

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

FORM 8-K/A
(Amendment No. 2)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2026 (August 5, 2026)

Ensysce Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-38306
(Commission
File Number)

82-2755287
(I.R.S. Employer
Identification Number)

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

92037
(Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value \$0.0001 per share	ENSC	The Nasdaq Stock Market LLC

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. ☐

Explanatory Note.

On August 6, 2026, Ensysce Biosciences, Inc., a Delaware corporation (“we,” “us,” “our,” or the “Company”), filed a Current Report on Form 8-K with the Securities and Exchange Commission (the “Original 8-K”), which reported information under Items 1.01, 2.01, 3.02, 3.03, 5.02, 5.03, 7.01 and 9.01 of Form 8-K. The Original 8-K was amended on August 6, 2026, to file exhibits and correct an error. This Current Report on Form 8-K/A (“Amendment No. 2”) includes (i) certain risk factors relating to the transactions previously reported (“Risk Factors”), (ii) an overview of the business (“Business Overview”) of Cy Biopharma, Inc. (“Cy Biopharma”), (iii) historical financial statements of Cy Biopharma and our unaudited *pro forma* condensed combined financial information giving effect to our merger with Cy Biopharma as of and for the six months ended June 30, 2026, and for the fiscal year ended December 31, 2025.

The *pro forma* financial information included herein has been presented for informational purposes only. It does not purport to represent the actual results of operations that we and Cy Biopharma would have achieved had the companies been combined during the periods presented in the *pro forma* financial information and is not intended to project the future results of operations that the combined company may achieve.

The Business Overview and Risk Factors are filed as Exhibits 99.1 and 99.2, respectively, to this Amendment No. 2 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

The historical audited consolidated financial statements of Cy Biopharma as of and for the years ended December 31, 2025 and 2024 are filed as Exhibit 99.3 to this

Amendment No. 2 and incorporated herein by reference.

The unaudited condensed consolidated financial statements of Cy Biopharma as of and for the six months ended June 30, 2026 and 2025 are filed as Exhibit 99.4 to this Amendment No. 2 and incorporated herein by reference.

(b) Pro forma financial information.

The unaudited *pro forma* condensed combined balance sheet as of June 30, 2026, the unaudited *pro forma* condensed combined statements of operations for the six months ended June 30, 2026, the unaudited *pro forma* condensed combined statements of operations for the year ended December 31, 2025, and the related notes of the Company with respect to the transaction described in the Original 8-K, are filed as Exhibit 99.5 to this Amendment No. 2 and incorporated herein by reference.

(d) Exhibits

Exhibit Number	Description
23.1	Consent of EisnerAmper LLP
99.1	Business Overview
99.2	Risk Factors
99.3	Audited Consolidated Financial Statements of Cy Biopharma, Inc. as of and for the fiscal years ended December 31, 2025, and December 31, 2024, and the related notes thereto.
99.4	Unaudited Condensed Consolidated Financial Statements of Cy Biopharma, Inc. as of June 30, 2026, and for the six months ended June 30, 2026 and 2025, and the related notes thereto.
99.5	Unaudited <i>pro forma</i> condensed combined financial statements of Ensysce Biosciences, Inc. as of and for the six months ended June 30, 2026, and for the year ended December 31, 2025, and the related notes thereto.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Dated: October 15, 2026

Ensysce Biosciences, Inc.

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Ensycse Biosciences, Inc. on Forms S-8 (No. 333-295451, No. 333-286948, No. 333-275095, No. 333-262419 and No. 333-260116) and Forms S-3 (No. 333-296499, No. 333-294939, No. 333-291892, No. 333-286943, No. 333-286584, No. 333-286580, No. 333-282563, No. 333-269472, No. 333-269157, No. 333-267001, No. 333-276537, and No. 333-275456) of our report dated May 13, 2026, on our audits of the financial statements of Cy Biopharma, Inc. as of December 31, 2025 and 2024 and for each of the years then ended, which report is included in this Form 8-K/A (Amendment No. 2) to be filed on or about October 15, 2026. Our report includes an explanatory paragraph about the existence of substantial doubt concerning Cy Biopharma, Inc.'s ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
October 15, 2026

BUSINESS OVERVIEW

Corporate Information

We were originally incorporated in the State of Delaware in April 2003 as PharmacoFore, Inc. and, in January 2012, we changed our name from PharmacoFore, Inc. to Signature Therapeutics Inc. (“*Signature*”). In December 2015, Signature merged with and into Ensysce Biosciences, Inc. (“*Former Ensysce*”). In June 2021, Former Ensysce merged with and into Leisure Acquisition Corporation (“*LACQ*”). As part of the transaction, LACQ changed its name to “Ensysce Biosciences, Inc.”

On August 5, 2026, we completed our acquisition of Cy Biopharma, Inc. (“*Cy Biopharma*”) pursuant to an Agreement and Plan of Merger, dated August 5, 2026 (the “*Merger Agreement*”), by and among us, PHRMA Merger Sub I, Inc. (“*First Merger Sub*”), PHRMA Merger Sub II, LLC (“*Second Merger Sub*”) and Cy Biopharma (the “*Acquisition*”). The Acquisition was effected in two steps: first, First Merger Sub merged with and into Cy Biopharma, with Cy Biopharma surviving as our wholly owned subsidiary; immediately thereafter, Cy Biopharma merged with and into Second Merger Sub, with Second Merger Sub surviving as our wholly owned subsidiary. The Acquisition is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. As consideration for the outstanding equity interests of Cy Biopharma, we issued to Cy Biopharma’s equityholders the right to receive 282,122 shares of our Series C Preferred Stock, par value \$0.0001 per share (the “*Series C Preferred Stock*”), each of which is convertible into 1,000 shares of our common stock, subject to applicable conditions, including stockholder approval of the conversion of the Series C Preferred Stock. Concurrently with the Acquisition, we completed a private placement in which we issued 66,811 shares of Series C Preferred Stock for gross proceeds, before deducting placement agent fees and other transaction expenses, of approximately \$21.5 million. Before the Acquisition, Cy Biopharma also completed a convertible note financing that provided approximately \$17.1 million in cash.

The mailing address of our principal executive office is 7946 Ivanhoe Avenue, Suite 201, La Jolla, California 92037. Our corporate telephone number is (858) 263-4196. Our website address is www.ensysce.com. Information contained on our website, or connected thereto, does not constitute part of, and is not incorporated by reference into, our Annual Report on Form 10-K.

Channels for Disclosure of Information

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

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

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

Business Overview

We are a clinical stage pharmaceutical company seeking to develop innovative solutions for severe chronic pain relief while reducing the potential for opioid misuse, abuse, and overdose.

We are currently developing product candidates designed to improve the safety of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Prescription opioid abuse presents major burdens to society, resulting in significant costs, illnesses, and deaths, many of which we believe could be prevented through the use of our proprietary technologies. We believe the intertwined issues of (1) the widespread abuse of prescription opioids and (2) the resultant reluctance of many prescribers to write prescriptions for opioid analgesics have resulted in the persistent under-treatment of patients with moderate-to-severe pain. Our platforms utilize a novel molecular delivery technology designed to deter prescription opioid abuse at the molecular level, provide a number of safety features and have been shown to provide what we believe are advantages over currently prescribed opioid medication. Following the closing of the Acquisition, we have also expanded our pipeline to include novel neuroplastic therapeutic approaches for severe chronic and complex pain disorders.

Our existing development pipeline included two new drug platforms— an abuse-resistant opioid prodrug technology – the Trypsin Activated Abuse Protection platform (the “*TAAP platform*”), and an overdose protection opioid prodrug technology – the Multi-Pill Abuse Resistance platform (“*the MPAR® platform*”). The TAAP platform is designed to seek to improve the care of patients with severe pain while reducing the human and economic costs associated with prescription opioid drug abuse. The MPAR® platform when combined with our TAAP prodrugs is designed not only to seek to prevent abuse of prescription drugs but also to reduce overdose occurrences. Each prodrug is intended to be able to be combined with our MPAR® technology for overdose protection. With our acquisition of Cy Biopharma, our development pipeline was expanded to include Cy Biopharma’s technology platform based on serotonergic modulation of neural networks through the 5-HT_{2A} serotonin receptor and a neuroplastic approach intended to address neural circuitry associated with severe chronic and complex pain disorders.

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

Utilizing this approach, we filed an Investigational New Drug application, or IND (116794), and commenced a Phase 1 clinical trial for PF614, which was completed in February 2018. The clinical data from the Phase 1 trial demonstrated that oxycodone released from PF614 as chemically-designed, and that it was absorbed following oral administration of the TAAP PF614, resulting in blood levels that matched the same release profile as the extended release oxycodone product, OxyContin OP, yet provided a longer half-life indicating that PF614 was a product that could be more effective on a twice daily prescribing basis. A second multi-ascending dose study with a bioequivalent arm was completed in July 2022 and a nasal human abuse potential (HAP) study was completed in October 2022. A second oral HAP study was completed in March 2023. A study to evaluate efficacy was completed in December 2023. A Phase 3 efficacy study in abdominoplasty was initiated with enrollment beginning in 2025 and is ongoing.

The MPAR® technology is designed to limit the bioavailability of active opioid following co-ingestion of more than prescribed doses, whether inadvertent or intentional, through a combination of a TAAP prodrug with nafamostat. Nafamostat is a small molecule that clinical studies have shown to have a steep dose response curve and to be a highly potent trypsin inhibitor. When combined with our TAAP prodrugs, our MPAR® technology is designed not to affect metabolism and the release of the active pharmaceutical ingredient. However, if the MPAR® combination product is taken in larger quantities than intended, the excess nafamostat is designed to inhibit trypsin, thereby

limiting metabolic activation and the release of active opioid. We believe the potential benefits to society of an opioid that resists both oral and parenteral abuse are considerable. A Phase 1 study to explore the combination of PF614 and nalfamostat, PF614-MPAR-101 was initiated in December of 2021, and early data from the study reported in May 2022 showed a reduction in the release of oxycodone over that of PF614 delivered alone. A second part of this trial to confirm overdose protection from PF614-MPAR 25 mg was completed in 2023 and data reported in May 2023. PF614-MPAR was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (the “FDA”) in January 2024. A second study, PF614-MPAR-102, designed to evaluate the overdose protection across a range of dosages, initiated enrollment of subjects in December 2024 and has completed enrollment, with final data expected in late Q4 2026.

Unlike our TAAP and MPAR® platforms, which are designed to improve the safety profile of existing prescription opioid therapies, Cy Biopharma’s technology platform is designed to act on the underlying neurobiology thought to drive and sustain severe chronic pain disorders, such as Complex Regional Pain Syndrome (“CRPS”), based on serotonergic modulation of neural networks through the 5-HT_{2A} serotonin receptor and a neuroplastic approach intended to address neural circuitry associated with severe chronic pain disorders. CY200, a clinical-stage psilocybin-based therapy whose active ingredient has received U.S. FDA Orphan Drug Designation, is a psilocybin-predominant botanical extract being developed as an oral therapy for the treatment of CRPS Type 1; psilocybin is converted in vivo to psilocin, which acts at 5-HT_{2A} receptors. CY201 is a proprietary psilocin-dominant oral liquid formulation being evaluated as an alternative oral formulation, with potential composition-of-matter and distribution advantages. Cy Biopharma’s preclinical product candidates include CY30X and CY40X, a library of novel 5-HT agonists being evaluated for partial 5-HT_{2A} agonism, high 5-HT_{1A} activity and low 5-HT_{2B} risk, among other receptor activity.

Our pipeline has been developed over the course of more than twenty years of research and investment. As a result of our acquisition of Cy Biopharma, our combined pipeline includes three clinical-stage product candidates. In addition to lead product candidates that are geared towards combating abuse and overdose of opioid drugs, the acquisition of Cy Biopharma has expanded our capabilities into neuroplastic therapies for severe chronic and complex pain. We have, over the years of research and development, discovered and recognized qualities and unique features of certain product candidates that may be useful in addressing additional treatment indications.

PF614

PF614 is our lead TAAP prodrug candidate under development for the treatment of acute or chronic pain. PF614 is a delayed release TAAP prodrug designed to release oxycodone under certain specific physiological circumstances when taken orally. PF614 was evaluated for safety and pharmacokinetic release of oxycodone in a Phase 1 single ascending dose clinical trial in 64 healthy subjects. The trial showed that PF614 was well tolerated with no serious adverse events. The study also showed pharmacokinetics had a maximum blood concentration of oxycodone at 4 to 6 hours after swallowing PF614, demonstrating its delayed release profile. A second Phase 1b multi-ascending dose study (MAD) was initiated in 2021 to evaluate PF614 delivered to healthy subjects twice daily for 4.5 days. This study evaluated both safety and PK, with a second part to evaluate the bioequivalence (BE) of PF614 versus OxyContin. Final data from this trial was reported in July 2022. The MAD study demonstrated both the safety of PF614 showing it was well tolerated at doses up to 200 mg, which was comparable to 80 mg of OxyContin both delivered twice daily. The BE study arm followed the successful completion of the multi-ascending twice-daily dosing study of PF614 and compared the release of oxycodone from PF614 versus OxyContin® administered to subjects in both fasted and fed states. It was concluded that 100 mg PF614 was bioequivalent to 40 mg OxyContin under both fasted and fed conditions. This data is critical to understand future prescribing criteria for PF614 as an agent bioequivalent to OxyContin and therefore may be developed through the 505(b)(2) regulatory path as defined by the FDA. The intranasal (IN) and oral human abuse potential of PF614 was assessed in two different studies. In study 1, PF614-103, we evaluated the abuse potential of PF614 100 mg relative to crushed oxycodone immediate-release (IR) tablets 40 mg (equivalent opioid doses) and placebo following intranasal administration. In study 2, PF614-104, we evaluated the oral abuse potential of intact PF614 at 3 different dose levels 50, 100 and 200 mg to IR oxycodone 40 mg and placebo. The purpose of this study is to assess the PK and human oral abuse potential of PF614. An efficacy study, PF614-201 was conducted to evaluate 50 and 100 mg PF614 in 16 healthy male subjects for the time of onset of pain relief and the ability of PF614 to relieve pain. The data was used to design our Phase 3 clinical trial.

We initiated our pivotal Phase 3 trial, PF614-301, examining the efficacy of PF614 in post-operative acute pain following abdominoplasty in July 2025 and enrollment began in December 2025. We believe PF614 has the potential to provide a safer alternative to the abuse deterrent formulated opioid products that are currently commercially available.

PF614-MPAR

PF614-MPAR, a combination product of PF614 and nalfamostat has been designed to limit abuse potential by providing resistance to use through injection or inhalation and to provide overdose protection against excessive oral ingestion. Our IND application (150966) for PF614-MPAR received FDA allowance on April 27, 2021 following the release of a Full Clinical Hold from January 8, 2021. We addressed deficiencies from the initial IND submission, amended the protocol and submitted a response to the clinical hold letter on March 29, 2021. We initiated a Phase 1 clinical trial, PF614-MPAR-101, to evaluate safety and PK in healthy subjects in December 2021. Initial data from this trial was reported in May of 2022. The PF614-MPAR-101 overdose protection study examined PF614 administered orally alone or in combination with the trypsin inhibitor nalfamostat (MPAR®) to healthy volunteers. The initial data showed reduced release of oxycodone from PF614 in a simulated overdose situation. It also demonstrated the PF614 in the systemic circulation (simulated injection) did not convert to oxycodone. We completed the clinical portion and reported data from Part A of this study in December 2022. Part B of the study to test the overdose protection of the selected PF614-MPAR 25 mg formulation by administering an escalating number of dose units to a group of healthy subjects completed enrollment in March 2023. The PK data from Part B successfully showed that PF614-MPAR® 25 mg administered at a prescribed dose of one or two dose units (capsules) provided oxycodone in an equivalent manner to PF614 without MPAR®. However, the simultaneous administration of 3 dose units or greater of PF614-MPAR 25 mg, resulted in reduced oxycodone in the circulation, as compared to the unprotected PF614. There was a highly significant difference between the oxycodone blood levels following delivery of PF614 200 mg versus 8 dose units of PF614-MPAR 25 mg (200 mg PF614 total) demonstrating the reduction in oxycodone exposure produced by the MPAR® technology. This was reported in May of 2023. PF614-MPAR was granted Breakthrough Therapy designation by the FDA in January 2024.

A second three-part trial, PF614-MPAR-102, began in December 2024 to examine a 100 mg dose of PF614-MPAR. Parts 1, 2 and 3 of the trial have been completed and final data is expected in late Q4 2026. MPAR was tested clinically in partnership with Quotient Sciences, using its integrated Translational Pharmaceuticals® platform to search for a PF614-MPAR formulation that allows conversion into oxycodone within the prescribed dose range but reduces conversion to oxycodone at higher than prescribed dose levels in an overdose scenario.

CY200 and CY201

Through our acquisition of Cy Biopharma, we acquired CY200, a psilocybin-predominant botanical extract being developed as an oral neuroplastic therapy for the treatment of CRPS Type 1. Psilocybin has received U.S. FDA Orphan Drug Designation for the treatment of CRPS. CY200 is designed to act on the underlying neurobiology thought to drive and sustain CRPS through serotonergic modulation of neural networks via 5-HT_{2A} receptor activation, with the goal of producing durable clinical benefit. We are advancing a randomized, double-blind, placebo-controlled Phase 2 proof-of-concept and dose-finding trial of CY200 in CRPS Type 1.

Prior to the acquisition, Cy Biopharma funded an investigator-initiated, observational, open-label proof-of-concept pilot conducted by Bendable Therapy, a nonprofit psilocybin service center licensed under Oregon’s Measure 109. The pilot comprised a small number of patients with CRPS or other chronic pain conditions who were dosed with a psilocybin formulation supplied under Oregon’s Measure 109 program rather than with CY200; the pilot was not approved by an institutional review board for cohorts 1 and 2 and was intended solely for program and measurement development. A private institutional review board approved a third cohort in the first quarter of 2026. Observations from the pilot included pain reductions in certain participants and an observed duration of effect exceeding two months in three patients; however, no conclusions regarding efficacy should be inferred from the pilot data. Separately, an active Phase 2 clinical trial (NCT06001749) led by Dr. Yvan Beaussant at Dana-Farber Cancer Institute, funded in part by Cy Biopharma, is assessing the feasibility, safety and preliminary efficacy of psilocybin-assisted therapy to alleviate opioid-refractory pain in patients with advanced cancer.

We also acquired CY201, a proprietary psilocin-dominant oral liquid formulation being developed as an alternative to CY200. Psilocin is the active metabolite of psilocybin and the active moiety covered by the Orphan Drug Designation for psilocybin. CY201 offers potential composition-of-matter protection and distribution advantages relative to CY200, and a pharmacokinetic bridging study is planned, which we expect to begin in 2027.

Market Opportunity

Drug Abuse and Drug Overdose

Opioid pain medications are essential for improving the care and outcomes of a majority of Americans who live with chronic pain. In 2023, 24.3% of adults had chronic pain, with 8.5% of those having high impact chronic pain. Millions of adults suffered from pain every day for the preceding three months and almost 40 million adults experience severe levels of pain, which is linked to worse health status. High impact chronic pain is characterized by extended periods of suffering which impair life quality to a severe degree. Prescription opioids drugs, such as morphine, hydromorphone, hydrocodone, and oxycodone, have a long history of use for the management of severe and chronic pain. Prescriptions for opioid medications in 2023 totaled almost 140 million, with \$3.8 billion in market size in the United States.

The U.S. Centers for Disease Control and Prevention (“CDC”) recently provided recommendations for clinicians who provide pain care, defining acute pain (duration less than 1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease related pain management, cancer pain treatment, palliative care, and end-of-life care. These guidelines are based on the indications, acute and chronic pain, that we intend to explore for our TAAP and MPAR® opioid products including PF614.

Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches, and other dose forms. Oxycodone is one of the most effective pain killers available today. This drug helps the patient to overcome pain and focus on his or her work. Opioids have a risk of dependence and, when used improperly, a common side effect of high doses of opioids like oxycodone can be euphoria, or a “high.” As a result of these side effects, opioids have become among the most misused or abused prescription drugs in the United States. Opioid abuse was declared a public-health emergency in 2017 when more than 91 people died each day from opioid-related overdoses. In 2021, the total number of opioid-related deaths rose to 109,600, whereas in 2023 that number declined to 79,358. Almost 80,000 people still die each year from opioid overdose, of which prescription opioids factor into approximately 12% of these deaths (<https://drugabusestatistics.org/opioid-epidemic/>).

