# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 2021**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-38306**

# Ensysce Biosciences, Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| | |
|---|---|
| **Delaware** | **82-2755287** |
| **( State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **7946 Ivanhoe Avenue, Suite 201 La Jolla, California** | **92037** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.0001 par value per share | ENSC | The Nasdaq Stock Market LLC |
| Warrants to purchase one share of Common Stock | ENSCW | The Nasdaq Stock Market LLC |

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| Emerging growth company | ☒ | | |

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of August 13, 2021, the registrant had 24,255,786 shares of common stock, $0.0001 par value per share, outstanding.

## FORWARD-LOOKING STATEMENTS

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

- the risk that Ensysce's lead product candidate PF614 and PF614-MPAR™ may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- reliance by 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;
- the ability to meet and maintain applicable listing standards of the Nasdaq;
- the ability to recognize the anticipated benefits of the Business Combination (as defined below), which may be affected by, among other things, the factors described above;
- potential litigation associated with the Business Combination;
- other factors disclosed in this registration statement/prospectus; and
- other factors beyond Ensysce's control.

The foregoing list of forward-looking statements is not exhaustive. These statements speak only as of the date of this report and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The section of this report titled "Section 1A. Risk Factors" identifies important factors that could harm our business and financial performance and cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as required by law.

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## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

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

| | June 30, 2021 (Unaudited) | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,011,782 | $ 194,214 |
| Unbilled receivable | 75,354 | — |
| Right-of-use asset | 9,415 | 23,538 |
| Prepaid expenses and other current assets | 261,517 | 130,124 |
| Total current assets | 8,358,068 | 347,876 |
| Property and equipment, net | 50 | 151 |
| Other assets | 838,091 | 3,780 |
| **Total assets** | $ 9,196,209 | $ 351,807 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,140,721 | $ 1,724,598 |
| Accrued expenses and other liabilities | 411,941 | 344,792 |
| Lease liability | 10,200 | 25,500 |
| Notes payable and accrued interest | 466,055 | 4,245,082 |
| Embedded derivative on convertible notes | — | 670,262 |
| Total current liabilities | 4,028,917 | 7,010,234 |
| | | |
| **Total liabilities** | 4,028,917 | 7,010,234 |
| Commitments and contingencies (Note 6) | | |
| **Stockholders' equity (deficit)** | | |
| Preferred stock, $0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at June 30, 2021 (unaudited) and December 31, 2020 | — | — |
| Common stock, $0.0001 par value, 150,000,000 shares authorized; 24,275,541 and 15,768,725 shares issued at June 30, 2021 (unaudited) and December 31, 2020, respectively; 24,255,786 and 15,768,725 shares outstanding at June 30, 2021 (unaudited) and December 31, 2020, respectively | 2,425 | 1,577 |
| Additional paid-in capital | 63,250,511 | 49,516,337 |
| Accumulated deficit | (57,841,991) | (55,958,716) |
| Total Ensysce Biosciences, Inc. stockholders' equity (deficit) | 5,410,945 | (6,440,802) |
| Noncontrolling interests in stockholders' deficit | (243,653) | (217,625) |
| **Total stockholders' equity (deficit)** | 5,167,292 | (6,658,427) |
| **Total liabilities and stockholders' equity** | $ 9,196,209 | $ 351,807 |

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **Federal grants** | $ 444,516 | $ 1,824,681 | $ 695,091 | $ 2,687,081 |
| **Operating expenses:** | | | | |
| Research and development | 463,219 | 1,404,246 | 787,595 | 2,243,217 |
| General and administrative | 393,914 | 281,354 | 884,386 | 559,047 |
| Total operating expenses | 857,133 | 1,685,600 | 1,671,981 | 2,802,264 |
| **Income (loss) from operations** | (412,617) | 139,081 | (976,890) | (115,183) |
| Other income (expense): | | | | |
| Change in fair value of derivative liability | 712,899 | (643,840) | 673,314 | (1,083,174) |
| Interest expense | (910,327) | (201,715) | (1,258,161) | (531,364) |
| Loss on extinguishment of debt | (347,566) | — | (347,566) | — |
| Total other income (expense), net | (544,994) | (845,555) | (932,413) | (1,614,538) |
| **Net loss** | $ (957,611) | $ (706,474) | $ (1,909,303) | $ (1,729,721) |
| Net loss attributable to noncontrolling interests | $ (22,067) | $ (1,976) | $ (26,028) | $ (1,976) |
| Net loss attributable to common stockholders | $ (935,544) | $ (704,498) | $ (1,883,275) | $ (1,727,745) |
| **Net loss per share, basic and diluted:** | | | | |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.06) | $ (0.04) | $ (0.12) | $ (0.11) |
| Weighted average common shares outstanding, basic and diluted | 16,053,550 | 15,768,725 | 15,943,867 | 15,768,725 |

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

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

| | Stockholders' Deficit | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional | | | |
| | Number of Shares | Amount | Paid-In Capital | Accumulated Deficit | Noncontrolling interests | Total |
| **Balance on March 31, 2020** | **15,768,725** | **$ 1,577** | **$ 49,370,144** | **$ (57,038,733)** | **$ —** | **$ (7,667,012)** |
| Stock-based compensation | — | — | 36,065 | — | — | 36,065 |
| Net loss | — | — | — | (704,498) | (1,976) | (706,474) |
| **Balance on June 30, 2020** | **15,768,725** | **$ 1,577** | **$ 49,406,209** | **$ (57,743,231)** | **$ (1,976)** | **$ (8,337,421)** |
| | | | | | | |
| **Balance on March 31, 2021** | **16,053,550** | **$ 1,605** | **$ 49,822,991** | **$ (56,906,447)** | **$ (221,586)** | **$ (7,303,437)** |
| Stock-based compensation | — | — | 36,373 | — | — | 36,373 |
| Settlement of convertible notes | 1,357,968 | 136 | 5,696,567 | — | — | 5,696,703 |
| Issuance of common stock for business combination, net of transaction costs | 6,844,268 | 684 | 7,694,580 | — | — | 7,695,264 |
| Net loss | — | — | — | (935,544) | (22,067) | (957,611) |
| **Balance on June 30, 2021** | **24,255,786** | **$ 2,425** | **$ 63,250,511** | **$ (57,841,991)** | **$ (243,653)** | **$ 5,167,292** |

