publicly available and of all information furnished to it by or on behalf of the Company. Except as required by applicable law, Consultant shall keep confidential all non-public information provided to it by the Company and its representative and affiliates, and Consultant shall not disclose such information to any third party, other than such of its employees and authorized advisors as Consultant determines to have a need to know such information, all of whom shall be advised by Consultant of the confidentiality of such information. The Company understands and agrees that Consultant will not be responsible for the accuracy or completeness of such information, and shall not be liable for any inaccuracies or omissions therein. Any advice (whether written or oral) rendered by Consultant pursuant to this Agreement is intended solely for use by the officers and directors of the Company (solely in their capacity as such), and such advice may not be relied upon by any other person or entity or used for any other purpose. The terms of this Agreement may not be disclosed without Consultant's written consent. For the avoidance of doubt, (a) Consultant shall only make representations concerning the Company's products that are provided in information furnished by the Company, and further subject to any limitations on such information as may be imposed by any regulatory body including the FDA and SEC as advised by the Company and (b) Consultant agrees to comply with all applicable laws in the performance of its services pursuant to this Agreement.
- 5. <u>Personnel</u>. Consultant will be directly engaged in this project and may collaborate with David Tanzer and certain other personnel. Consultant reserves the right to include additional personnel to work in the project upon consultation with the Company.
- 6. <u>Miscellaneous</u>. This Agreement shall be binding upon the parties hereto and their respective successors, heirs and assigns and any successor, heir or assign of any substantial portion of such parties' respective businesses and/or assets. Nothing in this Agreement, express or implied, is intended to confer or does confer on any person or entity, other than the parties hereto, the Indemnified Parties and each of their respective successors, heirs and assigns, any rights or remedies (directly or indirectly as a third-party beneficiary or otherwise) under or by reason of this Agreement or as a result of the services to be rendered by Broker hereunder.

The parties understand that Consultant is being engaged hereunder as an independent contractor to provide the services described above solely to the Company, and that Consultant is not acting as a general agent or fiduciary of the Company, the security holders or creditors of the Company or any other person or entity in connection with this engagement, and the Company agrees that it shall not make, and hereby waives, any claim based on an assertion of such an agency or fiduciary relationship. Any duties arising by reason of this Agreement or as a result of the services to be rendered by Consultant hereunder will be owed solely to the Company.

The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect pursuant to the terms hereof.

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The Company understands that Consultant is not undertaking to provide any legal, regulatory, accounting, insurance, tax or other similar professional advice.

This Agreement is the complete and exclusive statement of the entire understanding of the parties regarding the subject matter hereof, and supersedes all previous agreements or understandings regarding the same, whether written or oral.

This Agreement may not be amended, and no portion hereof may be waived, except in a writing duly executed by the parties.

This Agreement has been reviewed by the signatories hereto and their counsel. There shall be no construction of any provision against Company because it had drafted the Agreement. Consultant and the parties waive any statute or rule of law to such effect.

Each of Consultant and the Company has all requisite power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly and validly authorized by all necessary action on the part of the Company and Consultant and has been duly executed and delivered by the Company and Consultant and constitutes a legal, valid and binding agreement of the Company and Consultant, enforceable in accordance with its terms.

This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which will constitute one and the same instrument. Such counterparts may be delivered by one party to the other by facsimile or other electronic transmission, and such counterparts shall be valid for all purposes.

GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAWS. EACH OF CONSULTANT AND THE COMPANY (ON ITS OWN BEHALF AND, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ON BEHALF OF ITS EQUITY HOLDERS) IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED UPON CONTRACT, TORT OR OTHERWISE) RELATED TO OR ARISING OUT OF THE ENGAGEMENT OF BROKER PURSUANT TO, OR THE PERFORMANCE BY BROKER OF THE SERVICES CONTEMPLATED BY, THIS AGREEMENT.

Please confirm that the foregoing terms are in accordance with your understanding by signing and returning a copy of this Letter Agreement.

Sincerely,

## **ENSYSCE BIOSCIENCES, INC.**

By: /s/ Lynn Kirkpatrick Lynn Kirkpatrick Chief Executive Officer

Accepted and agreed to as of the date first written above.

## MERCURY FUNDINGCO, LLC

By: /s/ David Tanzer David Tanzer

Managing Member

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#### Appendix A - Services

#### **Purpose**

· Support successful and timely achievement of Company's media objectives, which Consultant understands to include

- Assist in creating retail and/or institutional demand sufficient to provide liquidity to large holders of Company stock
- o Assist in discussions concerning cash funding for short-term liquidity requirements
- Assist in discussions concerning longer-term funding
- Assist with developing media and messaging strategy to promote the Company's image
- As requested, provide strategic advice to assist with the Company's regulatory and commercialization strategies
- As appropriate, and at the request of the Company, assist in supporting other strategic, regulatory, and other objectives, including making appropriate introductions.