The overall overdose deaths is now driven by use of synthetic opioids, in particular fentanyl, as prescription opioids have become harder to obtain. Prescription opioid-involved deaths were 14,139 in 2019, rose to 16,706 in 2021 and were 14,716 in 2022. However, 6.1 million Americans over the age of 12 were reported to be suffering from opioid use disorder (“OUD”) in 2024. Based on information from the CDC, the most common drugs involved in prescription opioid overdose deaths include methadone, oxycodone (such as OxyContin®), and hydrocodone (such as Vicodin®). The CDC indicates that improving opioid prescribing, treatment of opioid use disorder, and prevention of opioid use disorder would help to improve the opioid crisis. Misuse or abuse of opioids is often done in one of the following manners:

- *Oral Excessive Tablet Abuse.* Generally recognized as the most prevalent route of administration by abusers, an abuser orally ingests more tablets (or capsules) than is recommended for pain relief.
- *Nasal snorting.* Crushed tablets are insufflated for absorption of the drug through the nasal tissues.
- *Injection.* The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.
- *Oral Manipulated Tablet Abuse.* Extended-release tablets or patches are crushed, chewed, or otherwise physically or chemically manipulated to defeat an extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.
- *Poly-pharmacy.* Opioids are sometimes used in conjunction with alcohol, methamphetamine, benzodiazepines or other drugs to enhance the euphoria.
- *Overdose.* Users may accidentally introduce excessive quantities of drugs in their systems or combine drugs that may heighten the chance of adverse effects of drugs. Some patients may over-ingest drugs accidentally or with the express intent of suicide.
- *Chronic or prolonged use.* Chronic or prolonged use of opioids other than as prescribed, resulting in dependence, is another form of misuse or abuse.

Amphetamines like Adderall are manufactured in pill form and are intended for oral ingestion. As of late 2022, seventy-five percent of Adderall prescriptions are prescribed to the 10.5 million adults, age 22 or older, that are diagnosed with attention deficit hyperactivity disorder, or ADHD. The number of prescriptions has fallen in 2023 and 2024 due to shortages of Adderall medication. ADHD is the most common neurodevelopment disorder in children. Five million adults misuse stimulant medication annually, by using alternative consumption methods to achieve a more intense high faster; snorting or injecting are most-common methods of abuse, something our TAAP technology is intended to prevent.

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

CRPS

CRPS is a severe chronic pain disorder. We estimate that approximately 200,000 people in the United States live with CRPS and approximately 50,000 new U.S. cases occur annually. There is currently no FDA-approved therapy specifically indicated for CRPS. Current treatment options include pharmacologic management, nerve blocks, physical therapy and interventional procedures such as spinal cord stimulation, with reported costs for certain interventions ranging from approximately \$30,000 to \$150,000. We estimate that the market opportunity in CRPS exceeds \$1 billion in the United States and Europe.

Our Technology Platform Solution

TAAP Prescription Drugs

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

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

Cy Biopharma's Product Candidates

Cy Biopharma's technology platform is designed to act on the underlying neurobiology thought to drive and sustain severe chronic pain disorders, such as CRPS, based on serotonergic modulation of neural networks through the 5-HT_{2A} serotonin receptor and a neuroplastic approach intended to address neural circuitry associated with severe chronic pain disorders. CY200 and CY201 are both botanically derived. CY200 is psilocybin-predominant and CY201 is psilocin-dominant. Psilocybin is converted in vivo to psilocin, which acts at 5-HT_{2A} receptors.

Our Development Programs

We are currently developing product candidates designed to provide severe chronic pain relief by improving the safety and performance of prescription drugs and addressing the underlying neurobiology that drives and sustains severe chronic pain. In addition to product candidates that are geared towards combating abuse and overdose of opioid drugs, following the acquisition of Cy Biopharma, we have a lead product candidate entering clinical development to address severe chronic and complex pain.

Our primary focus has been on opioid pain products and opioid use disorder products. Each prodrug is intended to be able to be combined with our MPAR® technology for overdose protection. Besides our clinical candidates, we have a product portfolio of other TAAP and MPAR® opioids, amphetamines, ergoline and psilocin analogues that could potentially be developed to build on this pipeline.

Clinical agents

PF614

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

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

PF614-101 Phase 1 Clinical Trial

PF614 (IND 116794) has been evaluated in a Phase 1 clinical study for safety and pharmacokinetics of oxycodone release in 64 healthy subjects in seven different dosing cohorts from November 2016 to January 2018. This study was conducted for us by PRA Health Sciences – Early Development Services Lenexa, Kansas, principal investigator, Daniel Dickerson, M.D., Ph.D. to evaluate the safety and pharmacokinetics of PF614, as well as the pharmacokinetics of oxycodone at doses sufficient to characterize the extent to which plasma oxycodone is produced and maintained following oral ingestion of PF614 and was compared to the oxycodone released from extended release oxycodone from OxyContin OP. Subjects were randomized to receive a single dose of PF614 (dose of 15, 25, 50, 100, and 200 mg with 6 subjects per dosing group) or OxyContin OP (dose of 10, 20, 50, and 80 mg with 2 subjects per dosing group). New subjects were recruited for each cohort. Cohort 1 compared subjects receiving PF614 and OxyContin OP with and without naltrexone blockade. Naltrexone is an opioid blocker to prevent opioids from attaching to the opioid receptors, preventing the effect of the opioid medication such as pain relief, feeling of euphoria or respiratory depression. The single ascending dose study also compared the release of oxycodone from PF614 under both fasted and fed conditions at the highest dose of PF614 evaluated, 200 mg. The pharmacokinetics of the prodrug fragments was also evaluated. In addition, this study instructed as to the “conversion efficiency” of the PF614 prodrug to oxycodone, with respect to OxyContin.

Pharmacokinetic Analyses

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

Safety

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

PF614-102 Phase 1b Clinical Trial

A Phase 1b study was conducted by ICON (formerly PRA Health Sciences) with Dr. M Johnston as Principal investigator. This was a 2-part study comprised of a MAD study (Part A) and a comparative bioavailability/bioequivalence and food effect study (Part B) in healthy subjects. Part A treated a total of 24 subjects and utilized a randomized, open-label, MAD design with up to 3 separate dose groups of 8 subjects per group. Within each dose group, subjects were randomized to receive either PF614 (n=6) or OxyContin (n=2). Subjects received repeated BID doses, planned to be administered every 12 hours (q12h) over a 5-day period, for a total of 9 doses. PF614 doses were 50 mg, 100 mg, and 200 mg, which were expected to be approximately equivalent to the 20 mg, 40 mg, and 80 mg OxyContin doses, for Dose Groups 1, 2, and 3, respectively. Serial PK sampling was performed for the first day/first dose (Day 1) and for the last day/last dose (Day 5). Only trough PK samples were taken within 30 minutes prior to the morning dose on Days 2, 3, and 4. Safety assessments, including regular assessments of adverse events (AEs), vital signs (pulse rate, blood pressure, respiratory rate, and oxygen saturation [SpO₂]), clinical laboratory tests, 12-lead electrocardiograms (ECGs), and cardiac telemetry were monitored throughout the study. Subjects were monitored for hypotension, hypopnea, apnea, and oxygen desaturation.

Part B treated a total of 60 subjects and utilized an open-label, single-dose, randomized, 4-way crossover design. Subjects were randomized to receive each of the following single oral doses of study drugs in a Williams design crossover manner (1 at each treatment period):

- Treatment A: 100 mg PF614, administered under fasted conditions (hereafter referred to as 100 mg PF614, fasted)
- Treatment B: 100 mg PF614, administered under fed conditions (high-fat breakfast) (hereafter referred to as 100 mg PF614, fed)
- Treatment C: 40 mg OxyContin, administered under fasted conditions (hereafter referred to as 40 mg OxyContin, fasted)
- Treatment D: 40 mg OxyContin, administered under fed conditions (high-fat breakfast) (hereafter referred to as 40 mg OxyContin, fed)

Each treatment was separated by a washout interval of 5 days. Serial PK sampling was performed after each study drug administration up to 120 hours post dose. Safety including regular assessments of AEs, vital signs (pulse rate, blood pressure, respiratory rate, and SpO₂), clinical laboratory tests, and 12-lead ECGs were monitored. Subjects were monitored for hypotension, hypopnea, apnea, and oxygen desaturation.

Pharmacokinetics

Part A: The shape of the plasma concentration versus time curve of oxycodone was similar following administration of PF614 and OxyContin (oxycodone extended release). Oxycodone plasma exposure (T_{max} , $C_{max,ss}$ and AUC_{tau}) were assessed and PF614 showed similar trends as OxyContin following administration of multiple oral BID doses. Due to the small sample number for OxyContin some PK parameters could not be calculated. Trough concentrations of oxycodone were generally similar from Day 2 through Day 4, suggesting that subjects achieved steady state after repeated oral BID dosing of PF614 and OxyContin at all dose levels.

Part B: A total of 57 subjects were included in the PK analyses. The data for C_{max} , AUC_{0-12} and AUC_{0-inf} of oxycodone post 100 mg PF614 versus 40 mg OxyContin dosing under fasted and fed conditions were completely contained within the standard bioequivalence limits of 80% to 125%. Therefore, it was concluded that 100 mg PF614 was bioequivalent to 40 mg OxyContin under both fasted and fed conditions.

Safety

PF614 was generally safe and well-tolerated following oral administration of 50 mg, 100 mg, or 200 mg PF614 BID for 5 days. There was no apparent difference in the safety profile of single oral doses of 100 mg PF614 when administered in the fasted or fed state or between PF614 and OxyContin when administered in the fasted and fed state. PF614 was generally safe and well-tolerated following single and multiple oral doses under naltrexone blockade.

PF614-103 Intranasal Human Abuse Potential Clinical Trial

PF614-103 was a randomized, double-blind, placebo- and active-controlled, 3-way crossover study to evaluate the abuse potential and pharmacokinetics of intranasally administered PF614, relative to crushed oxycodone IR tablets and placebo, in non-dependent recreational opioid users conducted by Lotus Clinical Trials LLC through Ohio Clinical Trials, Inc with Principal investigator, Dr. G. Apseloff.

The study consisted of 4 phases: Screening, Qualification, Treatment, and Follow-up. Subjects were randomized to receive PF614 100mg or crushed oxycodone 40 mg intranasally. The primary objective of the study was to evaluate the abuse potential of PF614 relative to crushed oxycodone immediate-release (IR) tablets and placebo following intranasal administration in non-dependent recreational opioid users (n=26), with the primary pharmacodynamic endpoint being the maximum effect (E_{max}) for Drug Liking (“*at this moment*”) measured up to 24 hours after dosing using a visual analogue scale (“VAS”). The secondary objectives of the study were to evaluate the pharmacokinetic profile of PF614 relative to crushed oxycodone IR tablets following intranasal administration, to evaluate the safety of PF614 following intranasal administration.

In the study, PF614 powder produced a statistically significant lower peak “drug liking” (E_{max}) when compared with intranasal crushed IR oxycodone ($p = 0.0133$) using the full modified completer population in a 3-period crossover of PF614 vs. crushed oxycodone and placebo. Furthermore, in a first period analysis of initial impressions of each drug, a statistically significant difference was noted between PF614 (n=8) and crushed IR oxycodone (n=10) ($p = 0.0175$), even with this smaller cohort of subjects.

Statistically significant differences in peak effects (E_{max}) between PF614 and crushed IR oxycodone intranasal were also demonstrated for the secondary endpoint of “take drug again,” also using a first period analysis ($p < 0.0001$).

The intranasal HAP study was designed to test if known recreational drug users “liked” the product and is critical for labeling claims for new drugs in this class. The primary measure in this study, “*drug liking*,” is recommended by the FDA in their Guidance on “Assessment of Abuse Potential of Drugs.” This measure is known to correlate with a drug’s potential for abuse. The results demonstrated that inhaled powdered PF614 had significantly lower drug liking than inhaled crushed IR oxycodone.

PF614-104 Oral Human Abuse Potential Clinical Trial

PF614-104 was a randomized, double-blind, placebo- and active-controlled, 5-way crossover study to evaluate the abuse potential and pharmacokinetics of orally administered PF614, relative to oxycodone IR tablets and placebo, in non-dependent recreational opioid users conducted by DVCR, Kansas.

The study consisted of 4 phases: Screening, Qualification, Treatment, and Follow-up. Subjects were randomized to receive PF614 50, 100 and 200 mg, oxycodone 40 mg or placebo orally. The primary objective of the study was to evaluate the abuse potential of PF614 relative to oxycodone immediate-release (IR) tablets and placebo following oral administration in non-dependent recreational opioid users (n=28), with the primary pharmacodynamic endpoint being the maximum effect (E_{max}) for Drug Liking (“*at this moment*”) and “Take Drug Again” E_{max} (Secondary endpoint) measured up to 24 hours after dosing using a VAS. The secondary objectives of the study were to evaluate the pharmacokinetic profile of PF614 relative to oxycodone IR tablets and to evaluate the safety of PF614.

PF614 produced statistically lower effects than oxycodone, the lowest dose $p < 0.0001$, and statistically significant overall “Drug Liking” at both the low and the mid doses $p < 0.0001$ and $p = 0.0025$, respectively. PF614 took a significantly longer median time to reach E_{max} for “Drug Liking” than oxycodone at all three dose levels, which is highly important for reducing drug abuse. Similar findings were noted with a second endpoint “Take Drug Again”. The secondary endpoint was met at both the low and mid dose of PF614 with highly significant values of $p < 0.001$ and $p = 0.0038$, respectively, and was numerically lower than comparator even at double the dose, demonstrating that recreational users would be less motivated to abuse PF614 compared to immediate release oxycodone.

In November 2022, we received written guidance from the FDA that an acute pain indication may be appropriate for PF614. The FDA guidance, while not binding, states that our proposed clinical development approach of conducting at least two adequate and well-controlled clinical trials in two different pain models comparing PF614 to a placebo and to another immediate release (IR) opioid, such as IR oxycodone, appears reasonable to support a new drug application for PF614 for an acute pain indication. The FDA guidance also provides additional guidance with respect to the non-clinical studies and clinical trials planned by us. The clinical development pathway of PF614 for an acute pain indication may reduce the development timeline and be more cost-effective than initially pursuing a chronic pain indication for PF614.

PF614-201 Time of Onset clinical study

PF614-201 was a randomized, double-blind, placebo-controlled study of PF614 50 and 100 mg to evaluate the onset of analgesia following administration of a single oral dose of PF614 in healthy male subjects in an experimental pain model (cold pressor test [CPT]). This study was initiated in September of 2023 and enrolled 16 subjects. The Treatment Phase consisted of 2 treatment periods; PF614 50 mg or 100 mg versus placebo. The CPT, pharmacodynamic (PD), and safety assessments were conducted prior to dosing and for six hours after each study drug administration. This study was the first to successfully demonstrate the efficacy of PF614. Data was reported December 2023, stating the time-of-onset of pain relief from both doses of PF614 was identified, and PF614 did decrease the intensity of pain.

PF614-301 Phase 3 Clinical Trial

The pivotal PF614-301 trial is a multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of PF614 for the treatment of moderate to severe pain following abdominoplasty. The study is designed to demonstrate PF614's ability to provide strong, consistent post-surgical pain relief while incorporating an innovative chemical mechanism intended to reduce the risk of abuse. The trial will also evaluate PF614's potential to provide a smoother, safer treatment of severe acute pain using twice daily dosing with reduced highs and lows in blood drug concentration, an approach which is seen as beneficial by leaders in the field. Enrollment in the study began in December 2025.

PF614-MPAR

We initiated a Phase 1 study that is evaluating PF614-MPAR in a study entitled "A Single Dose, 2 Part Study to Evaluate the Pharmacokinetics of Oxycodone and PF614, when PF614 Solution is Co-Administered with nalfamostat, as an Immediate Release Solution and/or Extended Release (ER) Capsule Formulations in Healthy Subjects." We are clinically testing MPAR® in partnership with Quotient Sciences, using its integrated Translational Pharmaceuticals® platform to search for a PF614-MPAR formulation that allows conversion into oxycodone within the prescribed dose range but reduces conversion to oxycodone at higher than prescribed dose levels in an overdose scenario.

PF614-MPAR-101 Phase 1 Clinical Trial

The primary objectives of the Phase 1 study are to assess the pharmacokinetics of oxycodone, when PF614 solution is administered alone and with nalfamostat as an immediate release solution and/or extended-release capsule prototypes. The study is designed to aid in the selection of the optimal nalfamostat formulation and dose to combine with PF614 in order to provide oxycodone when a prescribed dose is taken yet attenuate the maximum plasma concentration (C_{max}) and the area under the concentration time curve (AUC) of oxycodone when more than the prescribed PF614-MPAR dose is taken. Initial data was reported in May 2022 that demonstrated nalfamostat administered in combination with PF614 in a simulated overdose situation reduced the release of oxycodone from PF614 as designed. We completed the clinical portion of Part A of this study in December 2022, with the identification of an optimal drug product formulation. A second, Part B was initiated in January 2023 to test the overdose protection of the selected formulation by administering an escalating number of dose units to a group of healthy subjects. Enrollment was completed in March 2023.

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Part B was a dose escalation study of PF614 25 mg alone, or increasing dose units of PF614-MPAR 25 mg (PF614 25 mg with 1 mg formulated nalfamostat), and enrolled 6 to 8 healthy subjects in each cohort. PF614-MPAR 25 mg was delivered at 1, 2, 3, 5, and 8 doses simultaneously, with safety and PK endpoints. The plasma PK of oxycodone released from PF614 or PF614-MPAR was measured and compared to prior data where PF614 was delivered up to 200 mg alone. Additionally, the PK of parent PF614 and metabolic fragments were measured.

The results of the study successfully demonstrated that up to 2 dose units of PF614-MPAR delivered oxycodone at the same level as was derived from PF614 without MPAR®. At 3 units of PF614-MPAR the amount of oxycodone delivered was reduced compared to a 75 mg dose of PF614. At 8 dose units there was a significant decrease ($p < 0.00333$) in the maximal oxycodone plasma concentration (C_{max}) as compared to that delivered from unprotected PF614 200 mg. In addition, delivering 2 doses of PF614-MPAR sequentially, 12 hours apart did not affect the release of oxycodone from the 2nd dose. Data from this study was reported in May 2023.

PF614-MPAR was granted Breakthrough Therapy designation by the FDA in January 2024. A Type D meeting request to discuss the non-clinical program for PF614-MPAR was submitted in 2023 and responses to questions were received in February 2024.

PF614-MPAR-102 Phase 1b Clinical Trial

The primary objectives of the Phase 1b study are to assess the pharmacokinetics of oxycodone when PF614 is administered alone and with formulated nalfamostat, evaluate a food effect, and explore PF614-MPAR delivered in a multi-ascending dose study. The study initiated in December 2024 and is expected to be completed in 2026.

Cy Biopharma Programs

CY200 and CY201

CY200 is a psilocybin-predominant botanical extract being developed as an oral neuroplastic therapy for CRPS Type 1. Psilocybin is converted in vivo to psilocin, which acts at 5-HT_{2A} serotonin receptors. The development rationale is that serotonergic modulation and associated changes in neural plasticity may affect neural networks implicated in chronic pain and central sensitization. Psilocybin has received U.S. FDA Orphan Drug Designation for the treatment of CRPS.

Prior to the acquisition, Cy Biopharma funded an investigator-initiated, observational, open-label proof-of-concept pilot conducted by Bendable Therapy, a nonprofit psilocybin service center licensed under Oregon's Measure 109. The pilot comprised a small number of patients with CRPS or other chronic pain conditions who were dosed with a psilocybin formulation supplied under Oregon's Measure 109 program rather than with CY200. The pilot was not approved by an institutional review board for cohorts 1 and 2 and was intended solely for program and measurement development. A private institutional review board approved a third cohort in the first quarter of 2026. Observations from the pilot included pain reductions in certain participants, with reported reductions ranging from approximately 20% to 80% on pain numerical rating scales, and an observed duration of effect exceeding two months in three patients. Independent academic case reports associated with UCSD, Johns Hopkins and NYU (Lyes et al., Pain 2023;164:698–702; Jevotovsky et al., Clin Case Rep 2024;12:e9421) have also reported pain reductions in CRPS patients following psilocybin administration, including one treatment-resistant CRPS case where pain was reduced to 0-1 on a numerical rating scale (approximately 75%-100% relief) at nine-month follow-up, even after intravenous ketamine at 1,200 mg had failed to provide adequate relief. These observations were generated in small, uncontrolled settings and were not generated in controlled pivotal trials; no conclusions regarding efficacy should be inferred.

Separately, an active Phase 2 clinical trial (NCT06001749) led by Dr. Yvan Beaussant at Dana-Farber Cancer Institute, funded in part by Cy Biopharma, is assessing the feasibility, safety and preliminary efficacy of psilocybin-assisted therapy to alleviate opioid-refractory pain in patients with advanced cancer. While that study involves a different indication than CRPS, data generated from the trial may inform the broader understanding of psilocybin's potential analgesic mechanisms.