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

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

| | Stockholders' Deficit | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional | | | |
| | Number of Shares | Amount | Paid-In Capital | Accumulated Deficit | Noncontrolling interests | Total |
| **Balance on December 31, 2019** | **15,768,725** | **$ 1,577** | **$ 49,337,658** | **$ (56,015,486)** | **$ —** | **$ (6,676,251)** |
| Stock-based compensation | — | — | 68,551 | — | — | 68,551 |
| Net loss | — | — | — | (1,727,745) | (1,976) | (1,729,721) |
| **Balance on June 30, 2020** | **15,768,725** | **$ 1,577** | **$ 49,406,209** | **$ (57,743,231)** | **$ (1,976)** | **$ (8,337,421)** |
| | | | | | | |
| **Balance on December 31, 2020** | **15,768,725** | **$ 1,577** | **$ 49,516,337** | **$ (55,958,716)** | **$ (217,625)** | **$ (6,658,427)** |
| Exercise of stock options | 284,825 | 28 | 262,834 | — | — | 262,862 |
| Settlement of convertible notes | 1,357,968 | 136 | 5,696,567 | — | — | 5,696,703 |
| Issuance of common stock for business combination, net of transaction costs | 6,844,268 | 684 | 7,694,580 | — | — | 7,695,264 |
| Stock-based compensation | — | — | 80,193 | — | — | 80,193 |
| Net loss | — | — | — | (1,883,275) | (26,028) | (1,909,303) |
| **Balance on June 30, 2021** | **24,255,786** | **$ 2,425** | **$ 63,250,511** | **$ (57,841,991)** | **$ (243,653)** | **$ 5,167,292** |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (1,909,303) | $ (1,729,721) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 101 | 100 |
| Accrued interest | 312,197 | 171,507 |
| Accretion of discounts on promissory notes | 945,969 | 359,857 |
| Change in fair value of embedded derivative | (673,314) | 1,083,174 |
| Loss on extinguishment of debt | 347,566 | — |
| Stock-based compensation | 80,193 | 68,551 |
| Lease cost | (1,177) | — |
| Changes in operating assets and liabilities: | | |
| Unbilled receivable | (75,354) | 173,552 |
| Prepaid expenses and other assets | 103,245 | (1,299,728) |
| Accounts payable | 347,420 | 826,563 |
| Accrued expenses and other liabilities | (127,004) | (214,428) |
| Net cash used in operating activities | (649,461) | (560,573) |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of convertible notes | 50,000 | 800,000 |
| Proceeds from issuance of promissory notes to related parties | 350,000 | — |
| Proceeds from exercise of stock options | 262,862 | — |
| Proceeds from issuance of common stock for business combination | 7,804,167 | — |
| Contribution from noncontrolling interest | — | 20 |
| Net cash provided by financing activities | 8,467,029 | 800,020 |
| Increase in cash and cash equivalents | 7,817,568 | 239,447 |
| **Cash and cash equivalents beginning of period** | 194,214 | 341,536 |
| **Cash and cash equivalents end of period** | $ 8,011,782 | $ 580,983 |
| | | |
| **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 | $ — | $ 414,323 |
| Settlement of Convertible Notes into common stock | $ 5,696,703 | $ — |
| Deferred transaction costs for business combination offset against additional paid-in capital | $ 1,200,412 | $ — |
| Net assets acquired from LACQ | $ 1,068,950 | $ — |

The accompanying notes are an integral part of these 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™ (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.

On January 31, 2021, Leisure Acquisition Corp., a Delaware corporation ("LACQ"), entered into an Agreement and Plan of Merger (as amended, the "Merger Agreement") with Ensysce Biosciences, Inc., a Delaware corporation ("Former Ensysce"), and EB Merger Sub, Inc., a Delaware corporation and wholly-owned, direct subsidiary of LACQ ("Merger Sub"). Pursuant to the Merger Agreement, on June 30, 2021 (the "Closing Date"), Merger Sub was merged with and into Former Ensysce, with Former Ensysce surviving the merger ("Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Business Combination"). In connection with the closing of the Business Combination on the Closing Date (the "Closing"), Former Ensysce became a wholly owned subsidiary of LACQ and the stockholders of Former Ensysce, as of immediately prior to the effective time of the Merger, received shares of LACQ and hold a portion of the shares of Common Stock, par value $0.0001 per share (the "Common Stock"), of LACQ.

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

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

In June 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, Covistat, Inc., a Delaware corporation. Pursuant to the articles of incorporation, Covistat was authorized to issue 1,000,000 shares of common stock, $0.001 par value per share, and 100,000 shares of preferred stock, $0.001 par value per share. Ensysce is a 79.2% stockholder 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 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.