#### Scope of Work

- Support ongoing investor strategy by reviewing the Company's financial information and prospects, its investor presentation and its communications strategy. This work
  may include
  - Assist the Company in its effort to identify and introduce potential investors to the Company, including hedge funds, family offices and other investors with deep biotech investing experience, it being agreed that no part of Consultant's compensation is tied to securing such funding
  - o If desired by the Company, assist in securing the services, on advantageous terms, of a leading investment bank with deep biotech experience
- Support the Company in strategic discussions with investors/companies/other parties, including with Global Emerging Markets (GEM), as required.
- Provide introductions and contacts that advance the development of PF614, PF614-MPAR<sup>™</sup> and nafamostat for opioid, ADHD and other applications. This could include media, industry, regulatory and medical resources as requested by the Company and that Consultants can facilitate.
- Consultants agree to devote such time and efforts as are required to achieve the purposes set forth above.

## 8

#### <u>Appendix B</u>

## Compensation Schedule

Subject to the provisions of Section 3 "Term" of the Agreement, and subject to the conditions set forth below, registered common stock in the form of restricted stock units and/or non-transferable warrants exercisable for common stock for five years. The restricted stock units for [ ] this Agreement shall be granted on the Effective Date and subject to the vesting provisions set forth below. If the renewal term occurs, then an additional grant of restricted stock units shall occur preceding the renewal term.

- At the Effective Date of the Consulting Agreement:
  - $\circ$  ~ 500,000 warrants at FMV (Fair Market Value) will be issued, and
  - [ ] shares of common stock will be issued, and
  - [ ] restricted stock units will be granted, subject to vesting as follows:
- At the date [ ]months following the Effective Date (Notice Date is [ ]months following the Effective Date):
  - [ ] restricted stock units will vest, and
  - [] restricted stock units will vest only if the following condition has been satisfied: over the []] consecutive trading days the average stock price exceeds \$[]/share.
- At the date [ ]months following the Effective Date (Notice Date is [ ]months following the Effective Date):
  - [ ] restricted stock units will vest, and
  - [] restricted stock units will vest only if the following condition has been satisfied: over the [ price exceeds \$[]]/share.

- At the date [ ] months following the Effective Date (Notice Date is [ ] months following the Effective Date):
  - [ ] restricted stock units will vest, and
  - [] restricted stock units will vest only if the following condition has been satisfied: over the []] consecutive trading days the average stock price exceeds \$[]/share.
- Renewal [ ]: Following grant of additional restricted stock units after completion of the initial []-month term of the agreement, []] restricted stock units to vest per month for a period of []] months, for each []] that the average stock price exceeds \$[]]/share, or at the discretion of the Board if lower, but in the range of \$[]]/share, and provided that the Consultants continue to provide services to the Company in accordance with the Consultant's past practice. Company agrees that if the Company has not previously terminated this Agreement and all prior restricted stock units have vested, it may not terminate during this twelve-month period except in the event of material breach of this Agreement.

Effect of Termination. The Company will not be obligated to issue shares to the extent their issuance date would occur after the Company elects to terminate the engagement except for any shares previously earned. The Parties to determine the most tax efficient method for issuance of the shares but Consultant responsible for its own tax liabilities. The consideration above is the full and complete consideration under any and all circumstances.

Registration of stock to be granted: the shares to be granted hereunder are not currently registered, but the Company affirmatively undertakes to register them as soon as reasonably practicable.



Subsidiaries of Ensysce Biosciences, Inc.

Legal Entity	Jurisdiction of Organization
Covistat, Inc. (79.2%)	Delaware
EBI OpCo, Inc.	Delaware
EBI Operating, Inc.	Delaware

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Ensysce Biosciences, Inc. (the "Company") (f/k/a Leisure Acquisition Corp.) on Form S-1 of our report dated March 15, 2021, except for the effects of the restatement discussed in Note 2 and Contingent Forward Purchase Contract in Note 7, as to which the date is June 7, 2021, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audit of the financial statements of Leisure Acquisition Corp. as of December 31, 2020 and 2019 and for the years then ended, which report appears in the Prospectus, which is part of this Registration Statement. We were dismissed as auditors on July 7, 2021 and, accordingly, we have not performed any audit or review procedures with respect to any financial statements appearing in such Prospectus for the periods after the date of our dismissal. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus which is part of this Registration Statement.

/s/ Marcum llp

Marcum llp West Palm Beach, FL August 6, 2021

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Form S-1 of our report dated March 15, 2021, with respect to the consolidated financial statements of Ensysce Biosciences, Inc. as of December 31, 2020 and 2019 and for the years then ended (which report includes an explanatory paragraph regarding the existence of substantial doubt about the Company's ability to continue as a going concern), and to the reference to us under the heading "Experts" included in the prospectus, which is part of this Registration Statement.

/s/ Mayer Hoffman McCann P.C.

San Diego, California August 6, 2021