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We are advancing a randomized, double-blind, placebo-controlled Phase 2 proof-of-concept and dose-finding trial evaluating the efficacy, safety and tolerability of CY200 in participants with CRPS Type 1. The Phase 2 trial, planned to be conducted in the United Kingdom, includes four groups (dosed twice three weeks apart: placebo and placebo;

10 mg and placebo; 25 mg and placebo; and 25 mg and 25 mg of CY200, respectively), with a primary endpoint of the proportion of participants achieving at least a 30% reduction from baseline in mean pain numerical rating scale (“NRS”) score over the seven days from Day 15 to Day 21 following the first dose, and key secondary endpoints including the change from baseline in mean pain NRS score over the same seven days and over the seven days from Day 36 to Day 42, and Patient Global Impression of Change at Day 20 and Day 43. The trial design contemplates two doses, administered on Day 1 and Day 22, with safety follow-up. The trial is designed to randomize approximately 130 participants, so that 104 participants complete the trial. We submitted the clinical trial application to the UK Medicines and Healthcare products Regulatory Agency (the “MHRA”) and a research ethics committee on September 11, 2026. No decision has yet been received and no participant has been enrolled. We expect a decision in early December 2026.

CY201 is a proprietary psilocin-dominant oral liquid formulation being developed as an alternative to the CY200 oral capsule. The formulation is intended to deliver psilocin as the active moiety and is being evaluated for potential composition-of-matter protection, formulation and distribution advantages. Our development plan includes a pharmacokinetic bridging study, which we expect to begin in 2027.

CY30X and CY40X

CY30X and CY40X are preclinical-stage programs based on a proprietary library of novel 5-HT agonists. The compounds are being evaluated for receptor activation profiles that include partial 5-HT2A agonism, high 5-HT1A activity, low 5-HT2B risk and balanced engagement of 5-HT2C and 5-HT6/7 receptors.

Competition

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

The key competitive factors that are expected to affect the development and commercial success of our product candidates include safety and tolerability, the ability of our product candidates to limit human abuse potential, bioavailability and therapeutic efficacy of our product candidates, market indications and convenience of dosing and distribution. PF614 will also face competition from commercially available generic and branded extended-release and long-acting opioid drugs other than oxycodone, including, but not limited to, fentanyl, hydromorphone, oxymorphone, and methadone, as well as opioids that are currently in clinical development.

We believe that obtaining an abuse-deterrent label through the FDA for our prodrugs would provide us with a significant competitive advantage. There are only three commercially available (in the United States) opioid drugs for chronic pain relief that have an abuse-deterrent label. These drugs are OxyContin® ER and Hysingla® ER, both of which are marketed by Purdue Pharma, LP, and Collegium Pharmaceutical, Inc.’s Xtampza®ER. However, obtaining an abuse-deterrent label involves a lengthy and complicated process with no certainty of success. We believe abuse-deterrent opioids represent a therapeutic option to maximize pain relief in patients for whom opioid analgesia is indicated, while reducing the risks of abuse and diversion.

A number of other companies including, but not limited to, Pfizer Inc., Daiichi Sankyo, Endo Health Solutions, Nektar Therapeutics, Teva Pharmaceutical, Inc., Egalet Ltd., KemPharm Inc., Elysium Therapeutics Inc., and Acura Pharmaceutical, have had either extended-release or abuse-deterrent products in various stages of development. Other companies offer products indicated for chronic, severe, long-term pain with various delivery technologies, but these products do not have abuse-deterrent claims on their labels. Vertex has recently announced the approval of a non-opioid pain product, suzetrigine, that inhibits NaV1.8. The clinical data provided to date has indicated that suzetrigine did not provide superior pain relief compared to the opioid control arm of the Phase 3 study.

We do not believe there are other companies developing products that have an overdose mechanism similar to our MPAR® technology.

Current treatment options for CRPS and other severe chronic pain disorders include opioids, nerve blocks, physical therapy, ketamine and other pharmacologic approaches, as well as interventional procedures such as spinal cord stimulation and other neurostimulation devices. These approaches are generally directed to symptom management and may involve limitations in efficacy, durability, cost or access. Spravato (esketamine) developed by Janssen Pharmaceuticals (Johnson & Johnson) and Epidiolex (cannabidiol) marketed by Jazz Pharmaceuticals are approved products used for other indications and are commercial analogues for regulated central nervous system and orphan-disease therapies, but neither is approved specifically for CRPS. Ambros Therapeutics is conducting a Phase 3 trial of neridronate, a bisphosphonate, in CRPS Type 1, within six months of onset (whereas CY200/CY201 is being developed for established CRPS more than 12 months after onset). Patients may also have access to off-label or unregulated ketamine or psychedelic treatments. Other pharmaceutical, biotechnology and academic organizations may develop psilocybin-, psilocin-, serotonergic- or other neuroplasticogenic therapies, including products at preclinical or clinical stages, including Compass Pathways plc, which has reported two positive Phase 3 trials of its psilocybin product candidate COMP360 in treatment-resistant depression and has begun a rolling submission of its new drug application to the FDA.

Intellectual Property

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

Patents and Patent Applications

We own numerous patents and applications in the United States and significant commercial markets, such as Europe, China, and Japan, relating to our product candidates currently in development, as well as other product candidates that may be developed in the future. These patents and applications are projected to expire between 2028 and 2047, subject to any patent term adjustment or extension that might be available in a particular jurisdiction. A table of the key patent families and their natural or projected expiry dates is presented below.

	Countries of Filings*	Natural or Projected Expiry Date
TAAP and MPAR Patents and Applications for Opioids		
Compositions Comprising Enzyme-Cleavable Ketone-Modified Opioid Prodrugs and Optional Inhibitors Thereof	U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Mexico, Russia	2030
Compositions Comprising Enzyme-Cleavable Opioid Prodrugs and Inhibitors Thereof	U.S.	2030
Compositions Comprising Enzyme-Cleavable Oxycodone Prodrugs	U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Russia	2032
Compositions Comprising Enzyme-Cleavable Prodrugs and Controlled Release Nafamostat and Methods of Use Thereof	U.S., PCT, Taiwan	2042

Active Agent Prodrugs with Heterocyclic Linkers	U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Russia	2032
Enzyme-Cleavable Methadone Prodrugs and Methods of Use Thereof	U.S., PCT, Europe, Brazil, China, Japan, Korea, Canada, Mexico, Australia, India, Israel	2042
Nafamostat Patents and Applications		
Methods of Treating Coronavirus Infections and COVID-19	U.S., Canada, Europe	2041
Oral formulations of Nafamostat	U.S., PCT, Taiwan, Europe, Brazil, China, Japan, Korea, Canada, Mexico, Australia, India, Israel	2042
Methods of Treating Respiratory Diseases with Mucostasis	Germany, France, Italy, United Kingdom	2028
TAAP and MPAR Patents and Applications for Amphetamines		
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	U.S., Europe	2031
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	U.S., Europe, Hong Kong	2040
CY200 Patent Applications		
Methods of Using CY200	U.S., Australia, Canada, Europe	2043
CY201 Patent Applications		
Pharmaceutical Compositions of CY201	U.S.	2047
CY30X and CY40X Patent Applications		
Composition of Matter of CY30X and CY40X	PCT	2045

*"Europe" refers to patent applications filed in, and patents issued by, the European Patent Office ("EPO"), which can provide the basis for rights in multiple countries that are members of the European Patent Convention.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our product candidates.

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

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

TAAP and MPAR® Patents and Applications for Opioids

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

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

Nafamostat Patents Applications

We own pending applications in the U.S., Canada and Europe directed to the use of orally administered nafamostat and extended-release formulations of nafamostat. Some of the claims are directed to the use of oral nafamostat for the treatment of infections caused by coronaviruses, including COVID-19, and pending United States, PCT, and Taiwan patent applications directed to oral formulations of nafamostat. We intend to pursue these applications in the United States and other significant commercial markets and any patents that may be issued would expire in 2041 and 2042, respectively, subject to any applicable patent term adjustment or extension in a particular jurisdiction. We believe that one patent covering nafamostat will be eligible for up to five years of patent term extension in the United States and Europe and intend to pursue such extension. In addition to patent exclusivity, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that nafamostat will be eligible for five-year NCE regulatory exclusivity, during which time no 505(b)(2) NDA or ANDA can be approved that contains the same active moiety as the chemical entity in the nafamostat NDA. In addition, if an ANDA or 505(b)(2) applicant were to file its application referencing the NDA for nafamostat before expiration of our use patent and the applicant asserted that the patent is invalid or would not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory thirty-month stay, starting at the end of the five-year NCE regulatory exclusivity period, if we sue for infringement, or a shorter period if the patent expires or there are certain settlements or judicial decisions in the patent litigation) and may ultimately be required to wait until the natural expiration of our compositions patents if the patents are found to be valid and infringed by the challenging applicant. For more information please see *"Patent and Patent Applications."*

TAAP and MPAR® Patents and Applications for Amphetamines

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

CY200 Patent Applications

We own pending applications in the U.S., Australia, Canada and Europe with claims directed to methods of using CY200, which if issued, are expected to expire in May 2043, subject to any applicable patent term adjustment or extension that might be available in a jurisdiction.

CY201 Patent Applications

We own a pending U.S. provisional patent application directed to pharmaceutical compositions of CY201, where patent applications filed claiming the benefit and priority to this provisional application, if issued, are expected to expire in February, 2047, subject to any applicable patent term adjustment or extension that might be available in a jurisdiction.

CY30X and CY40X Patent Applications

We own two pending PCT (Patent Cooperation Treaty) patent applications directed to the composition of matter of CY30X and CY40X, where patent applications claiming the benefit of these PCT patent applications, if issued, are expected to expire in May, 2045, subject to any applicable patent term adjustment or extension that might be available in a jurisdiction.

Trademarks and Trade Secrets

We intend to pursue trademark registrations in the United States and other significant commercial markets for our product candidates as they progress through clinical development. We received registration of our trademark for MPAR on May 16, 2023.

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

Manufacturing and Supply

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. Our drug substance and drug products are manufactured for us by CMOs, to our specifications. Any manufacturing problem or the loss of a CMO could be disruptive to our operations.

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

We currently engage third parties to provide clinical supplies of PF614 and nafamostat. We also currently engage a CMO to provide drug product manufacture of PF614, PF614-MPAR and nafamostat. We currently have sufficient supplies of PF614 and nafamostat on hand for our current clinical trial needs. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality.

CY200 drug substance and drug product are manufactured by a third-party contract manufacturing organization in North America and quality-tested, packaged and labeled by a third-party good manufacturing practice ("GMP") facility in the United Kingdom. Our contract manufacturer is currently the sole source of CY200 drug substance and drug product. Cy Biopharma has commissioned and received an independent audit of the manufacturing facility for EU GMP compliance.

Government Grants

We have received funding under federal grant award programs through governmental agencies, such as the NIH and NIDA. For the year ended December 31, 2025, we received federal grant funding totaling \$4.8 million from NIH related to the Phase 1 clinical trial for PF614-MPAR. The PF614-MPAR grant also includes \$5.3 million funding from June 2026 through May 2027. We may apply for additional grant funding from these or similar governmental agencies in the future.

Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, and those pharmaceutical products that are controlled substances are also subject to extensive regulation by the DEA. The Federal Food, Drug, and Cosmetic Act (the “*FDC Act*”), the Controlled Substances Act (“*CSA*”), and other federal, state, and local statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, prescribing, dispensing, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Pharmaceutical products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs, revocation of licensing authority, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. Comparable requirements apply outside the United States. In particular, our Phase 2 trial in the United Kingdom for CY200 is subject to regulation by the MHRA and, because CY200 contains a controlled drug, the UK Home Office.

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The FDA Drug Approval Process

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

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

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

In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence.

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

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product’s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding \$4.6 million for Fiscal Year 2027. Under an approved NDA, the applicant is also subject to an annual program fee, currently exceeding \$416,000 for Fiscal Year 2027. These fees typically increase annually. Under limited circumstances, an applicant may be exempt from or seek a waiver of the application fee requirement.

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

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

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

prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Before approval, the FDA evaluates the results from in vitro manipulation and extraction, pharmacokinetics, and clinical human abuse potential studies to determine whether the accumulated evidence is sufficient to warrant claims of abuse deterrence. Post-marketing studies may also be required to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting.

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

Use of Foreign Clinical Data

Our Phase 2 trial of CY200 is being conducted in the United Kingdom and is not being conducted under an IND. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND as support for an IND or an application for marketing approval if, among other things, the study was conducted in accordance with good clinical practice, including review and approval by an independent ethics committee before initiation of the study and the obtaining and documenting of informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary. A sponsor or applicant submitting data from such a study must also describe to the FDA the actions it took to ensure that the research conformed to good clinical practice. Although the FDA will examine data from a foreign study that does not meet these conditions, it will not accept that study as support for an IND or marketing application. In addition, marketing approval of a new drug based solely on foreign clinical data is governed by separate FDA regulations, under which the FDA may approve an application based solely on foreign data only if the data are applicable to the U.S. population and U.S. medical practice, the studies were performed by clinical investigators of recognized competence, and the data may be considered valid without the need for an FDA on-site inspection or, if the FDA considers an inspection necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. The FDA may conclude that data from our UK Phase 2 trial are not adequate to support an IND or a future NDA for CY200 or CY201, and we expect that any registrational program for CY200 or CY201 would include clinical trials conducted in the United States under an IND.

Section 505(b)(2) NDAs

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

Fast Track Designation and Priority Review

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

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

Breakthrough Therapy Designation

FDA Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. The primary intent of Breakthrough Therapy designation is to develop evidence needed to support approval as efficiently as possible. The designation provides all the features of Fast Track designation, such as timely communication and rolling review, along with intensive guidance involving FDA senior managers on an efficient drug development program. While a drug with this designation is also eligible for separate expedited pathways like Accelerated Approval and Priority Review, these programs must still meet their own independent criteria.

Disclosure of Clinical Trial Information

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

The Hatch-Waxman Amendments

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

Patent Term Extension

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

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a nonprovisional patent application related to the patent. A U.S. patent also may be accorded patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for a patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. PTE cannot extend the remaining term of a patent beyond a total of fourteen years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for PTEs on patents covering products eligible for PTE. We plan to seek PTEs for any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

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

Under the Hatch-Waxman Act, patents covering the product such as patents claiming the approved composition of matter, approved methods of use, approved formulations, and approved dosing and administration shall be listed in the Orange Book, which identifies drug products approved by FDA under the FDC Act. Applicable regulatory exclusivities, such as the five-year NCE exclusivity and the three-year CI exclusivity, are also listed in the Orange Book. If an ANDA or 505(b)(2) applicant files its application before expiration of all patents listed in the Orange Book, it must submit a certification for each listed patent. If an Orange Book listed patent is challenged via a Paragraph IV certification and we sue the ANDA or 505(b)(2) applicant for infringement within 45 days of receiving notice of the certification, a statutory 30-month stay of FDA approval, will be put in place that will prohibit the FDA from finally approving the ANDA or 505(b)(2) application until the 30-months have expired or after a court has held in favor of the ANDA or 505(b)(2) applicant. If the application is submitted during the five-year NCE exclusivity period, the 30-month stay is extended as necessary so that it expires seven and one-half years after NDA approval. If in a Pediatric Written Request, or PWR, and we complete the pediatric study according to the terms of the PWR and FDA accepts the study reports, the periods of protection afforded by unexpired Orange Book listed exclusivities (patent or regulatory) will generally be extended by six months.

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

Orange Book Listing

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

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

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

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

Market Exclusivity

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

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, being one that affects fewer than 200,000 persons in the United States or, if it affects more, one for which there is no reasonable expectation that the cost of developing the drug and making it available in the United States will be recovered from its sales in the United States. Orphan Drug Designation does not shorten the regulatory review and approval process, but it entitles the sponsor to a tax credit for qualified clinical testing costs and, subject to conditions, an exemption from the FDA application fee. If a drug with Orphan Drug Designation receives the first FDA approval of that drug for the disease or condition for which it is designated, the FDA may not approve another application for the same drug for the same disease or condition for seven years, unless the holder of the exclusivity consents, cannot assure the availability of sufficient quantities of the drug, or the later drug is shown to be clinically superior. Orphan drug exclusivity does not prevent the approval of a different drug for the same disease or condition, and it extends only to the approved use within the designated disease or condition; exclusivity may not be available if the product is approved for a broader indication than the designated use and may be lost if the FDA later determines that the designation request was materially defective. The FDA has granted Orphan Drug Designation to Cy Biopharma AG, our subsidiary, for psilocybin for the treatment of CRPS.

Post-Marketing Requirements

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

Prescription drug advertising is subject to federal, state, and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("*PDMA*"), a part of the FDC Act. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "*track and trace*" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements were phased in over a ten-year period ending on November 27, 2023, although the FDA has granted exemptions that defer compliance with certain of these requirements for some trading partners. Unless the products were packaged prior to November 27, 2018, the DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "*pedigree*" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

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

The CSA and DEA Regulation

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

Controlled substances are classified into five schedules: Schedule I, II, III, IV, or V, depending on the abuse potential. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II substances are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements to guard against theft or diversion, and criteria for importation.

CY200 and CY201, our product candidates for the treatment of CRPS, contain psilocybin and psilocin, respectively. Psilocybin and its active metabolite, psilocin, are listed by the DEA as Schedule I controlled substances under the CSA. Because CY200 and CY201 contain Schedule I substances, each U.S. research site must, before conducting clinical trials, submit a research protocol to the DEA and obtain and maintain a DEA Schedule I researcher registration authorizing the site to handle and dispense the product candidate and to obtain it from our importer or manufacturer. As of the date hereof, we have not submitted an IND for CY200 or CY201 to the FDA and have not applied for any DEA registration or quota for CY200 or CY201, and we are not the sponsor of any clinical study of CY200 or CY201 in the United States.

PF614 will be classified as a Schedule II controlled substance under the CSA and regulations because it contains oxycodone which is already regulated as a Schedule II controlled substance. Consequently, the manufacturing, shipping, storing, selling, prescribing, and dispensing of our products is subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping, and reporting. Facilities must maintain complete and accurate inventories and records of all controlled substances received, manufactured, stored, and distributed. These facilities must comply with strict security requirements to prevent diversion of drugs in their possession. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be issued by a DEA-registered practitioner, either in writing or electronically, and may not be refilled, that is, a new prescription is required.

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

with DEA.

In addition, the CSA establishes an annual quota system that limits the manufacturing of API and dosage forms in the United States of Schedule I and II controlled substances. To the extent we or our contract manufacturers conduct manufacturing, repackaging or relabeling of CY200 or CY201 in the United States, we and our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements with respect to psilocybin and psilocin for so long as they remain controlled in Schedule I or II. In January 2026, the DEA finalized its aggregate production quotas for 2026, increasing the psilocybin production quota to 50,000 grams from 30,000 grams in 2025, and the psilocin production quota to 80,000 grams from 36,000 grams in 2025, reflecting growing research demand; however, there can be no assurance that future quota allocations will be sufficient for our needs or that the DEA will continue to increase quotas.

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

In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in calendar year 2018 by 20%. In October 2018, the SUPPORT Act was enacted, which included amendments to the CSA to require that appropriate quota reductions be made after estimating potential for diversion. DEA announced that the estimate is based on rates of overdose deaths and abuse, the overall public health impact related to specific controlled substances and may include other factors as appropriate. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. In October 2019, consistent with the SUPPORT Act, DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. In August 2023, DEA finalized these regulations, which established use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, the regulations also reduced inventory allowances and required procurement quota certifications. In May 2026, DEA proposed further revisions to its manufacturing and procurement quota regulations, including changes to quota applications and to the use-specific subcategories for domestic sale and export. . The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone), by an average of 28%. For 2021, the DEA decreased the aggregate quota for oxycodone by about 13% and for hydrocodone by about 10% from the final established 2020 quotas. For 2026, the DEA proposed further reductions from the 2025 established aggregate quotas for oxycodone (for sale), hydrocodone (for sale), and other Schedule II opioids, citing continued declines in medical usage and in requests for product development quota for oxycodone products, and in January 2026, the DEA finalized the 2026 aggregate production quotas, adopting the proposed reductions for oxycodone (for sale) and hydrocodone (for sale). Because PF614 is regulated as a Schedule II controlled substance, it is subject to the DEA's aggregate, individual production, and procurement quota scheme.

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

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

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

Individual states also independently regulate controlled substances, and we or our partners must obtain separate state registrations, permits or licenses in order to obtain, handle and distribute controlled substances for clinical trials or commercial sale.