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

**NOTE 2 - BASIS OF PRESENTATION**

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the United States Securities Exchange Commission ("SEC"). The consolidated financial statements include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

In the opinion of management, all adjustments considered necessary for a fair presentation have been included in the consolidated financial statements. Operating results for the three and six months ended June 30, 2021, are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The interim unaudited consolidated financial statements have been prepared under the presumption that users of the interim financial information have either read or have access to the audited consolidated financial statements for the fiscal year ended December 31, 2020, which may be found in the Company's Form S-1 registration statement filed with the SEC on August 9, 2021.

***Business Combination***

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

The Business Combination triggered the conversion of the 2015 convertible notes, the 2018 convertible notes and the 2021 convertible note of Former Ensysce into common stock. In connection with the Closing, the 2020 convertible notes were amended to provide for automatic conversion of the outstanding principal and interest into shares common stock of Ensysce. The Company had recorded $1.2 million of deferred transaction costs, consisting of legal and accounting fees directly related to the Business Combination, which were offset against the proceeds of the Business Combination within additional paid-in capital.

***Liquidity***

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 had working capital of $4.3 million at June 30, 2021. In December 2020, the Company executed an agreement with an investment group, which 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. On June 30, 2021, the Company consummated the Business Combination with LACQ, resulting in the Company's shares becoming publicly listed on Nasdaq on July 2, 2021.

As the Company's shares are now publicly traded and the Company therefore has access to its $60.0 million share subscription facility in addition to its working capital, the Company believes there is not substantial doubt about its ability to continue as a going concern.

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

***Use of Estimates and Assumptions***

Preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosed in the accompanying notes. Actual results may differ from those estimates and such differences may be material to the consolidated financial statements. The more significant estimates and assumptions by management include, but are not limited to, the expense recognition for certain research and development services, the valuation allowance of deferred tax assets resulting from net operating losses, 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 of five to six years. Depreciation expense of $50 and $101 was recognized for the three and six months ended June 30, 2021, respectively. Depreciation expense of $50 and $100 was recognized for the three and six months ended June 30, 2020, respectively. Depreciation expense is classified in general and administrative expense in the accompanying consolidated statements of operations.

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

All outstanding derivative liabilities were settled in connection with the conversion of outstanding notes payable on June 30, 2021. Refer to Note 7 for details of the conversion.

***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 June 30, 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 December 31, 2020, assumptions included a probability of exercise of the put option of 10% and a discount rate of 42.9%. As noted above, all outstanding derivative liabilities were settled upon the conversion of outstanding notes payable upon the consummation of the merger. Refer to Note 7 for details of the conversion.

The following table presents assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheet as of December 31, 2020. As of June 30, 2021, all contingent put options were settled upon conversion of the notes at the closing of the merger.

| | December 31, 2020 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Contingent put option | $ 670,262 | $ — | $ — | $ 670,262 |
| Total | $ 670,262 | $ — | $ — | $ 670,262 |

The following table summarizes the change in fair value of the Company's Level 3 contingent put options:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Beginning fair value | $ 670,262 | $ 2,646,347 |
| Issuance | 3,052 | 471,823 |
| Change in fair value | (673,314) | (2,447,908) |
| Ending fair value | $ — | $ 670,262 |

See Note 7 for further details on the settlement of 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 initial two-year period was approximately $5.4 million ($3.2 million and $2.2 million in years 1 and 2 respectively) of which the Company must contribute $1.1 million in the first year of the grant. In August 2019, the grant was amended such that the approved budget for the two-year period decreased to approximately $5.1 million ($2.1 million and $3.0 million in years 1 and 2, respectively). In June 2021, the Company received a Notice of Award for an additional $2.8 million of funding in year 3 under the MPAR Grant beginning July 1, 2021.

In 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 for Opioid Use Disorder ("OUD") (the "OUD 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.

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

| | Three months ended | | Six months ended | |
|---|---|---|---|---|
| | June 30, 2021 | June 30, 2020 | June 30, 2021 | June 30, 2020 |
| MPAR Grant | $ 53,386 | $ 1,703,884 | $ 127,112 | $ 2,395,016 |
| OUD Grant | 391,130 | 120,797 | 567,979 | 292,065 |
| Total | $ 444,516 | $ 1,824,681 | $ 695,091 | $ 2,687,081 |

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 and six months ended June 30, 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Stock options | 4,444,068 | 5,785,495 | 4,553,751 | 5,782,721 |
| Warrants | 19,755 | 19,755 | 19,755 | 19,755 |
| Total | 4,463,823 | 5,805,250 | 4,573,506 | 5,802,476 |

***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 freestanding instruments and embedded features that are accounted for as derivatives due to a failure to meet the settlement conditions of the derivatives scope exceptions. The FASB simplified the settlement assessment by removing the requirements to (a) consider whether the contract would be settled in registered shares, (b) to consider whether collateral is required to be posted, and (c) assess shareholder rights. The FASB also decided to enhance information transparency by making targeted improvements to the disclosures for convertible instruments and earnings-per-share guidance. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023 and early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. Entities must adopt the guidance as of the beginning of its annual fiscal year and a modified retrospective or fully retrospective transition approach is permitted. The Company is evaluating the impact of ASU 2020-06 on the consolidated financial statements.

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

Prepaid expenses and other current assets consisted of the following:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Prepaid insurance | $ 179,569 | $ 17,158 |
| Prepaid research and development | 11,498 | 112,966 |
| Other prepaid expenses | 70,450 | — |
| Total prepaid expenses and other current assets | $ 261,517 | $ 130,124 |

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

Accrued expenses and other liabilities consisted of the following:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Professional fees | $ 236,777 | $ — |
| Accrued research and development | 77,552 | 72,906 |
| Accrued scientific advisory board fees | 60,032 | 60,032 |
| Other accrued liabilities | 37,580 | 52,807 |
| Deferred grant revenue | — | 159,047 |
| Total accrued expenses and other liabilities | $ 411,941 | $ 344,792 |

**NOTE 6 - COMMITMENTS AND CONTINGENCIES**

***Litigation***

As of June 30, 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. See Note 11 for additional information about legal proceedings.