Regulation of Psilocybin and Psychedelic Substances

For CY200 or CY201 to be lawfully marketed for medical use in the United States, the relevant substance or drug product would need to be placed in Schedule II, III, IV or V, or otherwise removed from Schedule I. FDA approval would satisfy the accepted medical use element relevant to that scheduling determination. If CY200 or CY201 receives FDA approval, applicable federal scheduling action would be required before it could be prescribed to patients in the United States, because an FDA-approved drug product cannot remain in Schedule I. The scheduling determination will depend on FDA approval and the scheduling analysis and recommendation of the U.S. Department of Health and Human Services ("HHS"), and, if HHS recommends that the approved drug be controlled in Schedule II, III, IV or V, the DEA generally must issue an interim final rule controlling the drug no later than 90 days after the later of its receipt of HHS's scientific and medical evaluation and scheduling recommendation or notice of FDA approval. The interim final rule becomes immediately effective and must provide interested persons an opportunity to comment and request a hearing; a final rule follows after those proceedings. In August 2025, the DEA formally transmitted a petition it received to reschedule psilocybin from Schedule I to Schedule II of the CSA to HHS for review; however, no scheduling action has been taken as of the date hereof, and there can be no assurance as to the timing or outcome of such proceedings. The FDA or the DEA may also require additional data regarding the abuse potential of CY200 or CY201, including through a human abuse potential study or an equivalent study.

In July 2026, the FDA issued final guidance titled "Psychedelic Drugs: Considerations for Clinical Investigations," which sets out the FDA's current, nonbinding recommendations on matters including abuse-potential assessment, trial design, safety monitoring and psychological or behavioral interventions used in psychedelic-drug trials. Among other things, the guidance recommends that sponsors design trials to mitigate the impact of functional unblinding and expectancy bias, evaluate the durability of treatment effect, use trial designs that can distinguish the contribution of the drug from any psychological support or psychotherapy, and document their psychotherapy model, which may be incorporated into product labeling. The FDA has characterized these recommendations as nonbinding, but the agency's expectations as reflected in the guidance could influence the design and cost of our clinical program for CY200 or CY201.

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We plan to conduct CY200 clinical activity outside the United States, including a Phase 2 trial in the United Kingdom. In the United Kingdom, psilocybin is a Class A drug under the Misuse of Drugs Act 1971 and is listed in Schedule 1 to the Misuse of Drugs Regulations 2001. Research and clinical trials involving Schedule 1 substances in the UK require a Home Office domestic controlled drugs license, which can take months to process, and enhanced secure storage facilities. Each clinical trial requires new Home Office licensing approval. Our contract packager and each of the Phase 2 trial sites hold such licenses. In July 2025, the UK government accepted in principle the recommendations of the Advisory Council on the Misuse of Drugs (the "ACMD") to pilot an exemption from the Home Office license requirement for universities and hospitals conducting research clinical trials and other approved clinical trials with Schedule 1 drugs; however, because the policy is still being designed, standard Schedule 1 licensing requirements remain

fully in effect. UK clinical trials also require authorization from the MHRA under the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, and a favorable opinion from a UK research ethics committee. The MHRA may suspend or terminate a clinical trial, and sponsors, investigators and trial sites must comply with UK good clinical practice requirements. A Phase 3 pivotal trial in the United States, Europe and Australia will require applicable controlled-substance licensing requirements in each jurisdiction. Psilocybin and psilocin are also listed in Schedule I of the 1971 Convention on Psychotropic Substances, and parties to that Convention are generally required to apply licensing and authorization controls to the manufacture, trade, distribution, import and export of Schedule I substances.

Our current clinical supply chain depends on the export of CY200 from our contract manufacturer in North America and its import into the United Kingdom by our contract packager before onward supply to the Phase 2 trial sites. Each shipment requires export authorization from the manufacturer's jurisdiction and a Home Office import license, which our contract packager, as the holder of a Home Office controlled drugs license, must obtain for each shipment. Any export of controlled drugs from the UK would require a separate Home Office export license. If we conduct clinical trials in, or supply CY200 or CY201 to, the United States in the future, any import or export of CY200 or CY201 into or from the United States would also require applicable DEA registrations and import or export permits.

If CY200 or CY201 is approved by the FDA and the finished dosage form is listed by the DEA as a Schedule II, III, IV or V controlled substance, its manufacture, importation, exportation, domestic distribution, storage, sale, prescribing, dispensing and legitimate use will remain subject to significant regulation by the DEA. Depending on CY200/CY201's final schedule, labeling and any FDA-required risk-management measures, CY200/CY201 could be subject to supervised-administration or distribution restrictions that limit commercial uptake. The FDA may require a REMS as a condition of approval if it determines that such measures are necessary to ensure that the benefits of CY200/CY201 outweigh its risks. Separate scheduling determinations may be required under individual state controlled substance laws and regulations, many of which classify psilocybin and psilocin as Schedule I substances. While some states automatically schedule or reschedule a drug based on federal action, other states schedule drugs through rulemaking or legislative action.

UK Marketing Authorization

In the United Kingdom, a medicinal product may not be placed on the market unless it is the subject of a marketing authorization granted by the MHRA. An application for a UK marketing authorization must be supported by data demonstrating the quality, safety and efficacy of the product, and the MHRA may impose risk-management or risk-minimization measures as conditions of any authorization. Following authorization, the marketing authorization holder is subject to ongoing pharmacovigilance, labeling, advertising and variation requirements, and manufacturing, importing or supplying CY200/CY201 in the UK must comply with UK good manufacturing practice requirements enforced by the MHRA and requires applicable MHRA manufacturing or import authorizations and Home Office controlled drugs licenses. Because psilocybin is listed in Schedule 1 to the 2001 Regulations, an MHRA marketing authorization alone would not permit CY200/CY201 to be prescribed or supplied in the UK; the Home Office has indicated that, if an MHRA marketing authorization were granted, it would review the scheduling of psilocybin under the 2001 Regulations, subject to advice from the Advisory Council on the Misuse of Drugs (ACMD). In addition, in England, NHS coverage and reimbursement of CY200/CY201 would generally depend on a positive technology appraisal by the National Institute for Health and Care Excellence ("*NICE*"), which assesses clinical effectiveness and cost-effectiveness.

Legislative and Regulatory Initiatives for Opioids

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

Recent actions to address the opioid abuse epidemic include:

- **FDA guidance:** In April 2015, the FDA adopted final guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The guidance describes four categories of abuse-deterrence studies and clinical trials: Categories 1, 2, and 3 consist of pre-marketing studies and clinical trials designed to evaluate a product candidate's potentially abuse-deterrent properties under controlled conditions, while Category 4, post-marketing clinical trials and studies, assesses the real-world impact of abuse-deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.
- **FDA Opioids Action Plan:** In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The FDA's plan is part of a broader initiative led by the U.S. Department of Health and Human Services ("*HHS*"), to address opioid-related overdose, death, and dependence.
- **CDC Prescribing Guidelines:** In November 2022, the CDC released a new Guideline for Prescribing Opioids for Pain to update their 2016 Guidelines. The new guidance includes recommendations for managing acute (duration of <1 month), subacute (duration of 1–3 months), and chronic (duration of >3 months) pain. The guideline addresses the following four areas: 1) determining whether or not to initiate opioids for pain, 2) selecting opioids and determining opioid dosages, 3) deciding duration of initial opioid prescription and conducting follow-up, and 4) assessing risk and addressing potential harms of opioid use.
- **FDA Drug Safety Communication:** In April 2023, the FDA issued a communication that in the ongoing effort to address the nation's opioid crisis, it was making several updates to the prescribing information of opioid pain medicines to provide additional guidance on their use. The changes include label updates addressing addiction, abuse and misuse as well as life-threatening respiratory depression, accidental ingestion, risks from concomitant use with other CNS depressants, neonatal withdrawal and opioid analgesic risk evaluation and mitigation strategy.
- **FDA Labeling Changes Regarding Long-Term Use:** In July 2025, the FDA announced class-wide safety labeling changes for opioid pain medications to further emphasize and characterize the risks associated with long-term use. These include removing the phrase "extended treatment period" from the indications, emphasizing that higher doses are associated with increased risk of serious harm, adding quantitative estimates of the risks of addiction, abuse, misuse, and overdose in long-term use, and clarifying that extended-release/long-acting opioids should be used only when alternative therapies, including immediate-release opioids, are inadequate.
- **Enhanced Warnings and Safety Labeling:** In March 2016, the FDA announced required enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose, and death. Subsequently, there have been several class-wide labeling changes, including the addition of boxed warnings relating to serious risks of using certain opioids medications along with benzodiazepines and other central nervous system depressants, including alcohol (December 2016); and additional information relating to the new class-wide REMS (September 2018).
- **Enactment of the Comprehensive Addiction and Recovery Act ("*CARA*"):** In 2016, the CARA was enacted to address the national epidemics of prescription opioid abuse and heroin use. Consistent with the initiatives of HHS, this legislation sought to, among other things, expand the availability of naloxone for law enforcement and other first responders; form an interagency task force to develop best practices for pain management with opioid medications; and provide resources to improve state monitoring of controlled substances, including opioids.

- Enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“*SUPPORT Act*”): In October 2018, the SUPPORT Act was enacted as a comprehensive legislative response to the continuing opioid epidemic. It includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medication assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries. It also includes a number of requirements directed at reducing the potential for oversupply of opioids to reduce the potential for misuse and diversion. In December 2025, the SUPPORT for Patients and Communities Reauthorization Act of 2025 was enacted, reauthorizing and revising many of the SUPPORT Act’s substance use disorder prevention, treatment, and recovery programs through fiscal year 2030.

Properties

Our principal executive office is located at 7946 Ivanhoe Ave., Suite 201 in La Jolla, California, where we lease a total of 850 square feet of office space that we use for our administrative activities. All development activities are undertaken at contract research organizations. The lease expires in October 2026. We believe that our current arrangements will be sufficient to meet our needs for the foreseeable future, and that, should it be needed, suitable space will be available to accommodate our administrative activities. Cy Biopharma does not lease any premises.

Human Capital Resources (Employees)

Following the acquisition of Cy Biopharma, our workforce expanded to include personnel supporting both our existing programs and Cy Biopharma’s research and development activities. As of September 30, 2026, we had 7 full-time and 5 part-time employees, including 5 employees holding Ph.D. degrees. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

RISK FACTORS

You should carefully consider the risks described below that relate to the acquisition by Ensysce Biosciences, Inc., a Delaware corporation (“we,” “us,” “our,” or the “Company”), of Cy Biopharma, Inc., a Delaware corporation (“Cy”), in accordance with the terms of an Agreement and Plan of Merger, dated August 5, 2026 (the “Merger Agreement”), by and among the Company, PHRMA Merger Sub I, Inc., PHRMA Merger Sub II, LLC, and Cy. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. The Company has disclosed other risks in its Annual Report on Form 10-K for the year ended December 31, 2025 and in other reports filed with the U.S. Securities and Exchange Commission (the “SEC”). Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Relating to the Merger

The Company has incurred and will incur substantial costs related to the Merger and integration of Cy’s business.

The Company and Cy have incurred and expect to incur a number of non-recurring costs in connection with the Merger, including legal, financial advisory, accounting, consulting, and other advisory fees; regulatory filing fees; and other transaction-related costs. Additionally, integration costs may be substantial, and may include expenses related to facilities and systems consolidation with operations in the United States and the UK, employment-related obligations, and efforts to maintain employee morale and retain key personnel.

While the Company and Cy estimate a certain level of integration costs, many factors beyond our control could increase the total amount and timing of these expenses. Additionally, many of these costs are inherently difficult to estimate with precision. There can be no assurance that transaction and integration costs will not outweigh any benefits of the Merger.

The Company may fail to realize the anticipated benefits of the Merger.

The success of the Merger will depend, in part, on realizing anticipated benefits from integrating the businesses of the Company and Cy. To achieve these benefits, the Company and Cy must effectively merge and align operations in a manner that permits the realization of those benefits without adversely affecting future revenue and growth. If the Company and Cy do not successfully integrate their operations, the anticipated benefits of the Merger may not be realized fully or at all, or they may take longer to realize than expected. In addition, integration may result in additional or unforeseen expenses.

It is also possible that combining the two businesses could result in the disruption of ongoing operations or inconsistencies in standards, controls, procedures, and policies that adversely affect the ability to maintain relationships with customers, clients, and employees, or to achieve the anticipated benefits of the Merger. Moreover, integration efforts may divert management’s attention and resources, further impacting the combined company’s performance both during and after the integration period.

Furthermore, the Board of Directors (the “Board”) and executive leadership of the combined company will include individuals from both companies, which could require reconciling differing priorities and philosophies. Any difficulties in effectively unifying these teams may also delay or prevent realization of the anticipated benefits of the Merger.

Upon conversion of the preferred stock, existing holders of the common stock will experience substantial dilution of their ownership interest in the Company, which could materially reduce the value of their Company shareholdings.

Without giving effect to a possible reverse stock split, following stockholder approval of the conversion of preferred stock into common stock at a ratio of one share of preferred stock for 1,000 shares of common stock, an additional 358,292,000 shares of common stock will be issued, subject to the beneficial ownership limitations applicable to the preferred stock, with an additional 75,615,000 shares of common stock issuable upon conversion of preferred stock to be issued under the Securities Purchase Agreement, dated August 5, 2026, among the Company and the purchasers party thereto (the “Securities Purchase Agreement”) and to certain former Cy stockholders if the second closing under the Securities Purchase Agreement, which is subject to the achievement of a clinical trial milestone (the “Milestone”), occurs. Regardless of whether a reverse stock split occurs, the preferred stock conversion will result in an immediate and substantial increase in the number of outstanding shares of common stock, and substantial dilution of existing Company stockholders’ ownership of and voting power in the Company.

As such, existing stockholders should assume that their ownership stake and influence will be severely reduced upon the preferred stock conversion, and that such dilution will be compounded upon occurrence of the Milestone.

Additionally, the resale of common stock issuable upon the preferred stock conversion is being registered by means of a registration statement to be filed with the SEC. As a result, a substantial number of shares may become freely tradable. The presence of these newly registered shares or the perception that the shares may be sold could create an “overhang” in the market. Specifically, if the trading volume of the common stock cannot absorb the resale of these newly registered shares, the price per share of common stock may decline.

The Milestone may not occur, which could have a material adverse effect on our liquidity, financial condition and ability to fund our planned operations.

At the initial closing under the Securities Purchase Agreement, we issued 66,811 shares of preferred stock for gross proceeds of approximately \$21.5 million, and the purchasers under the Securities Purchase Agreement agreed to purchase an additional 53,449 shares of preferred stock at a price of \$402.24 per share (or \$0.40224 per share on an as-converted basis), for additional gross proceeds of approximately \$21.5 million, upon achievement of the Milestone. Certain former Cy securityholders have separately agreed to purchase up to an additional 22,166 shares of preferred stock on the same terms upon achievement of the Milestone. The Milestone has not been achieved, and there can be no assurance that it will be achieved on the timeline we expect, or at all. Clinical trials are inherently uncertain, and the Phase 2 clinical trial that is identified in the Milestone may be delayed, suspended or terminated, or may fail to produce results that satisfy the Milestone. If the Milestone does not occur, or is delayed, we will not receive the additional proceeds when anticipated, or at all, and we would need to obtain alternative financing to fund our planned operations, including the continued development of our products, CY200 and CY201, which may not be available on acceptable terms, or at all. Any such failure or delay could have a material adverse effect on our business, financial condition, results of operations and prospects and on the price of our common stock.

Future results of the combined company may suffer if it cannot effectively manage its expanded operations.

The combined company’s future success will depend, in part, on its ability to manage expanded operations, which may pose challenges for management, including challenges related to oversight and the associated increase in capital expenditures and complexity. The combined company may also experience a change in scrutiny from governmental and regulatory authorities because of the change of operations and product mix. There can be no assurance that the combined company will be successful or that it will realize the benefits currently anticipated.

The combined company may be unable to retain the Company’s and/or Cy’s personnel.

The success of the Merger will depend in part on the combined company's ability to retain the talents and dedication of key employees currently employed by the Company and Cy. It is possible that these employees may decide not to remain with the Company or Cy following the Merger. If the Company and Cy are unable to retain key employees, the combined company could experience a reduction in its operations, loss of key information, expertise, or know-how, and unanticipated recruitment costs. In addition, the combined company may be unable to locate or retain suitable replacements for any key employees who leave.

The unaudited pro forma condensed combined financial information of the Company and Cy is preliminary and the actual financial condition and results of operations of the combined company may differ materially.

The unaudited pro forma condensed combined financial information of the Company and Cy is presented for illustrative purposes only and is not necessarily indicative of what the combined company's actual financial condition or results of operations will be following the Merger. The unaudited pro forma condensed combined financial information reflects adjustments, which are based upon preliminary estimates. Among other things, the actual value of the consideration that the Company issued upon the consummation of the Merger may vary significantly from the value used in preparing the unaudited pro forma condensed combined financial information included in our Current Report on Form 8-K/A filed with the SEC on October 15, 2026. Accordingly, the final accounting adjustments may differ materially from the pro forma adjustments reflected in the unaudited pro forma condensed combined financial information.

The Company's directors, executive officers and principal stockholders will have substantial control over the Company, which could limit other stockholders' ability to influence the outcome of corporate matters and key transactions.

Following conversion of the preferred stock into common stock and approval of related matters by our stockholders, the Company's executive officers, directors and principal stockholders and their affiliates will own approximately 155.7 million shares of the common stock, or approximately 41.2% of the outstanding shares of the common stock, of which James Morrison, our President, beneficially owns 154.8 million shares, or approximately 41.0%, through Belgarion Ventures Ltd. Similarly, the holders of preferred stock who may seek to sell the common stock they receive upon the preferred stock conversion (the "Selling Securityholders"), including Belgarion Ventures Ltd., will own 358.3 million shares, or approximately 94.8% of the outstanding shares of the common stock, based on 377.7 million shares of common stock outstanding following the conversion of the preferred stock into common stock. If the Milestone is achieved, certain of the Selling Securityholders will own an additional 22.2 million shares of common stock. This significant concentration of ownership may have a negative impact on the trading price of the common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. In addition, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from other stockholders of the Company and may vote in a way with which other stockholders of the Company disagree. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of the Company, could deprive the Company's stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might ultimately affect the market price of the common stock.

Certain of the Company's directors and executive officers may have other interests that may differ from, or are in addition to, the interests of the Company's stockholders.

In addition to the conflicts of interest described above, if the stockholders approve the conversion of preferred stock into common stock and the election of directors at the annual meeting, the resulting changes in the Board and executive officer composition could result in the Company's directors and executive officers having other interests and arrangements that are different from, or in addition to, those of the Company's stockholders. These interests and arrangements may create potential conflicts of interest.

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

On May 21, 2026, we received notice from Nasdaq stating that due to the Company's non-compliance with the \$2.5 million stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1) as of March 31, 2026, the Company was subject to delisting unless it submitted a plan within 45 days (by July 6, 2026) to regain compliance. If the plan is accepted, the Company may be granted an extension of up to 180 days from May 21, 2026, to regain compliance. If the plan is not accepted, the Company may appeal to the Nasdaq Hearings Panel (the "Panel"). The Company submitted a timely plan. On August 25, 2026, Nasdaq notified the Company that Nasdaq has determined that the Company complies with Rule 5550(b)(1) but that the Company is subject to delisting if it fails to evidence compliance in its next periodic report filed with the Securities and Exchange Commission. The Company believes it will be able to evidence compliance in its next periodic report.

On February 25, 2026, we received notice from Nasdaq that we were no longer in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement") because the bid price of our common stock had closed below \$1.00 per share for the previous 30 consecutive business days. Initially, we had until August 24, 2026, to regain compliance with the Bid Price Requirement. The Company sought an extension to comply with the Bid Price Requirement. On August 25, 2026, Nasdaq granted the Company an additional 180 calendar days, or until February 22, 2027, to regain compliance.

In addition, on August 25, 2026, we received notice from Nasdaq that the transaction with Cy will constitute a change of control under Nasdaq Listing Rules and that we will need to complete a Nasdaq initial listing application and the Nasdaq initial listing process before obtaining shareholder approval for the conversion of preferred stock into common stock. The minimum bid price needed for an initial listing on the Nasdaq Capital Market is \$4.00 per share.

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

The procedures applicable to penny stocks require 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.

Risks Relating to Controlled Substance Laws and Regulation

Because CY200 and CY201 contain psilocybin and psilocin, respectively, each a Schedule I substance, they are subject to Schedule I controls under the U.S. Controlled Substances Act, including registration, security, recordkeeping and quota requirements administered by the U.S. Drug Enforcement Administration, and Schedule 1

controls under the UK Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001, including Home Office licensing, security and recordkeeping requirements, and this could delay or prevent the development and commercialization of CY200 or CY201.

In the United States, psilocybin and its active metabolite, psilocin, are listed by the U.S. Drug Enforcement Administration (the “DEA”) as controlled substances under the U.S. Controlled Substances Act (the “CSA”), specifically as Schedule I substances. Schedule I substances by definition have a high potential for abuse, have no currently “accepted medical use” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Schedule I and II substances are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements to guard against theft or diversion, and criteria for importation. Because CY200 and CY201 contain Schedule I substances, each U.S. research site must, before conducting clinical trials, submit a research protocol to the DEA and obtain and maintain a DEA Schedule I researcher registration authorizing the site to handle and dispense the applicable product candidate and to obtain the product from our importer or manufacturer. If the DEA delays or denies the grant of a researcher registration or approval of a research protocol to one or more research sites, our planned or ongoing clinical trials of CY200 or CY201 could be significantly delayed, and we could lose clinical trial sites. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must also be registered to perform those activities and must maintain the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All such facilities must renew their registrations annually, except dispensing facilities, which must renew every three years, and the DEA conducts periodic inspections of registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may delay the importation, manufacture or distribution of CY200 or CY201. In addition, to the extent we or our contract manufacturers conduct manufacturing or repackaging or relabeling in the United States, we and our contract manufacturers would be subject to the DEA’s annual manufacturing and procurement quota requirements with respect to psilocybin; psilocybin would be subject to such quotas while controlled in Schedule I or II unless it is placed in Schedule III, IV or V or descheduled, and the annual quota allocated to us or our contract manufacturers may not be sufficient to complete our clinical trials of CY200 or CY201 or, if CY200 or CY201 is approved, to meet commercial demand. In January 2026, the DEA finalized its aggregate production quotas for 2026, increasing the psilocybin production quota to 50,000 grams (from 30,000 grams in 2025), reflecting growing research demand; however, there can be no assurance that future quota allocations will be sufficient for our needs or that the DEA will continue to increase quotas. Any delay or refusal by the DEA in establishing our or our contract manufacturers’ procurement or production quotas could delay or stop our clinical trials or any product launch. In the United Kingdom, psilocybin is a Class A drug under the Misuse of Drugs Act 1971 and is listed in Schedule 1 to the Misuse of Drugs Regulations 2001 (the “2001 Regulations”). Schedule 1 drugs have no recognized medical use in the UK. Research and clinical trials involving Schedule 1 substances in the UK require a Home Office domestic controlled drugs license, which can take months to process and requires enhanced secure storage facilities. Any delay or refusal by the Home Office in granting such a license could delay or prevent our Phase 2 trial of CY200 in the United Kingdom. The UK government accepted in principle the Advisory Council on the Misuse of Drugs’ (“ACMD”) recommendations in July 2025 to pilot an exemption from the Home Office license requirement for universities and hospitals conducting research clinical trials and other approved clinical trials with Schedule 1 drugs. However, because the policy is still being designed, standard Schedule 1 licensing requirements remain fully in effect. UK clinical trials also require authorization from the Medicines and Healthcare products Regulatory Agency (the “MHRA”) under the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, effective April 28, 2026, and a favorable opinion from a UK research ethics committee. Any delay or refusal of approval could delay or prevent our Phase 2 trial from proceeding. As of the date of this Current Report, we have not yet submitted an investigational new drug application for CY200 or CY201 to the FDA and have not applied for any DEA registration or quota for CY200 or CY201. We are not yet the sponsor of any clinical study of CY200 or CY201 in the United States.

Because CY200 and CY201 contain Schedule I substances, approval by the U.S. Food and Drug Administration (the “FDA”) alone would not permit U.S. marketing of CY200 or CY201 until applicable controlled-substance scheduling action is effective, and an MHRA marketing authorization alone would not eliminate UK scheduling requirements; delays in either process could delay commercialization respectively in the U.S. and/or the UK.

For a product containing psilocybin or psilocin to be lawfully marketed for medical use in the United States, the relevant substance or drug product would need to be placed in Schedule II, III, IV or V, or otherwise removed from Schedule I. FDA approval would satisfy the “accepted medical use” element relevant to that scheduling determination. If and when CY200 or CY201 receives FDA approval, applicable federal scheduling action would be required before it could be prescribed to patients in the United States because an FDA-approved drug product cannot remain in Schedule I. That determination will depend on FDA approval and the scheduling analysis and recommendation of the U.S. Department of Health and Human Services (“HHS”), and, if HHS recommends that the approved drug be controlled in Schedule II, III, IV or V, the DEA generally must issue an interim final rule controlling the drug no later than 90 days after the later of its receipt of HHS’s scientific and medical evaluation and scheduling recommendation or notice of FDA approval. The interim final rule becomes immediately effective and must provide interested persons an opportunity to comment and request a hearing; a final rule follows after those proceedings. Delays in the HHS recommendation, FDA approval or other steps preceding issuance of the interim final rule, or in subsequent scheduling proceedings, could delay the launch of CY200 or CY201 in the United States. Moreover, even assuming categorization as a Schedule II or lower controlled substance, the active ingredient in the final dosage form could remain listed on Schedule I, and separate scheduling determinations may be required under state laws and regulations. In August 2025, the DEA formally transmitted a petition it received to reschedule psilocybin from Schedule I to Schedule II of the CSA to HHS for review. While this petition, if granted, could facilitate future rescheduling of psilocybin, no scheduling action has been taken as of the date of this Current Report, and there can be no assurance as to the timing or outcome of such proceedings. In the United Kingdom, no psilocybin-based medicines currently hold an MHRA marketing authorization. If an MHRA marketing authorization were granted, the Home Office has indicated that it would review the scheduling of psilocybin under the 2001 Regulations, subject to advice from the ACMD. This process could introduce delays separate from and in addition to any FDA-related scheduling delays and could affect whether and how CY200 or CY201 could be marketed, prescribed or supplied in the UK.

The FDA, the DEA, the MHRA, the Home Office, or comparable foreign regulatory authorities may require additional data regarding the abuse potential of CY200 or CY201, which could increase our development costs and delay approval and any rescheduling.

During the review process, and prior to approval, the FDA may determine that it requires additional data, from either non-clinical or clinical studies, including with respect to whether, or to what extent, CY200 or CY201 has abuse or misuse potential. The FDA, the DEA, the MHRA, the Home Office, or any foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate in order to establish whether or to what extent psilocybin has an abuse potential, including through a human abuse potential study or an equivalent study. Any such requirement could increase our development costs and delay the marketing approval, rescheduling and launch of CY200 or CY201. Any additional data requirement may also introduce a delay into the approval and any potential rescheduling process, and the length of that delay would depend on the quantity of additional data required. A human abuse potential study or equivalent study may also determine that, upon regulatory approval, CY200 or CY201 remains appropriately controlled in a restrictive schedule, which could limit its commercial attractiveness. Depending on the abuse-potential findings, labeling and any risk-management requirements imposed by the FDA or MHRA, and any controlled-substance requirements imposed by the DEA or Home Office CY200 or CY201 could be required to be administered at qualified trial or treatment sites rather than dispensed for self-administration, which could limit commercial uptake. We have not yet submitted an investigational new drug application for CY200 or CY201 to the FDA.

Regulators may require more nonclinical, clinical or chemistry, manufacturing and controls data for CY200 or CY201 than we expect, which could increase our costs, delay or prevent approval, or limit the scope of any approval.

We expect to rely in part on published nonclinical and clinical data on psilocybin and psilocin to support the development of CY200 and CY201. Published data on psilocybin and psilocin may concern studied test materials that differ from CY200 and CY201 in source, composition and formulation and the FDA, the MHRA, or other regulators may conclude that the published data do not support the safety or efficacy of CY200 or CY201 at our proposed dose or dosing regimen. The FDA, the MHRA or other regulators may require additional toxicology, clinical pharmacology, drug interaction or safety exposure data and, because CY200 and CY201 are botanically derived, additional data showing that their composition and therapeutic effect are consistent from batch to batch. Any such requirements could increase our costs and delay development.

The legal and regulatory regime applicable to psychedelic therapies is evolving rapidly and remains uncertain, and changes in law, regulatory guidance, agency leadership or enforcement priorities could adversely affect our CY200 and CY201 programs.

Given the limited recent experience with the clinical use of psychedelic drugs, it is likely that the regulatory landscape applicable to CY200 and CY201 will continue

to evolve, and it could do so rapidly. We cannot guarantee that we will be able to, or will have the resources to, adapt to changes in regulatory requirements. In July 2026, the FDA issued final guidance titled “Psychedelic Drugs: Considerations for Clinical Investigations,” which sets out the FDA’s current, nonbinding recommendations on matters including abuse-potential assessment, trial design, safety monitoring and psychological or behavioral interventions used in psychedelic-drug trials. The FDA has characterized these recommendations as nonbinding, but the agency’s expectations as reflected in the guidance could influence the design and cost of our clinical program. The FDA and foreign regulatory authorities may revise or supplement such recommendations through regulation, guidance or other communications at any time, as drug development in this area evolves. In the UK, the Misuse of Drugs Act 1971, the 2001 Regulations and the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, also establish requirements that may evolve, and the Home Office, the MHRA and the ACMD may revise or supplement their implementation or guidance. Because clinical trials take significant time, we cannot assure you that the design of our clinical program for CY200 or CY201 will remain consistent with future regulatory recommendations for clinical investigations involving psychedelic drugs.

State controlled substance laws, foreign controlled substance laws and international treaty obligations impose separate licensing and scheduling requirements that could delay or restrict the development and commercialization of CY200 or CY201.

Individual U.S. states have also established controlled substance laws and regulations, and many state laws classify psilocybin and psilocin as Schedule I controlled substances. Although state controlled substance laws often mirror federal law, because the states are separate jurisdictions they may separately schedule CY200 or CY201. While some states automatically schedule or reschedule a drug based on federal action, other states schedule drugs through rulemaking or legislative action. State scheduling may delay the commercial sale of CY200 or CY201 even if we obtain federal regulatory approval, and adverse scheduling could have a material adverse effect on the commercial attractiveness of the product. We or our partners must also obtain separate state registrations, permits or licenses in order to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those imposed by the DEA or otherwise arising under federal law. We plan to conduct CY200 clinical activity outside the United States, including a Phase 2 trial in the United Kingdom, which will be subject to the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001, including the UK controlled-substance licensing requirements applicable to Schedule 1 substances. We plan to conduct additional clinical activity for CY200 or CY201 outside the United States, including planned Phase 3 trials in the United States, Europe and Australia, and non-U.S. controlled-substance licensing requirements will accordingly apply to that activity. In the United Kingdom, the possession and supply of Schedule 1 controlled substances for the Phase 2 trial require Home Office licenses. Our contract packager and each of the Phase 2 trial sites hold such licenses. Our contract manufacturer holds the licenses required in its jurisdiction to manufacture CY200. Psilocybin and psilocin are listed in Schedule I of the 1971 Convention on Psychotropic Substances, and parties to that Convention are generally required to apply licensing and authorization controls to the manufacture, trade, distribution, import and export of Schedule I substances, subject to the Convention’s terms and domestic implementing law. Certain jurisdictions may not permit the use or production of psilocybin, nor provide any exemption or regulatory approval that could allow for the lawful use or production of such substances.

Any failure by us or by our third party contractors to comply with controlled substance laws could result in the loss of registrations or licenses, substantial fines and civil or criminal sanctions.

Failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion of controlled substances, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations, and in certain circumstances violations could lead to criminal proceedings. In the UK, violation of the Misuse of Drugs Act 1971 or the conditions of a Home Office license could similarly result in revocation of the license, criminal prosecution, and fines. Even assuming that CY200 or CY201 is approved and rescheduled by regulatory authorities to allow its commercial marketing, any controlled-substance active ingredient in CY200 or CY201 could remain a Schedule I substance, or the state or foreign equivalent. Violations of applicable U.S. federal, state, local or foreign controlled-substance laws could result in fines or other civil penalties, administrative sanctions, suspension or revocation of licenses or registrations or, in appropriate cases, criminal charges and penalties, including imprisonment. Any of the foregoing could have a material adverse effect on us, including on our reputation and ability to conduct business, our financial position, operating results, profitability or liquidity, and the market price of our common stock. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matter or for its final resolution, and such time or resources could be substantial. The clinical trial and commercial risks described above are compounded by the fact that the DEA registration of an investigator or site conducting a clinical trial may be revoked, or a Home Office license or other UK authorization may be revoked or suspended, which would require us to suspend or terminate activity at that site.

Restrictions on the importation, exportation and cross-border transportation of CY200 or CY201 and any controlled-substance component, including UK Home Office import and export licensing requirements, could interrupt our clinical supply.

The shipment, import and export of CY200 or CY201 and any controlled-substance active pharmaceutical ingredient used to manufacture it would require the registrations, permits and other authorizations applicable in the importing and exporting jurisdictions, including, where the United States is the importing or exporting jurisdiction, applicable DEA registrations and U.S. import or export permits. Importing CY200 or CY201 or any controlled-substance active pharmaceutical ingredient into the UK would require a separate Home Office import license, and exporting controlled drugs from the UK would require a separate Home Office export license; export from the manufacturing jurisdiction would also require corresponding export authorization. Our current clinical supply chain depends on the export of CY200 from our contract manufacturer in North America and its import into the United Kingdom by our contract packager, which holds a Home Office controlled drugs license and must obtain a Home Office import license for each shipment, before onward supply to the Phase 2 trial sites. These requirements are separate from applicable DEA registrations and U.S. import or export permits. We may not be granted, or if granted may not maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of active pharmaceutical ingredient and finished CY200 or CY201 drug product may be held up or lost in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges, and inappropriate storage may damage the shipment, resulting in delays in clinical trials or, upon any commercialization, a partial or total loss of revenue from one or more shipments. The DEA provides annual assessments and estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that it authorizes to be imported, and the failure to identify an importer or to obtain the necessary import authority, including for specific quantities, could affect the availability of CY200 or CY201. Applications to register as an importer of Schedule I or II controlled substances are subject to DEA public-interest review and Federal Register notice procedures. In addition, the CSA generally prohibits importation of Schedule I or II controlled substances except in specified circumstances, including when the Attorney General finds that domestic supplies are inadequate, competition among domestic manufacturers is inadequate, or limited quantities are needed exclusively for scientific, analytical or research uses. If CY200 or CY201 or a controlled-substance component could not lawfully be imported in the quantities needed for commercial supply, we could be required to manufacture that material in the United States through an appropriately registered manufacturer. The transportation of CY200 or CY201 to clinical trial sites is also subject to security requirements and other controls under applicable controlled substance laws and regulations.

Risks Relating to Clinical Development of CY200 and CY201

Clinical trials of CY200 or CY201 may be delayed, suspended or terminated, including as a result of clinical holds, a failure to obtain or maintain MHRA clinical trial authorization, an MHRA decision to suspend or terminate a clinical trial, or safety findings, and adverse side effects could result in a restrictive label, a risk mitigation program or the denial of regulatory approval.

We may experience delays in initiating, conducting or completing the randomized Phase 2 clinical trial of CY200 in Complex Regional Pain Syndrome Type 1 (“CRPS Type 1”) or any subsequent trial of CY200 or CY201. Such delays may result from a failure to obtain regulatory approval to commence or modify a trial, including the imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, such as following review of an investigational new drug application or amendment, a clinical trial application or amendment, a finding that the trial presents unreasonable risk to clinical trial participants, a negative finding from an inspection of our

clinical trial operations or study sites, or the occurrence of a suspected unexpected serious adverse reaction or a serious adverse event during a trial. The Phase 2 trial will be conducted in the United Kingdom and will require authorization from the MHRA under the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, effective April 28, 2026, together with a favorable opinion from a UK research ethics committee. The MHRA may suspend or terminate a clinical trial, and any delay, refusal, suspension or termination of the MHRA authorization or the research ethics committee's favorable opinion could delay or prevent our Phase 2 trial. We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, UK research ethics committees, or other ethics committees of the institutions in which the trial is being conducted, by the applicable data review committee or data safety monitoring board, by the FDA, MHRA, or other regulatory authorities, or if the DEA registration of an investigator or site conducting the clinical trial is revoked or an applicable Home Office license is revoked or suspended. As with pharmaceuticals generally, there may be unexpected or undesirable side effects, adverse events and other risks associated with the use of CY200 or CY201 that future clinical trials may reveal. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. Because of the high variability in how different individuals react to psilocybin, certain clinical trial participants may have negative experiences with the treatment that could subject us to liability or, if publicized, reputational harm. In addition to side effects caused by the product candidate itself, the administration process and related procedures can cause adverse side effects; if we are unable to demonstrate that any such adverse events were caused by the administration process or related procedures, the FDA, MHRA, or other regulatory authorities could order us to cease further development of, or deny approval of, CY200 or CY201. Undesirable side effects could also result in a more restrictive label, including contraindications or a boxed warning, a requirement that we implement a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the treatment outweigh its risks, or the delay or denial of regulatory approval. Clinical trials are by design based on a limited number of subjects and of limited duration of exposure, and we cannot be sure that all side effects of CY200 or CY201 will be uncovered; a more complete safety profile may be identified only with a significantly larger number of patients exposed for a longer duration, and even larger clinical trials may not identify rare serious adverse effects.

If CY200 or CY201 produces readily perceptible psychoactive effects, functional unblinding and expectancy bias could hinder the interpretability or regulatory acceptability of our clinical trial results.

Our later-stage clinical trials of CY200 or CY201 may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm given the potential difficulties related to maintaining the blind during the trial and the potential for placebo or nocebo effects. Even in a placebo-controlled or active-controlled trial, it is possible that participants and investigators will be able to discern whether the administered dose is the product candidate, a placebo or an active control, if the product candidate produces readily perceptible psychoactive effects – a phenomenon known as functional unblinding. Accordingly, placebo-controlled or active-controlled trials of CY200 or CY201 may be subject to limitations similar to those of open-label trials. Concerns about functional unblinding, expectancy bias or the impact of our model for supporting and monitoring participants during dosing sessions could hinder the interpretability or the regulatory acceptability of data from our clinical trials of CY200 or CY201. The FDA's July 2026 final guidance on psychedelic drug clinical investigations specifically addresses functional unblinding and expectancy bias and recommends that sponsors design trials to mitigate the impact of these phenomena. The guidance further recommends that sponsors evaluate durability of treatment effect, which could increase the cost and duration of our clinical program. These methodological challenges are heightened in our indication because the primary efficacy measure for CRPS Type 1 is based on the responder rate, in which a participant is deemed to be a responder if the mean pain numerical rating scale ("NRS") score over the seven days from Day 15 to Day 21 is at least 30% lower than baseline. The key secondary measures include the change from baseline in the mean NRS score over the same seven days and over the seven days from Day 36 to Day 42, and the Patient Global Impression of Change at Day 20. The primary and key secondary endpoints are patient-reported and therefore particularly susceptible to expectancy effects. In addition, regulatory authorities may change their views on aspects of our clinical program, including study designs, or on the ability of the studies as designed to support approval of CY200 or CY201, and may disagree with our interpretation of the resulting data or with the adequacy or statistical interpretability of our endpoints.

We may be unable to enroll and retain a sufficient number of patients with CRPS Type 1 in our clinical trials of CY200 or CY201, which could delay or prevent completion of our development program.

Identifying and qualifying trial participants is critical to our success, and the timing of our clinical trials depends on the speed at which we can recruit participants and our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. Patient enrollment depends on many factors, including the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients; the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial; the safety profile of the product candidate to date; the willingness or availability of patients to participate, including in light of the perceived risks and benefits, stigma or side effects associated with the use of a controlled substance, which may be influenced by negative publicity; the proximity of patients to clinical sites; competition with other companies for clinical sites or patients; and our ability to recruit clinical trial investigators with the appropriate competencies and experience. These challenges are heightened for CY200 and CY201 because CRPS is a rare disorder for which psilocybin has received Orphan Drug Designation, and the limited size and geographic dispersion of the eligible patient population may make recruitment more difficult and more expensive than for more prevalent indications. Because the Phase 2 trial of CY200 will be conducted in the United Kingdom, it may present additional challenges related to recruiting CRPS Type 1 patients in a limited geographic area and the willingness of UK patients to participate in a trial involving a Class A controlled substance. The Phase 2 protocol requires participants to have been on a stable medication regimen for at least four weeks before dosing and excludes participants using high-dose opioid medication (more than 80 mg morphine equivalent daily dose) or an unstable opioid dose, or serotonin agonists within four weeks of dosing. Selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors are permitted at a stable dose. Delays in enrollment and withdrawals from a trial may result in increased costs and may affect the timing or outcome of our planned clinical trials. Even once enrolled, we may be unable to retain a sufficient number of patients to complete a trial or to have patients return for post-treatment follow-up, and lower-than-anticipated retention rates could compromise the interpretability of our data. Because the second tranche of our private placement financing will be funded only upon achievement of a clinical trial milestone that has not yet been achieved, any delay in enrollment or completion of the Phase 2 trial of CY200 could also delay or prevent our receipt of those additional proceeds. The Phase 2 trial is planned as a randomized, double-blind, placebo-controlled trial with four groups, each receiving two doses three weeks apart: placebo and placebo; 10 mg and placebo; 25 mg and placebo; and 25 mg and 25 mg. The trial is designed to randomize approximately 130 participants so that 104 participants complete the trial. As of the date of this Current Report, no participant has been enrolled.