***Lease***

During the three and six months ended June 30, 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 was October 1, 2020 and the lease will terminate October 31, 2021 with no option to renew. As of June 30, 2021, the future lease payments totaled $10,200.

The Company recognized total rent expense of $7,062 and $14,123 in the three and six months ended June 30, 2021, respectively. The Company recognized total rent expense of $5,721 and $15,448 in the three and six months ended June 30, 2020, respectively.

**NOTE 7 - NOTES PAYABLE**

The following table provides a summary of the Company's outstanding debt as of June 30, 2021:

| | Principal balance | Accrued interest | Unamortized debt discount | Net debt balance |
|---|---|---|---|---|
| 2020 promissory notes | $ 100,000 | $ 6,722 | $ — | $ 106,722 |
| 2021 promissory notes | 350,000 | 9,333 | — | 359,333 |
| Total | $ 450,000 | $ 16,055 | $ — | $ 466,055 |

The following table provides a summary of the Company's outstanding debt as of December 31, 2020:

| | Principal balance | Accrued interest | Unamortized debt 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 |

The interest expense recognized for notes payable was as follows:

| | Three months ended | | Six months ended | |
|---|---|---|---|---|
| | June 30, 2021 | June 30, 2020 | June 30, 2021 | June 30, 2020 |
| Stated interest accrual | $ 117,817 | $ 88,068 | $ 227,197 | $ 171,507 |
| Debt discount amortization | 771,556 | 113,647 | 945,969 | 359,857 |
| Total | $ 889,373 | $ 201,715 | $ 1,173,166 | $ 531,364 |

***2015 Convertible Notes Payable***

During 2015, the Company issued certain convertible promissory notes in the aggregate principal amount of $873,000. 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 $3,500,000 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).

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 2018 convertible 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.

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, the 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 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 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 at 80% 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***

In March and May 2021, the Company received financing totaling $350,000 under unsecured promissory notes issued to related parties including the Chief Executive Officer and members of the board of directors. 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.

***Settlement of Convertible Notes Payable***

On June 30, 2021, the Company consummated the Business Combination with LACQ, which triggered the automatic conversion into common stock of the 2015 convertible notes payable, the 2018 convertible notes payable, and the 2021 convertible notes payable. In connection with certain closing conditions, the 2020 convertible notes were amended to provide for automatic conversion of the outstanding principal and interest into common stock. The modification resulted in a loss on extinguishment of debt of $347,566 based on the share price on the date of conversion.

The Company applied ASC 470-20-40-1 to the accounting of the conversion, which requires the accelerated recognition of unamortized debt discounts as interest expense upon conversion. Accordingly, $554,911 of unamortized debt discount as of the June 30, 2021 conversion has been recognized as interest expense within the consolidated statement of operations.

The table below summarizes the conversion of each class of notes payable:

| | Immediately prior to merger | | | | |
|---|---|---|---|---|---|
| **Note series** | **Principal** | **Interest** | **Carrying value of debt converted** | **Shares of common stock issued** | **Outstanding debt, June 30, 2021** |
| 2015 Convertible Note | $ 100,000 | $ 31,151 | $ 131,151 | 15,116 | $ — |
| 2018 Convertible Notes | 3,500,000 | 901,466 | 4,401,466 | 1,259,837 | — |
| 2020 Convertible Notes | 700,000 | 64,438 | 764,438 | 77,000 | — |
| 2021 Convertible Note | 50,000 | 2,082 | 52,082 | 6,015 | — |
| Total | $ 4,350,000 | $ 999,137 | $ 5,349,137 | 1,357,968 | $ — |

**NOTE 8 - STOCKHOLDERS' EQUITY**

In June 2021, in connection with the Business Combination, the Company amended and restated its Certificate of Incorporation to authorize 150,000,000 shares of common stock and 1,500,000 shares of preferred stock, both with par value equal to $0.0001. As of June 30, 2021 and December 31, 2020, there were no shares of preferred stock issued and outstanding.

***Common Stock***

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

- 16,053,550 shares of common stock were issued to holders of Former Ensysce common stock.
- 6,219,268 shares of common stock outstanding were assumed by the Company.
- 1,357,968 shares of common stock were issued in settlement of $5.8 million of convertible debt. Refer to Note 7 for details of the conversion.
- 19,755 shares of restricted common stock were issued in exchange for previously outstanding warrants to purchase Former Ensysce common stock.
- 500,000 shares of common stock were issued in settlement of a termination agreement with a strategic advisor dated January 2021.
- 125,000 shares of common stock were issued in settlement of deferred underwriting costs.

***Warrants***

In February 2013, the Company issued 13,170 warrants to purchase common stock, with a ten-year life and an exercise price of $6.23 per share. In August 2019, in connection with the issuance of convertible debt, the Company issued 6,585 warrants to purchase common stock, with a ten-year life and an exercise price of $3.04. As of December 31, 2020, the warrants remained outstanding. On June 30, 2021, the Company issued 19,755 shares of common stock in settlement of the warrants, with such shares subject to restriction until certain conditions are met.

On June 30, 2021, as a result of the Closing, the Company assumed a total of 18,901,290 warrants previously issued by LACQ. The warrants provide holders the right to purchase common stock at a strike price of $11.50 per share and expire June 30, 2026, five years following the completion of the merger. A total of 10,000,000 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 8,901,290 warrants are private warrants with restrictions on transfer and which have the right to a cashless exercise at the option of the holder.