The dosing, administration, monitoring and session-protocol requirements for CY200 or CY201 have not been established with certainty, and regulators may disagree with our approach.

We may experience delays in establishing the appropriate dosage levels for CY200 or CY201 in clinical trials. Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug may have a positive effect on some patients but not others, and why some individuals may react to the drug differently from others. These differences may result in different reactions that affect the effectiveness of CY200 or CY201 and may cause the proportion of patients, if any, who achieve a clinically meaningful response to fluctuate. In addition, if CY200 or CY201 produces clinically significant psychoactive effects, regulators may require a structured dosing session with monitoring by trained healthcare professionals, together with preparation and post-administration follow-up. The appropriate duration and content of any such session, the level and qualifications of monitoring personnel, the extent to which psychological support or psychotherapy should be part of treatment, and the metrics used to characterize any psychoactive experience may be uncertain or subject to regulatory requirements, and the FDA, MHRA or other regulatory agencies may not accept the approach we adopt. The FDA's July 2026 final guidance recommends that sponsors employing psychological support or psychotherapy alongside drug administration use trial designs that can distinguish the contribution of the drug from any non-drug intervention, and that sponsors document their psychotherapy model since it may be incorporated into product labeling. These recommendations could affect the design and cost of our clinical trials and the labeling of CY200 or CY201, if approved. Regulatory authorities may require changes to our dosing regimen, session protocol or monitoring requirements at any time, including after the completion of clinical trials, and any such change could require additional clinical work, increase our costs, delay approval or reduce the commercial attractiveness of CY200 or CY201. Any protocol deviation by an investigator or site with respect to dosing or monitoring could also compromise our data and expose us to regulatory action and liability.

We depend on third-party contract research organizations, investigators and clinical trial sites to conduct our clinical trials of CY200 and CY201, and their failure to perform or to comply with good clinical practice requirements could delay or prevent regulatory approval.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, academic collaborators and contract research organizations (“CROs”), clinical data management organizations and medical institutions, to conduct our preclinical studies and clinical trials of CY200 and CY201 and to monitor and manage data for those programs. We rely on these parties for the execution of our studies and trials and control only certain aspects of their activities. Nevertheless, we remain responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and with legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good clinical practice (“GCP”) requirements, including U.S. GCP requirements enforced by the FDA and UK GCP requirements enforced by the MHRA, as well as comparable regulations and guidelines enforced by other regulatory authorities and which are intended to ensure that the health, safety and rights of patients are protected and that trial data integrity is assured. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators, our academic collaborators or any of our CROs fail to comply with applicable good clinical practice requirements, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA, the MHRA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing application for CY200 or CY201. If these third parties do not successfully carry out their contractual duties or obligations, do not meet expected deadlines, need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised, our clinical trials may be extended, delayed or terminated. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. These risks may be heightened because CY200 and CY201 contain Schedule I controlled substances, and the population of CROs and investigators with relevant controlled-substance experience may be limited; each participating U.S. site would need to obtain and maintain the applicable DEA researcher registration and protocol authorization, and the UK Phase 2 sites would need applicable Home Office controlled drugs licenses and MHRA authorization. Because the Phase 2 trial of CY200 will be conducted in the United Kingdom, the collection and processing of clinical trial data will be subject to UK data protection law, including the UK General Data Protection Regulation (the “UK GDPR”) and the Data Protection Act 2018, and any cross-border transfer of clinical trial data from the UK to the United States will need to comply with applicable transfer mechanisms under the UK GDPR.

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Negative results, adverse safety events or adverse publicity concerning other psychedelic programs, including studies not conducted by us, could adversely affect our CY200 and CY201 programs even if unrelated to CY200 or CY201.

We or regulatory authorities may learn of, and take action based on, side effects related to psilocybin or to compounds similar to CY200 or CY201 arising in studies not conducted by us, including investigator-initiated studies or studies conducted by other sponsors, spontaneous reports of the use of psilocybin outside of the clinical trial setting, or safety reports in the literature. Investigator-initiated studies of psilocybin may generate clinical trial data that raise concerns regarding the safety or effectiveness of psilocybin, and data generated in such studies may not be predictive of results in the populations or indications in which we are conducting, or plan to conduct, clinical trials. Adverse side effects caused by drugs that may be similar in nature to CY200 or CY201 could delay or prevent regulatory approval of CY200 or CY201, limit the commercial profile of any approved label, or result in significant negative consequences following any marketing authorization. The publication of negative results of studies or clinical trials, or of adverse safety events, relating to psychedelic compounds similar to CY200 or CY201 or to the therapeutic areas in which CY200 or CY201 would compete, could adversely affect our share price and our ability to finance future development of CY200 or CY201. In August 2024, the FDA issued a complete response letter declining to approve midomafetamine (MDMA)-assisted therapy for post-traumatic stress disorder (PTSD), citing concerns including functional unblinding, selection bias, durability, safety reporting, data integrity and the need for additional studies. While that decision related to a different compound and indication, it underscored the regulatory challenges facing the broader psychedelic drug development field and could affect investor and public perception of psychedelic therapies generally, including CY200 and CY201. Future adverse events in psychedelic research generally, or in the pharmaceutical industry more broadly, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of CY200 or CY201.

Topline, interim or preliminary data from our clinical trials of CY200 or CY201 may not be representative of final results, and early results may not be predictive of the outcome of later-stage trials.

From time to time we may publish or report topline, interim or preliminary data from our clinical trials of CY200 or CY201, including topline data from the randomized Phase 2 trial of CY200 in CRPS Type 1 that our recent financings are intended to fund. Topline, interim or preliminary data may not be indicative of the final results of a trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues or as more patient data become available. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, topline, interim or preliminary data should be viewed with caution until final data are available. In addition, the outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier phases. Apart from published academic case reports, the clinical data relied on by Cy Biopharma prior to the acquisition were generated in a small, uncontrolled, observational, open-label, proof-of-concept pilot run by a non-profit psilocybin service center licensed under Oregon’s Measure 109, and funded by Cy Biopharma. The pilot was not approved by an institutional review board for cohorts 1 and 2 and was intended solely for program and measurement development and from which no conclusions regarding efficacy should be inferred. The pilot comprised a small number of patients with CRPS or other chronic pain conditions who were dosed with a psilocybin formulation supplied under Oregon’s Measure 109 program rather than with CY200. A private institutional review board approved a third cohort in the first quarter of 2026. These data are not predictive of the results of our randomized Phase 2 trial or of any registrational trial. If the Phase 2 trial of CY200 does not produce results that we and regulatory authorities consider supportive, we may be unable to advance CY200 or CY201 into registrational development, we may fail to satisfy the clinical trial milestone required for the second tranche of our private placement financing, and the value of the assets we acquired in the Cy Biopharma acquisition could be materially impaired.

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Even if CY200 or CY201 is approved, the approved indication may be narrower than we seek.

Regulators may approve CY200 or CY201 only for a subset of patients with CRPS, a particular dosing regimen or a more limited claim than we seek, depending on the endpoints and populations studied. A narrower label could reduce the commercial potential of CY200 or CY201.

Orphan Drug Designation may not result in marketing exclusivity for CY200.

The FDA has granted Orphan Drug Designation for psilocybin for the treatment of CRPS. Designation does not mean that CY200 will be approved. Orphan drug exclusivity, which lasts seven years in the United States, is available only if CY200 is the first product containing the same active moiety to be approved for the designated use and we may not be entitled to exclusivity if CY200 is approved for a broader indication than the designated use. If another product containing the same active moiety is approved for the same use first, we would need to show that CY200 is clinically superior to obtain exclusivity, and we could be blocked from obtaining approval of CY200 for that use until the competing product’s exclusivity expires. Even if we obtain exclusivity, it would not prevent the approval of different drugs for CRPS or of the same drug for different uses. It also would not prevent the approval of the same drug for the same use if the later product is shown to be clinically superior. Exclusivity could be lost if we cannot supply sufficient quantities of CY200 to meet the needs of patients, or if the FDA later determines that the designation request was materially defective. In the United Kingdom, orphan status can be assessed only when an application for marketing authorization is made. We have not sought orphan designation in any other jurisdiction, and we may not obtain orphan designation or comparable exclusivity outside the United States.

We depend heavily on CY200 and CY201, and our other programs may not produce viable product candidates.

CY200 is the only clinical-stage product candidate we acquired with Cy Biopharma. A pharmacokinetic bridging study of CY201 is planned, but regulators may not accept bridging data as sufficient to rely on data generated with CY200, and additional studies of CY201 may be required. If their development fails or is delayed, our business would be materially harmed. Our preclinical programs, including CY30X and CY40X, may not yield product candidates suitable for clinical development, and we may spend significant resources on them without return.

Risks Relating to Manufacturing and Supply

Our reliance on third-party manufacturers and suppliers for CY200 and CY201 could expose us to supply, quality and capacity disruptions that delay clinical development or commercialization.

Neither we nor Cy Biopharma owns or operates any manufacturing capability used for CY200 or CY201. CY200 drug substance and drug product are manufactured by a third-party contract manufacturing organization in North America and quality-tested, packaged and labeled by a third-party GMP facility in the United Kingdom. To the extent we rely on third-party contract manufacturing organizations (“CMOs”) for the development, manufacture or production of CY200 or CY201 drug substance or drug product, we will depend on those third parties to supply material meeting applicable quality and regulatory requirements. Reliance on third-party providers exposes us to more risk than if we manufactured CY200 or CY201 ourselves. We do not control the manufacturing processes of our CMOs and are dependent on them for production in accordance with current good manufacturing practice (“cGMP”) requirements and applicable DEA regulations, including quality control, quality assurance and the maintenance of records and documentation, and, for manufacturing, importing or supplying CY200 or CY201 in the UK, UK good manufacturing practice (“UK GMP”) requirements as enforced by the MHRA and applicable Home Office controlled drugs licensing requirements. Manufacturing, importing or supplying CY200 or CY201 in the UK would require appropriate Home Office controlled drugs licenses in addition to MHRA manufacturing or import authorizations, and failure to obtain or maintain those licenses or authorizations could interrupt supply. Because CY200 and CY201 contain Schedule I controlled substances, our CMOs operating in the United States must also comply with enhanced DEA physical-security, recordkeeping and reporting requirements applicable to Schedule I substances, which may limit the number of CMOs available and willing to manufacture CY200 or CY201 and increase manufacturing costs. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect the supply of CY200 or CY201. If we rely on a limited number of CMOs, a disruption at one of those third parties could materially interrupt the supply of CY200 or CY201 and delay clinical development or commercialization. Because CY200 and CY201 contain Schedule I controlled substances, the number of suppliers authorized and capable of supplying the relevant controlled-substance material may be limited, and we or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient necessary to produce CY200 or CY201 in the quantities needed for our clinical trials or, if approved, for commercialization, as a result of demand from competing businesses, quota restrictions, capacity constraints, or delays or disruptions in the market. If we were to experience an unexpected loss of supply, or if any supplier were unable to meet our demand, we could experience delays in our research, planned clinical studies or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost, and the long transition periods necessary to switch manufacturers and suppliers may significantly delay our clinical studies and any commercialization. In some cases, the technical skills required to manufacture CY200 or CY201 may be unique or proprietary to the original CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier. Our contract manufacturer is currently the sole source of CY200 drug substance and drug product. Cy Biopharma has commissioned and received an independent audit of the manufacturing facility for EU GMP compliance.

Because CY200 and CY201 use botanically derived drug substances, manufacturing may present additional purity, potency and consistency risks, and manufacturing or formulation changes could require additional comparability work and delay development.

Because the active pharmaceutical ingredients of CY200 and CY201 are botanically extracted, achieving consistent purity, potency, stability and batch-to-batch consistency may be more difficult than for a wholly synthetic compound, and such source materials are also subject to additional controlled-substance handling requirements. Our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and that CY200 or CY201 is made strictly and consistently in compliance with that process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. Slight deviations affecting quality attributes and stability may result in unacceptable changes in the product. Although our suppliers are expected to maintain detailed procedures for testing product, there can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. In addition, as product candidates advance from early clinical trials toward potential approval and commercialization, it is common for various aspects of the development program, such as manufacturing methods and formulation, including excipients, salt forms, polymorphic forms and packaging, to be altered in an effort to optimize processes and results. Any such change could cause CY200 or CY201 to perform differently and affect the results of planned clinical trials, may require additional testing, FDA notification or FDA approval, MHRA notification or authorization, and may require us to conduct bridging or bioequivalence studies to relate the modified product to earlier versions. Changes in manufacturing site, scale, process controls or batch size as development advances may require additional comparability data or bridging work before or during registrational development and could delay the initiation or completion of a trial. The manufacture of commercial-quality product may have long lead times, may be very expensive and requires significant effort, including scale-up of production to anticipated commercial scale, process characterization and validation, analytical method validation, identification of critical process parameters and product quality attributes, and multiple process performance and validation runs.

Risks Relating to Commercialization and Market Acceptance

Even if CY200 or CY201 is approved and rescheduled in the United States, or receives an MHRA marketing authorization and any necessary UK scheduling action, post-approval controlled substance restrictions on prescribing, dispensing, distribution and handling could materially limit its commercial uptake.

If CY200 or CY201 is approved by the FDA and the finished dosage form is listed by the DEA as a Schedule II, III, IV or V controlled substance, its manufacture, importation, exportation, domestic distribution, storage, sale, prescribing, dispensing and legitimate use will remain subject to significant regulation by the DEA. Prescribing and dispensing of Schedule II controlled substances is subject to heightened restrictions; for example, Schedule II prescriptions are subject to specific form and signature requirements and generally may not be refilled; limited emergency exceptions apply under DEA regulations. If CY200 or CY201 is scheduled as Schedule II, III, IV or V, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the product, and those distributors would need to obtain the corresponding distribution registrations. Any limitation on our ability to distribute CY200 or CY201 more broadly may limit commercial uptake and could negatively affect our prospects, and the failure to obtain, delay in obtaining, or loss of any such registration could result in increased costs. If CY200 or CY201 is a Schedule II drug, participants in our supply chain would be subject to enhanced DEA physical-security, recordkeeping and inventory requirements, which may include alarms and specified secure storage depending on the activity, facility and dosage form, which may discourage some pharmacies from carrying the product. Depending on the final schedule, labeling and any FDA-required risk-management measures applicable to CY200 or CY201, the product could be subject to supervised-administration or distribution restrictions that limit commercial uptake. Furthermore, state controlled-substance laws and enforcement initiatives intended to reduce prescription drug abuse, including requirements in some states that prescribers consult a prescription drug monitoring program, may make prescribers less willing to prescribe, and pharmacies less willing to dispense, controlled substances. These restrictions may be particularly consequential for CY200 or CY201 because the target patient population is treated for chronic pain, an area already subject to heightened prescribing scrutiny. In addition, prescription drug monitoring programs and state-level prescribing restrictions applicable to controlled substances could create additional administrative burdens for prescribers of CY200 or CY201, potentially discouraging prescribing and limiting patient access. Commercial marketing of CY200 or CY201 in the UK would require an MHRA marketing authorization and a subsequent review of psilocybin’s scheduling under the Misuse of Drugs Act 1971 and the 2001 Regulations. Even if an MHRA marketing authorization were granted, the timing and outcome of that review, and any continuing Home Office controlled-substance licensing requirements, could delay or restrict the prescribing, dispensing, distribution and handling of CY200 or CY201 in the UK.

The FDA could require a REMS for CY200 or CY201, and the MHRA may impose comparable risk-management or risk-minimization measures as conditions of any UK marketing authorization, and supervised-administration or certified-site requirements could restrict patient access and commercialization.

The FDA may require a REMS as a condition of approval for CY200 or CY201 if it determines that such measures are necessary to ensure that the benefits of the product outweigh its risks; the MHRA may impose comparable risk-management or risk-minimization measures as conditions of any UK marketing authorization, and comparable measures may apply in other jurisdictions. This could entail requirements for patient monitoring, a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, certified sites, patient registries and other risk minimization tools. REMS programs are costly and time-consuming for providers to comply with and involve a high administrative burden, which could delay or limit our ability to commercialize CY200 or CY201. If a REMS or approved labeling requires administration only at certified or otherwise qualified sites, the number of sites available to administer CY200 or CY201 could be limited. Sites may also have difficulty satisfying the requirements of any REMS or comparable foreign program. Any such limitations could make it impracticable or impossible for some potential patients to access CY200 or CY201, if approved, which could limit the overall size of our potential patient population and harm our results of operations. If site certification or qualification is required, commercialization could depend on the availability of a sufficient network of third-party treatment sites that satisfy applicable requirements. If we are unable to establish or collaborate with such a network, it would have a material adverse effect on our business and ability to grow. Given the novel nature and scheduled-drug status of CY200 and CY201, third-party treatment sites may face additional financial and administrative burdens in order to deliver the treatment, and the certification process can be very costly and time-consuming, which could delay a site's ability to provide CY200 or CY201 and materially adversely affect our commercialization trajectory. Third-party treatment sites could also demand higher payments to administer CY200 or CY201, which could result in higher costs for payors and patients, and reimbursement levels may be inadequate to cover sites' costs of delivering the treatment.

If CY200 or CY201 requires supervised administration by trained healthcare professionals, limited provider and site capacity and the duration and cost of treatment sessions could restrict commercial scalability.

Our current CY200 Phase 2 clinical protocol requires pre-dose participant preparation and post-dose supervision and care at each dosing visit, with participants discharged approximately six to eight hours after dosing. Cy Biopharma and its designated contract research organization will determine the qualifications and training required for administering or monitoring personnel. If CY200 or CY201 is approved with comparable requirements, commercial administration could depend on an adequate number of trained healthcare professionals and appropriately equipped treatment sites. If third-party sites fail to recruit, train and retain a sufficient number of qualified healthcare professionals, or if they demand substantial financial resources from us to do so, our ability to offer and administer CY200 or CY201 would be greatly harmed, which may in turn reduce the market acceptance rate of the treatment. If administration requires supervision by healthcare professionals, failures to follow applicable protocols or other misconduct during administration could put patients at risk and subject us to potential liability, regulatory proceedings and reputational harm. Any required site infrastructure, equipment or dedicated treatment space could deter sites from offering CY200 or CY201 and reduce the number of patients who can be treated and may make the economics of delivering CY200 or CY201 unattractive to providers, notwithstanding that CY200 and CY201 are being developed as intermittently dosed therapies administered in supervised sessions, with the CY200 Phase 2 design contemplating two doses, administered on Day 1 and Day 22.

Coverage and adequate reimbursement for CY200 or CY201 may not be available, and the limited evidence base for psilocybin in chronic pain may make it difficult to demonstrate value to payors.

The successful commercialization of CY200 or CY201 will depend in part on the extent to which governmental authorities and private health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs, and no uniform policy for coverage and reimbursement of drug therapies exists among third-party payors in the United States, so coverage and reimbursement can differ significantly from payor to payor. Obtaining and maintaining reimbursement status is time-consuming and costly. Governmental payors, health maintenance organizations, managed care organizations, pharmacy benefit managers and other third-party payors are increasingly attempting to manage healthcare expenditures by limiting both coverage and the level of reimbursement of new drugs, and they may not cover or provide adequate reimbursement for CY200 or CY201. If CY200 or CY201 requires supervised, session-based administration, reimbursement may be particularly difficult to secure because payment would need to cover not only the drug product but also the site, personnel and monitoring time associated with administration, and existing billing codes and payment methodologies may not accommodate that model. In addition, research regarding the medical benefits, viability, safety, efficacy and dosing of psychedelic compounds remains at a relatively early stage, and there have been few clinical trials of psilocybin in chronic pain indications generally or in CRPS Type 1 specifically. Future research and clinical trials may draw opposing conclusions to the articles, reports and studies on which we have relied, or may reach negative conclusions regarding the medical benefits, viability, safety, efficacy or dosing of psilocybin. In England, NHS coverage and reimbursement would generally depend on a positive technology appraisal by the National Institute for Health and Care Excellence ("NICE"), which assesses clinical effectiveness and cost-effectiveness. Without a favorable NICE recommendation, CY200 or CY201 may not be available through the NHS, and patient access in the UK could be limited to private prescriptions. Obtaining reimbursement in the UK through NICE presents particular challenges for novel psychedelic therapies given the limited clinical evidence base and the need to demonstrate cost-effectiveness compared to existing treatments. The duration of benefit following a single administration and the need for repeat dosing have not been established, and our internal commercial model assumes repeat administration over a time-limited treatment period. The available evidence on duration of effect is limited to an observed duration of effect exceeding two months in three patients in the observational studies described above, together with preclinical mouse data in which a single dose of psilocybin produced sustained reversal of allodynia. If repeat administrations are needed, treatment costs will be higher and reimbursement correspondingly more difficult to secure. Failure to obtain or maintain coverage and adequate reimbursement would limit our ability to market CY200 or CY201 and decrease our ability to generate revenue.

Public perception, stigma and adverse publicity concerning psilocybin and psychedelic therapies may generate controversy, delay approval and limit market acceptance of CY200 or CY201.

Treatments containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in the approval of, and increased expenses for, CY200 or CY201, and opponents of these treatments, which may include regulators, may seek to prevent approvals, restrict marketing or demand the withdrawal of any regulatory approvals, and may seek to generate negative publicity in an effort to persuade the medical community to reject these treatments. Adverse publicity relating to psychedelic substances may result from political or social opposition to controlled substances, from recreational misuse or abuse, or from clinical trial conduct. Adverse publicity from misuse of psychedelic substances or risky behavior associated with recreational use may adversely affect our ability to obtain regulatory approval of CY200 or CY201 and, if approved, may adversely affect its commercial success or market penetration. The psychedelic therapy market faces specific marketing challenges given the status of these substances as controlled substances, which has resulted in past and current public perception that such products have negative health and lifestyle effects and the potential to cause physical and social harm due to their psychoactive effects and concerns regarding abuse or misuse; any marketing efforts by us would need to overcome this perception to build confidence among physicians, patients and payors. In addition, certain U.S. states and local jurisdictions have legalized or decriminalized psilocybin for non-medical use, which could create public confusion about the distinction between our FDA-regulated product candidates and unregulated psilocybin products, and could expose patients to uncontrolled products that may differ materially in purity, potency and safety from CY200 or CY201. Even if CY200 or CY201 is approved, physicians, patients, payors or the medical community may be unwilling to accept, use or recommend it, and we may face limited adoption if third-party treatment sites, healthcare professionals or patients are unwilling to try a novel treatment derived from a controversial substance. Efforts to educate the medical community, third-party payors and health technology assessment bodies on the benefits of CY200 or CY201 may require significant resources and may never be successful.

Competition from other psychedelic and pain-development programs, limited patent protection for psilocybin itself and alternative treatment models could reduce the commercial potential of CY200/CY201.

We operate our CY200 and CY201 programs in a relatively new industry and market. In addition to general business risks, we must build awareness in this industry and market through significant investment in strategy, operational capacity, quality assurance and regulatory compliance, and there is no assurance that the industry and market will continue to exist or grow as currently estimated or anticipated. Because the psychedelic therapy industry is at a nascent stage with uncertain boundaries, there is a lack of

information about comparable companies available for investors to analyze, and few, if any, established companies whose business model we can follow. Any event or circumstance that adversely affects the psychedelic therapy industry generally could have a material adverse effect on us. The pharmaceutical and psychedelic industries are also intensely competitive and subject to rapid and significant technological change. Our competitors include large, well-established pharmaceutical companies, biotechnology companies, universities and other research institutions, many of which have substantially greater financial, technical and human resources than we do and significantly greater experience in conducting preclinical testing and clinical trials, scaling up manufacturing operations and obtaining regulatory approvals. Companies specifically pursuing the development of psilocybin and other tryptamines principally for psychiatric and mental health indications rather than for chronic pain include a number of public and private companies. There are currently no therapies approved by the FDA, and no licensed pharmacotherapies available in the United States, for the treatment of CRPS. Ambros Therapeutics is conducting a Phase 3 trial of neridronate, a bisphosphonate, in CRPS Type 1, within four months of onset (whereas CY200 and CY201 are being developed for established CRPS more than 12 months after onset); the closest commercial analogues are products approved for other indications, such as Spravato (esketamine) for major depressive disorder and Epidiolex (cannabidiol) for orphan epilepsy conditions. Because psilocybin is a naturally occurring substance, composition-of-matter patent protection for psilocybin itself may be unavailable or limited, and our competitive position may depend more heavily on patents covering formulations, methods of use, dosing, manufacturing or other aspects of our CY200 and CY201 programs. Our intellectual property position for CY200 and CY201 currently rests on pending patent applications: applications in the United States, Australia, Canada and Europe with claims directed to methods of using CY200, and a U.S. provisional patent application directed to pharmaceutical compositions of CY201. No patent has yet issued on these applications and no enforceable claim scope has been established. We have also received U.S. FDA Orphan Drug Designation for psilocybin for the treatment of CRPS, which could give rise to orphan-drug exclusivity upon approval for the orphan-designated indication. Our ability to protect our CY200 and CY201 programs therefore depends substantially on the eventual claim scope of these applications, the jurisdictions in which protection is obtained and the expiration dates of any resulting patents.

We face product liability risk arising from the administration of CY200 or CY201 in clinical trials and, if approved, in commercial treatment sessions.

We face an inherent risk of product liability and professional indemnity exposure related to the testing of CY200 or CY201 in human clinical trials, and we would face an even greater risk if we commercially market CY200 or CY201. Claims may be brought by patients or healthy volunteers who receive CY200 or CY201 in clinical trials and, if regulatory approval is obtained, by patients who receive it under prescription, as well as by healthcare providers, pharmaceutical companies, our collaborators or other third parties. If CY200 or CY201 is administered in a supervised session and produces significant psychoactive effects, claims may arise not only from the pharmacological effects of the product candidate but also from the conduct of the session itself, including allegations of inadequate monitoring, psychological harm or misconduct by healthcare professionals during administration. The failure of our CMOs to operate in compliance with cGMP or other applicable quality-related regulations could also result in product liability claims in the event such failure results in defective product that causes injury or harm. Any claims against us, regardless of their merit, could be difficult and costly to defend, could result in substantial liabilities and could materially adversely affect the market for CY200 or CY201 or any prospects for its commercialization. Our insurance coverage may be insufficient to cover any such claims, and we may be unable to obtain or maintain adequate insurance on acceptable terms.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Cy Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cy Biopharma, Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, comprehensive income (loss), shareholders' deficit, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has experienced operating losses and negative cash flows from operations since inception and has an accumulated deficit at December 31, 2025. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EISNERAMPER LLP

We have served as the Company's auditor since 2025.

EISNERAMPER LLP
Iselin, New Jersey
May 13, 2026

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CY BIOPHARMA GROUP
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Assets		
Current assets:		
Cash	\$ 638,591	\$ 500,080
Prepaid expenses and other current assets	89,435	14,127
Total current assets	<u>728,026</u>	<u>514,207</u>
Total assets	<u><u>\$ 728,026</u></u>	<u><u>\$ 514,207</u></u>
Liabilities, mezzanine equity and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 213,657	\$ 27,047

Accrued expenses	819,032	203,807
Other current liabilities	3,869	16,310
Total current liabilities	1,036,558	247,164
Convertible loan notes	1,100,000	800,000
SAFE liabilities	1,084,771	430,257
Total liabilities	\$ 3,221,329	\$ 1,477,421
Commitments and contingencies (Note 12)		

Mezzanine equity

Series seed 1 convertible preferred stock, \$0.00001 par value; 452,625 shares authorized as of December 31, 2025 and 2024; 452,625 shares issued and outstanding as of December 31, 2025 and 2024; liquidation preference of \$600,000 as of December 31, 2025 and 2024

600,000 600,000

Series seed 2 convertible preferred stock, \$0.00001 par value; 1,941,582 shares authorized as of December 31, 2025 and 2024; 1,941,582 shares issued and outstanding as of December 31, 2025 and 2024; liquidation preference of \$1,150,000 as of December 31, 2025 and 2024

1,042,515 1,042,515

Total mezzanine equity

1,642,515 1,642,515

Shareholders' deficit

Common shares, par value \$0.00001; 10,870,697 shares authorized as of December 31, 2025 and 2024; 6,500,000 issued and outstanding as of December 31, 2025 and 2024.

65 65

Accumulated deficit

(3,922,982) (2,457,288)

Accumulated other comprehensive loss

(212,901) (148,506)

Total shareholders' deficit

(4,135,818) (2,605,729)

Total liabilities, mezzanine equity and shareholders' deficit

\$ 728,026 \$ 514,207

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

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CY BIOPHARMA GROUP CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2025	2024
Operating expenses:	\$	\$
Research and development	(473,380)	(732,743)
General and administrative	(1,075,268)	(161,363)
Loss from operations	(1,548,648)	(894,106)
Other income/(expenses):		
Change in fair value of SAFE Liabilities	95,486	(40,257)
Interest income	7	—
Interest expense	(54,228)	(18,550)
Foreign currency transaction gain/(loss), net	41,689	(78,608)
Net loss before income tax	\$ (1,465,694)	\$ (1,031,521)
Income tax expense	—	(4,807)
Net loss	\$ (1,465,694)	\$ (1,036,328)
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	(64,395)	68,885
Total comprehensive loss, net of tax	\$ (1,530,089)	\$ (967,443)

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

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CY BIOPHARMA GROUP CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT

	Mezzanine equity				Common shares		Accumulated other comprehensive (loss)/income	Accumulated deficit	Total shareholders' deficit
	Series seed 1 convertible preferred stock		Series seed 2 convertible preferred stock						
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, January 1, 2024	—	—	—	—	6,500,000	\$ 65	\$ (217,391)	\$ (1,420,960)	\$ (1,638,286)
Net loss	—	—	—	—	—	—	—	(1,036,328)	(1,036,328)
Foreign currency translation adjustments	—	—	—	—	—	—	68,885	—	68,885
Conversion of convertible SAFEs	452,625	600,000	1,941,582	1,042,515	—	—	—	—	—
Balance, December 31, 2024	452,625	\$ 600,000	1,941,582	\$ 1,042,515	6,500,000	\$ 65	\$ (148,506)	\$ (2,457,288)	\$ (2,605,729)
Net loss	—	—	—	—	—	—	—	(1,465,694)	(1,465,694)
Foreign currency translation adjustments	—	—	—	—	—	—	(64,395)	—	(64,395)
Balance, December 31, 2025	452,625	\$ 600,000	1,941,582	\$ 1,042,515	6,500,000	\$ 65	\$ (212,901)	\$ (3,922,982)	\$ (4,135,818)

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

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CY BIOPHARMA GROUP
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (1,465,694)	\$ (1,036,328)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of SAFE liabilities	(95,486)	40,257
Net foreign currency transaction (gains) / losses	(45,546)	46,455
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(88,652)	48
Accounts payable and accrued expenses	782,925	(48,078)
Net cash used in operating activities	(912,453)	(997,646)
Cash flows from investing activities		
Related party loans (Ireland)	—	(9,556)
Net cash used in investing activities	—	(9,556)
Cash flows from financing activities		
Issuance of SAFE Notes	750,000	390,000
Issuance of Convertible loan notes	300,000	800,000
Net cash provided by financing activities	1,050,000	1,190,000
Increase in cash	139,247	182,800
Effect of exchange rate changes	(736)	8,874
Cash at beginning of year	500,080	308,406
Cash at end of year	\$ 638,591	\$ 500,080
Supplemental non-cash investing and financing activities:		
Conversion of SAFE liabilities into Series Seed convertible preferred stock	\$ —	\$ 1,642,515

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

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CY BIOPHARMA GROUP
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of business

Cy Biopharma Group (the “Company” or “Cy”) is a biopharmaceutical company focused on the development of treatments for chronic pain. The Company operates through a group structure that includes wholly owned subsidiaries in the United States, Switzerland, the United Kingdom, and Ireland.

Cy Biopharma AG, based in Switzerland, is a 100% owned subsidiary of the parent company and serves as a key operating entity within the Group. Cy Biopharma Limited, incorporated in the United Kingdom, is a 100% owned subsidiary of Cy Biopharma AG and supports the Group’s research, development, and operational activities in the UK.

Effective January 1, 2025, the Group expanded its presence in Europe through the addition of Cy Biopharma Limited, an entity incorporated in 2024 based in Ireland, which is 100% owned by the parent company. This subsidiary provides additional operational, regulatory, and development support to the Group’s activities across the EU.

For the purposes of these financial statements, the Company refers to the Group and does not represent a separate legal entity. The Group’s parent company is incorporated and domiciled in the United States (the “U.S.”) and registered in Delaware, and the Group operates through this parent entity and its subsidiaries.

2. Basis of presentation and summary of significant accounting policies

Basis of presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position, results of operations and cash flows for the periods presented.

The consolidated financial statements are presented in U.S. dollars, which is the reporting and functional currency of the Company.

The consolidated financial information comprises the financial statements of Cy Biopharma Group and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated on consolidation.

Going concern

The Company has prepared its financial statements on the basis that it will continue as a going concern. In accordance with the Financial Accounting Standards Board (“FASB”), Accounting Standards Update (“ASU”) 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern.

The Company has incurred losses from inception and anticipates that it will continue to incur losses for the foreseeable future, and had an accumulated deficit of \$3,922,982, and a working capital deficit of \$308,532 as of December 31, 2025. The Company has funded these losses through a combination of private equity and debt financings, and it expects it will continue to do so until such time as it can generate significant revenue from product sales, or other commercial revenues, if ever, or through licensing and/or collaboration agreements for its chronic pain product candidates.

On February 11, 2026, the Company entered into an Advance Subscription Agreement with an investor under which the investor committed to provide \$950,000 of advance subscription funds, of which \$950,000 has been received through the date the financial statements were available to be issued. See Note 14.

The Company has the ability to obtain additional funding through equity and debt financings, however, the Company may not be able to raise capital on terms acceptable to the Company. Without additional funds, it may be forced to delay, scale back or eliminate some of its operations. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting periods.

The most significant estimates in the Company's consolidated financial statements relate to research and development costs and clinical trial accruals, as well as the fair value measurement of SAFE liabilities.

Management does not consider other estimates used in the preparation of the consolidated financial statements to be critical, as they do not involve a significant degree of judgment, subjectivity, or estimation uncertainty.

Concentration of credit risk and significant counterparties

The Company is dependent on a number of third parties for the delivery of its programs and, where required, pays upfront deposits and fees in advance of the delivery of services. The Company considers all of its material counterparties to be creditworthy and the credit risk for each of its major counterparties to be low, but continues to assess credit risk as part of its management of these third-party relationships.

The Company maintains cash accounts with various financial institutions in the United States. At times, these balances may be in excess of the Federal Deposit Insurance Corporation ("FDIC") limit. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk in these accounts. The Company also maintains cash balances at banking institutions outside the United States, mainly in Switzerland and the United Kingdom, which is not protected by FDIC insurance. These cash balances outside the United States are approximately \$17,529 and \$500,080 at December 31, 2025 and 2024, respectively. The Company does not believe that these cash balances are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Our strategic plan does not require the repatriation of foreign cash in order to fund our operations in the U.S., and it is our current intention to indefinitely reinvest our foreign cash outside of the U.S. If we were to repatriate foreign cash to the U.S., we would be required to accrue and pay U.S. taxes in accordance with applicable U.S. tax rules and regulations as a result of the repatriation.

Research and development ("R&D") expenses

Research and development costs are expensed as incurred on an accruals basis and expensed when incurred as there is no alternative future use. These expenses are comprised of the costs of the Company's proprietary research and development efforts, including preclinical studies, clinical trials, product costs, contract services including external research and development expenses incurred under arrangements with third parties such as Contract Research Organizations ("CRO") and other related expenses. Research and development costs that are paid in advance of performance are recorded as a prepaid expense and expensed over the service period as the services are provided. Accruals and prepayments for research and development expenses typically include fees and costs to be paid to CROs in relation to clinical trials. These accruals and prepayments are calculated each period based on regular review and challenge by the management to determine their completeness and accuracy.

Income taxes

The Company accounts for income taxes under 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. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If determined that the Company would be able to realize its deferred tax assets in the future in excess of net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process in which (1) determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

Foreign currencies

The Company's reporting currency is the U.S. dollar. The functional currencies of its foreign subsidiaries are pound sterling, euro, and Swiss franc. Foreign currency translation adjustments arising from the consolidation of foreign subsidiaries are excluded from net loss and recorded as a component of other comprehensive income within shareholders' equity. Assets and liabilities of the Company's subsidiaries, whose functional currency is the local currency, are translated at the prevailing rate at the balance sheets date, and revenues and expenses are translated at the average exchange rates prevailing during the period. Gains and losses on transactions denominated in foreign currencies other than the local functional currency are recognized in other expense as incurred. Translation gains or losses are reported as accumulated other comprehensive loss within shareholders' deficit. The Company recognizes transaction gains and losses arising from intercompany transactions as a component of income (expense) in the accompanying consolidated statements of operations. During the years ended December 31, 2025 and 2024, the amount of transaction (loss) /gain was approximately \$41,689 and \$(78,608), respectively, and is recognized in the caption other income / (expenses) in the accompanying consolidated statements of operations.

Financial instruments

The Company's financial instruments consist of cash, accounts payable, certain accrued expenses, Simple Agreements for Future Equity ("SAFEs") liabilities and the liability components of convertible loan notes. Cash, accounts payable and accrued expenses are initially recorded and subsequently measured at cost, which is considered to approximate their fair value due to the short-term nature of such financial instruments. The carrying value of SAFE liabilities and convertible loan notes is further discussed in the sections below.

Convertible loan notes

The convertible promissory loan notes provide the holder with the right to convert outstanding principal and accrued interest into equity of the Company upon the occurrence of certain specified conversion events.

The Company evaluates all embedded features within the notes to determine whether they are required to be bifurcated as derivative instruments or qualify for the scope exception for contracts indexed to, and settled in, the Company's own equity. Any embedded conversion features that meet equity classification requirements are recorded in additional paid-in capital at inception. Where embedded features do not meet equity classification criteria, they are separately accounted for as derivative liabilities and measured at fair value with subsequent changes recognized in earnings. There were no embedded conversion features that required bifurcation as derivative instruments as of December 31, 2025 and 2024.

The debt instrument is recorded at amortized cost and accreted to its principal amount over the term of the notes using the effective interest method. The Company also evaluates modifications to the terms of convertible promissory notes to determine whether they should be accounted for as extinguishments or modifications. There were no modifications to be accounted for as of December 31, 2025 and 2024.

SAFE liabilities

The Company issued SAFEs as part of its financing activities during the period. The SAFEs do not meet the definition of equity as they require the Company to deliver a variable number of equity instruments upon the occurrence of certain future events. As such, the SAFE instruments are classified as liabilities. The SAFE agreements do not contain any redemption features that are within the control of the holder. Settlement events under the SAFEs are limited to the occurrence of a Qualified Financing, a Liquidity Event, or a Dissolution Event, none of which can be unilaterally triggered by the SAFE holder.

The SAFE liabilities are recorded at fair value, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss as a component of net loss. The SAFEs do not have a quoted market price and include company-specific terms such as conversion discounts, valuation caps, and assumptions regarding the probability and timing of future financing events. Their fair value is determined using valuation techniques that incorporate significant unobservable inputs. Accordingly, the SAFE liabilities are classified within Level 3 of the fair value hierarchy.

The SAFE liabilities are remeasured at each reporting date, and are derecognized when the instruments are ultimately settled, typically through conversion into equity upon a qualifying financing or other specified event.

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Fair value measurement

The Company follows the guidance for Fair Value Measurements and Disclosures which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value.

The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — quoted (unadjusted) market prices in active markets for identical assets or liabilities.
- Level 2 — valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.
- Level 3 — valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the consolidated financial statements on a recurring basis, the Company determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period. There were no transfers within the fair value hierarchy during the years ended December 31, 2025 and 2024.

Convertible preferred shares

Convertible preferred shares issued upon conversion of the SAFE liabilities is recorded within mezzanine equity at its par value, with any excess of the fair value of the equity instruments issued over par value recognized in additional paid-in capital. Immediately prior to conversion, the SAFE liabilities were remeasured to fair value with any resulting gain or loss recognized in the consolidated statements of operations and comprehensive loss. The carrying amount of the SAFE liabilities at the conversion date was then reclassified to equity in connection with the issuance of convertible preferred shares.

Convertible preferred shares issued upon conversion of the SAFE liabilities are classified as mezzanine equity because certain terms provide the holders with rights or preferences, that could require the Company to transfer cash or other assets, or that are not solely within the Company's control. As such, convertible preferred shares do not meet the criteria for permanent equity.