**NOTE 9 - STOCK-BASED COMPENSATION**

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

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

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

As of June 30, 2021 and December 31, 2020, the options outstanding under each plan were as follows:

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Legacy Plans | 264,866 | 543,106 |
| 2016 Plan | 4,034,332 | 4,034,332 |
| 2019 Directors Plan | 144,870 | 151,455 |
| Total options outstanding | 4,444,068 | 4,728,893 |

On June 30, 2021, in connection with the Business Combination, the Company assumed the 2021 Omnibus Incentive Plan, which was approved by LACQ's board and subsequently LACQ's stockholders at a special stockholder meeting on June 28, 2021. The 2021 Omnibus Incentive Plan provides for the conversion with existing terms of the 4,444,068 options outstanding under Former Ensysce stock plans and reserves for issuance an additional 1,000,000 shares for future awards under the 2021 Omnibus Incentive Plan. No further awards may be made under the Former Ensysce stock plans.

***Option Activity***

During the three and six months ended June 30, 2020, the Company granted stock options to purchase an aggregate of 65,850 shares of common stock to a member of the board of directors. The options vest over three years and have an exercise price of $3.35 per share.

The Company recognized within general and administrative expense stock-based compensation expense of $36,373 and $80,193 for the three and six months ended June 30, 2021, respectively. The Company recognized within general and administrative expense stock-based compensation expense of $36,065 and $68,551 for the three and six months ended June 30, 2020, respectively. During the three and six months ended June 30, 2021 and 2020, there was no stock-based compensation allocated to research and development expense.

The following table summarizes the Company's stock option activity during the six months ended June 30, 2021:

| | | Weighted average | | |
|---|---|---|---|---|
| | Options | Exercise price | Remaining contractual life | Intrinsic value |
| Outstanding at December 31, 2020 | 4,728,893 | $ 2.28 | 6.80 | $ 1,817,383 |
| Granted | — | — | — | — |
| Exercised | (284,825) | 0.91 | — | 472,453 |
| Expired / Forfeited | — | — | — | — |
| Outstanding at June 30, 2021 | 4,444,068 | 2.40 | 6.50 | 53,714,731 |
| Exercisable at June 30, 2021 | 4,337,971 | 2.38 | 6.40 | 52,524,462 |
| Vested and expected to vest | 4,444,068 | 2.40 | 6.50 | 53,714,731 |

***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:

| | Six months ended June 30, 2020 |
|---|---|
| Stock price | $ 2.58 |
| Exercise price | $ 3.34 |
| 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 six months ended June 30, 2020 was $2.21. There were no options granted during the six months ended June 30, 2021.

As of June 30, 2021, the Company had an aggregate of $79,259 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 1.9 years.

***Shares Reserved for Future Issuance***

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

| | June 30, 2021 |
|---|---|
| Stock options outstanding | 4,444,068 |
| Stock options available for future grant under 2021 Omnibus Incentive Plan | 1,000,000 |
| Warrants outstanding | 18,901,290 |
| Total shares of common stock reserved for future issuance | 24,345,358 |

**NOTE 10 - RELATED PARTIES**

The Company paid cash compensation during the three and six months ended June 30, 2021 of $10,752 and $40,314, respectively, to the Chief Executive Officer through a separate operating company with which the Chief Executive Officer is affiliated. Such cash compensation totaled $38,967 for the three and six months ended June 30, 2020. As of June 30, 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 $2.5 million as of December 31, 2020. All outstanding notes converted into common stock upon the closing of the merger on June 30, 2021.

As of June 30, 2021 and December 31, 2020, the Company had promissory notes outstanding which totaled $450,000 and $100,000, respectively, to three members of the board of directors, including the Chief Executive Officer and Chairman of the Board, as described in Note 7.

**NOTE 11 - SUBSEQUENT EVENTS**

On July 2, 2021, the Company's shares became publicly listed on Nasdaq under the ticker symbol ENSC. Pursuant to the terms of a $60.0 million share subscription facility, the public listing caused the Company to issue to an investor 1,106,108 warrants with an exercise price of $10.01 per share and a three-year contractual term. In addition, on the July 2, 2021 public listing date, the Company became obligated to pay a commitment fee 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 may be paid from the proceeds of a draw against the facility or in freely tradable common stock of the Company.

On July 12, 2021, following the Business Combination with LACQ, 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 resale Registration Statement on Form S-1 that it filed on August 9, 2021 (the "Resale 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 the Resale Registration Statement.

On July 15, 2021, the Company repaid the outstanding 2020 promissory notes and 2021 promissory notes in full.

On July 22, 2021, the Company engaged consultants to perform certain public and investor relations services in consideration for 500,000 shares of common stock issuable upon exercise of 500,000 warrants with a five-year term and an exercise price of $6.28, 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.

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

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

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

**Overview**

Ensysce Biosciences, Inc. is a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the fear of and the potential for 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 Ensysce's 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 removes the ability to crush, chew or manipulate and inject to achieve the medication more quickly than by swallowing. MPAR™ adds a layer of overdose protection to each TAAP product.

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

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

We have incurred significant operating losses since inception. As of June 30, 2021, we had an accumulated deficit of $57.8 million. We expect to continue to incur net losses for the foreseeable future, and we expect our clinical development expenses, and general and administrative expenses to continue to increase. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

- continue preclinical studies and continue existing and initiate new clinical trials for PF614, PF614-MPAR™ and nafamostat, our lead product candidates being tested for chronic pain and infectious disease;

- advance the development of our product candidate pipeline of other product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

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

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

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

*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.

**Business Combination Transaction**

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

**Components of Ensysce's Operating Results**

***Revenue***

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

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

***Operating Expenses***

*Research and development expenses*

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

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

We recognize external development costs as incurred. Any advance payments that we 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™ and nafamostat, as well as conduct other preclinical and clinical development, including submitting regulatory filings for our other product candidates. We also expect our discovery research efforts and our related personnel costs to increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, to increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

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

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

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

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

*General and administrative expenses*

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

We anticipate that our general and administrative expenses 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)**

*Change in fair value of derivative liability*

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

*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.

***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, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

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

***Results of Operations***

***Comparison of the three months ended June 30, 2021 and 2020***

The following table summarizes the significant items within our results of operations for the three months ended June 30, 2021 and 2020:

| | Three Months Ended June 30, | | Increase |
|---|---|---|---|
| | 2021 | 2020 | (Decrease) |
| Federal grant funding | $ 444,516 | $ 1,824,681 | $ (1,380,165) |
| | | | |
| Research and development expenses | $ 463,219 | $ 1,404,246 | $ (887,998) |
| General and administrative expenses | 393,914 | 281,354 | 112,480 |
| Other income (expense), net | (544,994) | (845,555) | 300,561 |

*Federal grant funding*

Funding from federal grants for the three months ended June 30, 2021 and 2020 totaled $0.4 million and $1.8 million, respectively, representing a decrease of $1.4 million. Funding decreased by $1.7 million under the MPAR Grant, offset by an increase of $0.3 million under the OUD Grant, due to the timing of research activities eligible for funding. We expect funding from federal grants to increase in the future due to the timing of preclinical and clinical development activities under the grants.

*Research and development expenses*

Research and development expenses for the three months ended June 30, 2021 and 2020 were $0.5 million and $1.4 million, respectively, representing a decrease of $0.9 million. The decrease was primarily the result of reduced external research and development costs related to preclinical programs for PF614-MPAR™ and Phase 1 clinical trial activities of nafamostat. Ensysce does not currently track expenses on a program-by-program basis. We expect research and development expenses to increase in the future due to planned clinical trials and higher preclinical and clinical development costs for our product candidates.

*General and administrative expenses*

General and administrative expenses for the three months ended June 30, 2021 and 2020 were $0.4 million and $0.3 million, respectively, representing an increase of $0.1 million. The increase was primarily a result of higher legal and other professional services expenses related to post-Business Combination corporate matters. We expect our general and administrative expenses to increase in the future due to increased director and officer insurance costs and various expenses related to operating as a public company.

*Other income (expense), net*

Other income (expense), net resulted in expense of $0.5 million for the three months ended June 30, 2021, compared to expense of $0.8 million for the three months ended June 30, 2020. The decrease in net expenses is largely driven by changes in fair value of the derivative liability which provided income of $0.7 million in the 2021 period compared to expense of $0.6 million in the 2020 period. The change resulted from the decreased likelihood of realization of the embedded derivative instrument in convertible notes payable. Interest expense increased $0.7 million in the 2021 period due to the accelerated recognition of $0.6 million of unamortized debt discounts upon the conversion of outstanding convertible notes on June 30, 2021. A loss on extinguishment of debt of $0.3 million in the 2021 period also contributed to the change in other income (expense), net.

***Comparison of the six months ended June 30, 2021 and 2020***

The following table summarizes the significant items within our results of operations for the six months ended June 30, 2021 and 2020:

| | Six Months Ended June 30, | | Increase |
|---|---|---|---|
| | 2021 | 2020 | (Decrease) |
| Federal grant funding | $ 695,091 | $ 2,687,081 | $ (1,991,990) |
| | | | |
| Research and development expenses | $ 787,595 | $ 2,243,217 | $ (1,402,593) |
| General and administrative expenses | 884,386 | 559,047 | 325,259 |
| Other income (expense), net | (932,413) | (1,614,538) | 682,125 |

*Federal grant funding*

Funding from federal grants for the six months ended June 30, 2021 and 2020 totaled $0.7 million and $2.7 million, respectively, representing a decrease of $2.0 million. Funding decreased by $2.3 million under the MPAR Grant, offset by an increase of $0.3 million under the OUD Grant, due to the timing of research activities eligible for funding. We expect funding from federal grants to increase in the future due to the timing of preclinical and clinical development activities under the grants.

*Research and development expenses*

Research and development expenses for the six months ended June 30, 2021 and 2020 were $0.8 million and $2.2 million, respectively, representing a decrease of $1.4 million. The decrease was primarily the result of reduced external research and development costs related to preclinical programs for PF614-MPAR™ and Phase 1 clinical trial activities of nafamostat. Ensysce does not currently track expenses on a program-by-program basis. We expect research and development expenses to increase in the future due to planned clinical trials and higher preclinical and clinical development costs for our product candidates.

*General and administrative expenses*

General and administrative expenses for six months ended June 30, 2021 and 2020 were $0.9 million and $0.6 million, respectively, representing an increase of $0.3 million. The increase was primarily driven by increases in accounting, auditing, and tax services as well as legal fees related to post-Business Combination corporate matters. We expect our general and administrative expenses to increase in the future due to increased director and officer insurance costs and various expenses related to operating as a public company.

*Other income (expense), net*

Other income (expense), net resulted in expense of $0.9 million for the six months ended June 30, 2021, compared to expense of $1.6 million for the six months ended June 30, 2020. The decrease in net expense was largely due to changes in fair value of the derivative liability which provided income of $0.7 million in the 2021 period compared to expense of $1.1 million in the 2020 period. The change resulted from the decreased likelihood of realization of the embedded derivative instrument in convertible notes payable. Interest expense increased $0.7 million in the 2021 period due to the accelerated recognition of $0.6 million of unamortized debt discounts upon the conversion of outstanding convertible notes on June 30, 2021. A loss on extinguishment of debt of $0.3 million in the 2021 period also contributed to the change in other income (expense), net.

**Liquidity and capital resources**

***Sources of liquidity and capital***

As of June 30, 2021, we had $8.0 million of cash and cash equivalents. Since inception, we have generated limited revenues and have incurred significant operating losses and negative cash flows from our operations, and we anticipate that we will continue to incur losses for at least the foreseeable future. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. As of June 30, 2021, we had an accumulated deficit of $57.8 million.

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

Current remaining funding under two approved federal research grants totals $6.6 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 certain milestones. We have met the required milestones under the MPAR Grant. The remaining milestone under the OUD Grant is identification of a R-methadone-TAAP clinical candidate that meet the specified criteria.

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

Under an agreement established in December 2020, an investor agreed to provide us with a share subscription facility of up to $60.0 million for a 36-month term following the public listing of our common stock. We control the timing and maximum amount of drawdown under this facility and have no minimum drawdown obligation. The investor will pay, in cash, a per-share amount equal to 90% of the average daily closing price of our stock during the 30 consecutive trading days following delivery of a draw notice, which shall not exceed 400% of the average trading volume for the 30 trading days immediately preceding delivery of the draw notice. We 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 our freely tradable common stock. On June 30, 2021, we consummated the Business Combination with LACQ, resulting in the public listing of our shares of common stock on Nasdaq on July 2, 2021. Concurrent with the public listing of our shares of common stock on Nasdaq, we were also required to issue to the investor 1,106,108 warrants with a strike price of $10.01 per share. The number of shares of common stock 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.

***Cash flows***

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Net cash used in operating activities | $ (649,461) | $ (560,573) |
| Net cash provided by financing activities | 8,467,029 | 800,020 |
| Net increase in cash and cash equivalents | $ 7,817,568 | $ 239,447 |

*Operating activities*

During the six months ended June 30, 2021 and 2020, we used cash in operating activities of $0.6 million and $0.6 million, respectively, primarily resulting from legal and accounting fees, changes in prepaid expenses and accrued expenses due to the advancement of our product candidates, and the timing of vendor invoicing and payments.

*Financing activities*

During the six months ended June 30, 2021, net cash provided by financing activities was $8.5 million, primarily consisting of proceeds from the Business Combination. During the six months ended June 30, 2020, net cash provided by financing activities was $0.8 million, primarily consisting of proceeds from the issuance of convertible notes.

***Funding requirements***

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

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

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, preclinical and clinical drug material and develop processes for late 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;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- obtain, maintain, expand and protect our intellectual property portfolio;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- manage the costs of operating as a public company.

***Going concern***

We have generated limited revenues and have incurred significant operating losses since our inception and, as of June 30, 2021, had an accumulated deficit of $57.8 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future.

Following the completion of the Business Combination and public listing of our common stock on Nasdaq, we now have access to up to $60 million from a share subscription facility entered into in December 2020. Management believes that its existing cash resources and the proceeds available through the existing share subscription facility are sufficient to allow us to fund current planned operations through the next 12 months following the filing of this Quarterly Report on Form 10-Q.

For additional information on risks associated with our capital requirements, please read the section titled "*Risk Factors*" included elsewhere in this Quarterly Report on Form 10-Q.

***Working capital***

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;

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

**Critical accounting policies and significant judgments and estimates**

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

While our significant accounting policies are described in more detail in Note 3 to our unaudited interim consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

***Accrued research and development expenses***

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

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

We 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.

***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 Former Ensysce common stock prior to the date of the Closing of the Business Combination, the estimated fair value of Former Ensysce 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 event, such as a strategic sale or a merger. A discount for lack of marketability 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 Former Ensysce common stock of $1.37 per share as of July 1, 2017, $1.82 per share as of February 28, 2018, $2.58 per share as of October 1, 2018, and $2.58 per share as of December 31, 2019 (prices adjusted for the exchange ratio of 0.06585 per the merger agreement).

In addition to considering the results of these third-party valuations, our board of directors 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;
- 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 trade on Nasdaq, so it will no longer be necessary for our board of directors 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 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 do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

**Recently issued accounting pronouncements**

A description of recently issued accounting pronouncements that may potentially impact Ensysce's financial position and results of operations is disclosed in Note 3 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

**Emerging growth company and smaller reporting company status**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company we are not 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.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

Our cash and cash equivalents as of June 30, 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.

***Inflation Risk***

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) as of June 30, 2021. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of June 30, 2021 due to the material weaknesses in our internal controls over financial reporting described below. Notwithstanding these material weaknesses, management has concluded that our financial statements included in this Quarterly Report on Form 10-Q are fairly stated in all material respects in accordance with GAAP for each of the periods presented therein.

**Material Weaknesses and Remediation Plan**

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2019, and our unaudited interim consolidated financial statements for the three and six months ended June 30, 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. Further, we plan to enhance our processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

**Item 1. Legal Proceedings.**

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

In July 2021, following the Business Combination with LACQ, our former financial advisor, Del Morgan Group, LLC and Globalist Capital, LLC (together, "*Plaintiffs*") filed an action against us and our 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 our Resale 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 Resale Registration Statement. The Resale Registration Statement was filed with the SEC on August 9, 2021.

**Item 1A. Risk Factors.**

**Summary of Risk Factors**

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 in the section below. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described below 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™ 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 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.
- Our predecessor 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.
- 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.

**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 $1.9 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $57.8 million. 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.

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 on 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™. 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 Business Combination, 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™ 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 faster than we currently anticipate, and we may need to seek additional 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;
- 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 Business Combination 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 of the Business Combination. 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.

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™ 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;
- 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 commercial organization, or collaborate with third parties for the 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™, 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 and disease 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™ 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™. 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.

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:

- 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 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 three 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.

***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 operations.

***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 quarantines 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.

***Some of our programs are partially supported by government grant awards, which may not be available to us in the future.***

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.

**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 manufacturer, 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.

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 that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates 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;
- 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™ 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 similar strategy as required by a regulatory authority.

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 state healthcare fraud 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 controlling unknown or unmanaged risks or losses or in protecting Ensysce 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 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 such additional financing on 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 in our favor. If the third party does not file a patent 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.

***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 trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential 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 efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

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;
- 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.

***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 for certain narcotic drugs, including oxycodone over the last five years. Also, in October 2018, Congress passed the SUPPORT Act which requires the DEA to consider potential 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™ 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™, 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. For 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 products with the same composition as our product candidate so long as the competitors do not infringe any method patents that we may hold. Method patents protect the 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 of others.

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 product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, 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.

There can be no assurances that we will be successful with respect to any litigation matters which may arise in the ordinary course of our business. Such a failure may have 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 on the grounds that our 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.

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 that we develop or license. Furthermore, while we intend to protect our 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.

***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 patents and pending 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 in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and 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 law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces 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 laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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.

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. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at 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 amphetamines. 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 or ownership. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership 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 or the use of 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.

***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 stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may be issued in the future, within our portfolio which could result in the invalidation of some or 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.

***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 attest to the effectiveness of our internal control over financial reporting on an annual basis. However, while we remain an emerging growth company, we are not be 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 compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting.

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;
- 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 would no longer be an emerging growth company as of the last day of such fiscal year. We cannot predict whether investors will 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 may be more volatile.

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,
- 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 become 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 Business Combination, 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 our predecessor prior to the Business Combination but did not remain so with respect to us after the Business Combination. In addition, we may soon register shares of common stock that we may issue under our 2021 Omnibus Incentive Plan. Shares of our common stock 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 Business Combination until the earlier to occur of (a) one year after the Business Combination 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 Business Combination, 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.

***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, our predecessor'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 our predecessor 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 our predecessor'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. Our predecessor concluded that, while the SEC Statement did not expressly refer to a multi-class structure (such as a structure where a SPAC had two classes of common stock), the SEC Statement with respect to a tender offer provision in a warrant agreement applied to a multi-class structure (such as a Class A and Class B structure) and not a single class structure like our predecessor'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.

Our predecessor 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). Our predecessor 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. Our predecessor 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 this position and restate our financial statements or treat private warrants as liabilities, which could have a material adverse effect on 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 6, 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, 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 of directors 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.

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 United States District Court for 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.

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

(a) 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 section of 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, between 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.

(b) Use of Proceeds

On June 30, 2021, we consummated the Business Combination. At the closing of the Business Combination, we received net proceeds of approximately $6.6 million after deducting total expenses of $1.2 million.

The Securities Act Registration Statement on Form S-4 (the "Form S-4") for which the use of proceeds from the Business Combination is being disclosed (SEC file number 333-254279) was declared effective on June 16, 2021 and all of the securities registered thereby were issued without use of an underwriter, all proceeds to the Company. The securities issued consisted solely of 18,000,000 shares of common stock, par value $0.0001 per share. The aggregate price of the offering amount registered was calculated for purposes of the Form S-4 as $2,733,485.

The Business Combination with LACQ triggered the conversion of the 2015 convertible notes, the 2018 convertible notes and the 2021 convertible note of Former Ensysce. In connection with the Closing, the 2020 convertible notes were also settled in shares of the combined entity. The 2020 promissory notes and 2021 promissory notes were repaid in July 2021 from the cash proceeds of the Business Combination with LACQ.

We expect to use the remaining net proceeds from the Business Combination and the transactions set forth above primarily to fund our preclinical and clinical development activities and for general corporate purposes.

(c) Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended June 30, 2021.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits.**

The following exhibits are filed as part of this report:

| Exhibit Number | Description |
|---|---|
| 3.1 | Third Amended and Restated Certificate of Incorporation previously filed with the SEC on July 7, 2021 as Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38306), which is incorporated herein by reference. |
| 3.2 | Amended and Restated Bylaws previously filed with the SEC on July 7, 2021 as Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38306), which is incorporated herein by reference. |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2* | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of San Diego, State of California, on this 16th day of August, 2021.

**ENSYSCE BIOSCIENCES, INC.**

Date: August 16, 2021

*/s/ Lynn Kirkpatrick*

Dr. Lynn Kirkpatrick
President and Chief Executive Officer

Date: August 16, 2021

*/s/ David Humphrey*

David Humphrey
Chief Financial Officer, Secretary and Treasurer

**Exhibit 31.1**

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

I, Lynn Kirkpatrick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ensysce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

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

**Exhibit 31.2**

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

I, David Humphrey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ensysce Biosciences, Inc,;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

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

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lynn Kirkpatrick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: August 16, 2021

*/s/ Lynn Kirkpatrick*

Lynn Kirkpatrick
Chief Executive Officer
(Principal Executive Officer)

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

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Humphrey, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Dated: August 16, 2021

*/s/ David Humphrey*
David Humphrey
Chief Financial Officer
(Principal Financial Officer)

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