Comprehensive income/(loss)

Comprehensive income/(loss) includes net income/(loss) as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders. The Company records unrealized gains and losses related to foreign currency translation as a component of other comprehensive loss in the consolidated statements of operations and comprehensive loss.

Common shares

Common shares are classified in shareholders' equity and represent issued share capital.

Additional paid-in capital

Additional paid-in capital is classified in shareholders' equity and includes the difference between the price paid per share and the nominal value.

Incremental costs incurred and directly attributable to the offering of equity securities are deducted from the related proceeds of the offering. The net amount is recorded as additional paid-in capital in the period when such shares are issued. Where such expenses are incurred prior to the offering, they are recorded in prepayments until the offering completes. Other costs incurred in such offerings are expensed as incurred and included in general and administrative expenses.

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Recently adopted accounting pronouncements

The Company considers the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or expected to have minimal impact on the consolidated financial statements.

Recently issued accounting pronouncements not yet adopted

ASU 2023-09 — Income Taxes (Topic 740): Improvements to Income Tax Disclosures

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures (“ASU 2023-09”), which is intended to enhance the transparency of income tax matters within financial statements, providing stakeholders with a clearer understanding of tax positions and their associated risks and uncertainties. ASU 2023-09 requires all entities subject to income taxes to disclose, on an annual basis, specific categories in the rate reconciliation and provide additional information for reconciling items that meet a specific quantitative threshold. ASU 2023-09 is effective for fiscal years beginning after December 15, 2025. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements and disclosures.

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2025	December 31, 2024
Prepaid research and development services	89,266	—
Security deposits	—	2,546
Other prepaid expenses and current assets	169	11,581
Total	<u>\$ 89,435</u>	<u>\$ 14,127</u>

Prepaid research and development services typically relate to CRO and clinical trial arrangements and are updated each period based on management’s review to ensure completeness and accuracy.

As of December 31, 2025 and 2024, the Company did not have any material operating or finance leases in relation to the security deposits. Accordingly, no right-of-use assets or lease liabilities were recorded on the consolidated balance sheet as of year-end.

5. Other current liabilities

Other current liabilities consist of the following:

	December 31, 2025	December 31, 2024
Tax payable	\$ 2,447	\$ 4,996
Other current liabilities	1,422	11,314
Total	<u>\$ 3,869</u>	<u>\$ 16,310</u>

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6. Accrued expenses

Accrued expenses consist of the following:

	December 31, 2025	December 31, 2024
Accrued professional fees/litigation	\$ 746,301	\$ 184,758
Accrued interest	72,274	18,296
Other interest expense	457	753
Total	<u>\$ 819,032</u>	<u>\$ 203,807</u>

Accrued expenses primarily consist of litigation-related accruals and professional fees. Refer to Note 12 for more details on the litigation-related accruals.

The remaining balance within accrued expenses relates to professional fees, including audit fees and consultancy fees for external professional services.

7. Fair value measurement

The following table summarizes the Company’s financial liabilities measured at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above:

	As of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Financial liabilities				
SAFE liabilities	\$ 1,084,771	—	—	\$ 1,084,771
	As of December 31, 2024			
	Total	Level 1	Level 2	Level 3
Financial liabilities				
SAFE liabilities	\$ 430,257	—	—	\$ 430,257

The SAFE liabilities are classified within Level 3 of the fair value hierarchy because they are not traded in active markets and their valuation requires the use of significant unobservable inputs, including the probability and timing of future financing, liquidity and dissolution scenarios, market-participant discount rates, credit spreads, guideline public company volatility and equity value assumptions.

There were no transfers between levels of the fair value hierarchy during the years ended December 31, 2025 and 2024.

8. Convertible loan notes

Throughout 2024 and 2025, the Company issued a series of convertible promissory loan notes (the “Loan Notes”), with an aggregate principal amount of \$1,100,000. The notes were issued in accordance with the terms and conditions set out in the financing agreement and represent unsecured obligations of the Company.

The Loan Notes accrue simple interest at 4% per annum on the outstanding principal from the effective date until the notes are repaid or converted. The Loan Notes are not convertible at the discretion of the holder, and there is no fixed conversion price or fixed number of common shares into which the notes may convert. Instead, the number of shares potentially issuable will be determined at the time of conversion based on the contractual conversion mechanics applicable to future financing events or maturity, calculated using a valuation-cap-based conversion price and the Company’s fully diluted capitalization at the applicable date.

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Unless earlier converted, all unpaid principal, accrued but unpaid interest, and any other amounts payable under the Loan Note become due and payable upon the earliest of:

- (i) ninety (90) days following a demand by the holder, which demand may not be made earlier than thirty-six (36) months from the effective date (the “Final Maturity Date”);
- (ii) the occurrence of a Change of Control; or
- (iii) the occurrence of an Event of Default, each as defined in the agreement.

As none of the embedded features required separate recognition, the Loan Notes were initially recorded at their stated principal amount. Subsequently, the debt is measured at amortized cost, with interest accreted to maturity using the effective interest method.

The conversion price and the number of shares to be issued upon conversion are not fixed and may change based on future events, including the timing and terms of a Qualified Financing (an equity financing meeting minimum proceeds specified in the SAFE), the Company’s fully diluted capitalization at the conversion date, and any Company election to issue a new series of preferred stock. These terms may result in different conversion prices or share quantities at the date of conversion. The variability in these terms becomes effective only upon a Qualified Financing or the Final Maturity Date, as applicable.

The Company’s convertible loan notes mature 90 days after a repayment demand, which cannot be made earlier than 36 months from the July 29, 2024 effective date. Accordingly, the notes are scheduled to mature in 2027 unless earlier converted. There are no sinking-fund requirements associated with these notes.

The carrying amount of the convertible debt instrument consists of the following:

	December 31, 2025	December 31, 2024
Principal amount	\$ 1,100,000	\$ 800,000
Accrued interest	72,274	18,296
Total	\$ 1,172,274	\$ 818,296

The Company recognized interest expense of \$53,978 and \$18,296 in relation to the Loan Notes in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and December 31, 2024 respectively.

9. SAFE liabilities

The Company has issued various SAFEs as part of its financing activities. These instruments comprise three principal cohorts outstanding during the periods presented:

- (i) an earlier 2021 and 2022 SAFE cohort comprised SAFEs issued to third-party investors for total funding of \$1.15 million, with standard Y Combinator post-money valuation cap terms, including no discount, a \$5.0 million valuation cap, automatic conversion in an equity financing, liquidity protection based on the greater of the cash-out amount or conversion amount, and only minimal recovery in a dissolution scenario.
- (ii) a 2024 SAFE cohort comprised multiple arm’s-length issuances to third-party investors, including five individuals and Token Ventures Ltd., with total funding of \$390,000 and standard Y Combinator SAFE terms covering equity financing, liquidity events and dissolution.
- (iii) a 2025 SAFE provided \$750,000 of funding with a \$50.0 million post-money valuation cap and, because it was issued to an existing shareholder, was not an arm’s-length transaction.

The SAFE liabilities are measured at fair value on a recurring basis, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss as a component of net loss. The SAFE liabilities are derecognized upon settlement, generally through conversion into equity securities in connection with equity financing or another specified event.

Settlement of the SAFEs is determined by the contractual trigger events (equity financing, liquidity event, or dissolution); the Company does not control the settlement outcome. The SAFEs will settle for a variable number of shares. Changes in the Company’s equity value directly affect both (i) the fair value of the liabilities and (ii) the expected number of shares issuable upon conversion. The contracts do not impose any maximum limit on either the potential cash settlement amount or the number of shares that could be issued.

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The 2021 and 2022 cohort of Simple Agreements for Future Equity (“SAFES”) converted into convertible preferred shares on August 23, 2024. The SAFE cohorts issued in 2025 and 2024 remained outstanding for the years ended December 31, 2025 and 2024.

The following table presents a reconciliation of the beginning and ending balances of the SAFE liabilities:

	SAFE liabilities	
	December 31, 2025	December 31, 2024
Balance at beginning of year	\$ 430,257	\$ 1,042,515
Issuances	750,000	390,000
Conversions	—	(1,042,515)
Change in fair value	(95,486)	40,257
Balance at end of year	\$ 1,084,771	\$ 430,257

The table below presents the fair value of the SAFE liabilities, disaggregated by cohort:

	December 31,	December 31,
	2025	2024
2024 SAFE	\$ 421,630	\$ 430,257
2025 SAFE	663,141	—
Total	\$ 1,084,771	\$ 430,257

The SAFE liabilities were valued using a scenario-weighted model that considered equity financing, liquidity, and dissolution outcomes.

Significant unobservable inputs included the Company's equity value, the expected timing and probability of future events, discount rates, a CCC-equivalent credit spread, volatility, and the specific contractual terms of each SAFE cohort, including valuation caps, discount features, liquidity protections, and conversion mechanics. Because the fair value measurement relies on significant unobservable inputs, it is inherently subjective and could change materially in future periods as those assumptions change.

10. Shareholders' Equity

As of December 31, 2025, the Company is authorized to issue 13,264,904 shares, consisting of 10,870,697 shares of Common Shares and 2,394,207 shares of convertible preferred shares (including 452,625 Series Seed-1 Convertible preferred and 1,941,582 Series Seed-2 Convertible preferred shares).

Common Shares

Holders of Common Shares are entitled to one vote per share, with no cumulative voting. Their rights are subordinated to the rights and preferences of Convertible preferred Shares.

Convertible preferred Shares

On a liquidation, dissolution, winding up, or Deemed Liquidation Event, before any distribution to Common Shareholders, preferred shareholders receive the greater of (i) the Original Issue Price plus unpaid declared dividends, or (ii) the amount payable assuming conversion into Common Shares immediately prior to the event. If insufficient assets exist, Convertible preferred holders share ratably.

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The Convertible preferred Shares are not callable and not subject to any sinking-fund or similar mandatory redemption provisions, and therefore there is no aggregate or per-share amount at which the Convertible preferred Shares may be redeemed.

Convertible preferred holders are entitled to receive any declared but unpaid dividends before Common Shareholders. The shares are convertible into Common Shares at the holder's option at the stated conversion rate, with conversion resulting in share settlement. The number of Common Shares issuable varies based on the conversion formula within the underlying agreement.

Reserves

Shares are reserved for Convertible preferred Share conversion, equity incentive plans, and other convertible instruments. The Company did not grant any equity awards and did not recognize any stock-based compensation expense during the years ended December 31, 2025 or 2024.

11. Income taxes

Income (loss) before provision for income taxes consisted of the following:

	Year Ended December 31,	Year Ended December 31,
	2025	2024
Domestic	\$ (1,251,117)	\$ (1,076,816)
Foreign	(214,577)	45,295
Loss before provision for income taxes	\$ (1,465,694)	\$ (1,031,521)

The components of the provision for income taxes is as follows:

	Year Ended December 31,	Year Ended December 31,
	2025	2024
Current expense (benefit):	\$ —	\$ —
Federal	—	—
State	—	—
Foreign	—	4,807
Total current expense (benefit):	—	4,807
Deferred expense (benefit):	—	—
Federal	—	—
State	—	—
Foreign	—	—
Total deferred expense (benefit):	—	—
Total income tax expense (benefit):	\$ —	\$ 4,807

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	Year Ended December 31,
	2025	2024
Income at US statutory rate	21.00%	21.00%
State taxes, net of federal benefit	1.42%	1.87%
Permanent differences	0.45%	(2.26)%
Tax law change	(0.81)%	0.00%

Foreign rate differential	(1.56)%	0.52%
Change in valuation allowance	(20.50)%	(21.60)%
Other	0.00%	0.00%
	(0.00)%	(0.47)%

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The net deferred tax asset balance related to the following:

	Year Ended December 31,	
	2025	2024
Capitalized R&D expenses	\$ 362,086	\$ 279,903
Accruals & reserves	(3,777)	2,500
Net operating loss carryforwards	322,596	94,076
Total deferred tax assets	\$ 680,905	\$ 376,479
Valuation allowance	(680,905)	(376,479)
Net deferred tax assets (liability)	\$ —	\$ —

As of December 31, 2025 and 2024, the Company had a federal net operating loss carryforward of \$1.3 million and \$0.4 million, respectively, which may be carried forward indefinitely. As of December 31, 2025 and 2024, the Company has state net operating loss (“NOL”) carryforwards of \$1.1 million and \$0.2 million, respectively. The state net operating loss carryforwards begin to expire in 2039. As of December 31, 2025 and 2024, the Company has foreign NOL carryforwards of \$0.2 million and \$0 million, respectively. The Company’s UK net operating loss carryforwards have an indefinite carryforward period. The Company’s Swiss net operating loss carryforwards begin to expire in 2032.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025 and 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2025 and 2024. The Company increased its valuation allowance by \$0.3 million as of December 31, 2025.

Under Internal Revenue Code Section 382, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has not completed a study to assess whether an “ownership change” has occurred or whether there have been multiple ownership changes since the Company became a “loss corporation” as defined in Section 382. Future changes in the share ownership, which may be outside of the Company’s control, may trigger an “ownership change.” In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an “ownership change.” If an “ownership change” has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to us.

For tax years beginning after December 31, 2024, One Big Beautiful Bill Act of 2025 (“OBGBA”) enacted a new rule under Section 174A allowing companies to immediately expense any domestic research and developmental (“R&D”) expenditures. For domestic R&D, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A. However, foreign R&D continues to require capitalization subject to the mandatory 15-year amortization period under Section 174.

The Company has elected to continue amortizing the previously capitalized costs over their remaining life and will immediately expense any domestic R&D expenditures. Any foreign R&D costs will continue to be capitalized and amortized over 15 years in accordance with the requirements of Section 174.

The calculation of the Company’s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which the Company operates or does business in. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

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The Company records uncertain tax positions as liabilities and adjust these liabilities when the judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2025 and 2024 the Company has not recorded any uncertain tax positions in the financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits as income tax expense in the accompanying consolidated statement of operations. The Company has no uncertain tax positions as of December 31, 2025 and 2024.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company’s tax years are still open under statute from December 31, 2022, to the present.

The Company is subject to the global intangible low-taxed income (“GILTI”) provisions under Section 951A of the Internal Revenue Code. The Company has elected to account for the tax effects of GILTI as a period cost in the year the tax is incurred, and accordingly, no deferred taxes have been recognized related to GILTI.

The Company asserts that the undistributed earnings of its foreign subsidiaries are indefinitely reinvested outside of the United States. As a result, no deferred tax liability has been recorded for U.S. federal and state income taxes, or applicable foreign withholding taxes, that would be due upon repatriation of those earnings.

12. Commitments and contingencies

Legal proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. As of December 31, 2025 and 2024, the Company was involved in certain legal matters for which accruals have been recorded as described below and in Note 6.

The Company was involved in a legal matter with its former Chief Executive Officer, which was settled after December 31, 2025. In connection with this matter, the Company has recorded an accrual of \$75,000 for the year ended December 31, 2025.

The Company was also involved in a legal matter relating to the former Chief Executive Officer of its Swiss subsidiary. The claim was raised during the year ended

December 31, 2025 and was settled after year end for 220,000 Swiss Francs. In connection with this matter, the Company has recorded an accrual of \$371,724 for the year ended December 31, 2025 and \$161,265 for the year ended December 31, 2024.

13. Related party transactions

The Company considers its directors, executive officers, significant shareholders, and entities controlled or influenced by such parties to be related parties. The Company also evaluates transactions with entities in which its directors or officers serve in key management roles.

Skye Biopharma SAS/Estudio Podesta

During the years ended December 31, 2025 and 2024, the Company entered into transactions with a third party service provider, Estudio Podestá, a legal services firm in Uruguay that provided research related activities on the procurement of regulatory licenses associated with the production of psilocybin-based products. Skye Biopharma SAS was an entity used within these research activities and is an entity under common director ownership and therefore considered a related party. These expenditures represent related party transactions, as the activities performed by the third-party service provider, using Skye Biopharma SAS, provided research for the Group.

Total payments to Estudio Podestá amounted to \$25,000 in 2025 and \$14,120 in 2024. These amounts were recognized as operating expenses in the consolidated statement of operations and comprehensive loss. No amounts were due to or from Skye Biopharma SAS or the third party service provider as of December 31, 2025 or 2024.

Cy Biopharma (Ireland) Limited

During 2024, the Company entered into related party transactions with Cy Biopharma (Ireland) Limited. This entity became part of the Group on January 1, 2025 and therefore is not considered a related party as of the reporting date, December 31, 2025. Total transactions with this entity during 2024 amounted to \$9,556. Effective January 1, 2025, the Group acquired 100% of the issued share capital of Cy Biopharma (Ireland) Limited, an entity incorporated in 2024 with nominal share capital of EUR 100. The acquisition was completed through the purchase of all shares from the previous director. No cash consideration had been transferred as of the acquisition date. The acquired entity had no operations, no assets other than nominal equity, and no liabilities other than amounts due to the Group for professional setup costs incurred in 2024. As the acquired company did not constitute a business, the transaction has been accounted for as an asset acquisition at book value, with no goodwill recognized.

Director-related transactions

During the year ended December 31, 2025, the Company made payments totaling \$6,585 to a director. No such payments were made during the year ended December 31, 2024.

14. Subsequent events

The Company evaluated subsequent events from the balance sheet date through to the date on which the consolidated financial statements were issued. As denoted in Note 2, on February 11, 2026, the Company entered into an Advance Subscription Agreement with an investor under which the investor committed to provide \$950,000 of advance subscription funds, of which \$950,000 has been received through the date the financial statements were available to be issued. The purpose of the funding is to support the Company's ongoing working capital requirements and transaction-related activities.

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CY BIOPHARMA GROUP
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash	\$ 5,797,368	\$ 638,591
Prepaid expenses and other current assets	27,069	89,435
Total current assets	5,824,437	728,026
Total assets	\$ 5,824,437	\$ 728,026
Liabilities, mezzanine equity and shareholders' deficit		
Current liabilities:		
Accounts payable	\$ 2,419,780	\$ 213,657
Accrued expenses	86,270	819,032
Other current liabilities	23,050	3,869
Total current liabilities	2,529,100	1,036,558
Convertible loan notes	6,777,691	1,100,000
SAFE liabilities	1,502,695	1,084,771
Total liabilities	\$ 10,809,486	\$ 3,221,329
Commitments and contingencies (Note 11)		
Mezzanine equity		
Series seed 1 convertible preferred stock, \$0.00001 par value; 452,625 shares authorized as of June 30, 2026 and December 31, 2025; 452,625 shares issued and outstanding as of June 30, 2026 and December 31, 2025; liquidation preference of \$600,000 as of June 30, 2026 and December 31, 2025	600,000	600,000
Series seed 2 convertible preferred stock, \$0.00001 par value; 1,941,582 shares authorized as of June 30, 2026 and December 31, 2025; 1,941,582 shares issued and outstanding as of June 30, 2026 and December 31, 2025; liquidation preference of \$1,150,000 as of June 30, 2026 and December 31, 2025	1,042,515	1,042,515
Advance subscription agreement	721,993	—
Total mezzanine equity	2,364,508	1,642,515
Shareholders' deficit		
Common shares, par value \$0.00001; 10,870,697 shares authorized as of June 30, 2026 and December 31, 2025; 6,500,000 issued and outstanding as of June 30, 2026 and December 31, 2025.	65	65
Accumulated deficit	(7,156,351)	(3,922,982)
Accumulated other comprehensive loss	(193,271)	(212,901)
Total shareholders' deficit	(7,349,557)	(4,135,818)
Total liabilities, mezzanine equity and shareholders' deficit	\$ 5,824,437	\$ 728,026

See accompanying notes to unaudited condensed consolidated financial statements.

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CY BIOPHARMA GROUP
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
UNAUDITED

	Six Months Ended June 30, 2026	2025
Operating expenses:	\$	\$
Research and development	(439,310)	(199,237)
General and administrative	(2,583,207)	(190,946)
Loss from operations	(3,022,517)	(390,183)
Other income/(expenses):		
Change in fair value of SAFE Liabilities	(417,924)	50,419
Change in fair value of Advanced Subscription Agreement	228,007	-

Interest expense		(4,630)	(17,936)
Foreign currency transaction income/(loss), net		(16,305)	123,968
Net loss before income tax	\$	(3,233,369)	\$ (233,732)
Income tax expense		—	(98)
Net loss	\$	(3,233,369)	\$ (233,830)
Other comprehensive loss– Foreign currency translation adjustments, net of tax		19,630	(32,731)
Total comprehensive loss, net of tax	\$	(3,213,739)	\$ (266,561)

See accompanying notes to unaudited condensed consolidated financial statements.

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CY BIOPHARMA GROUP
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT UNAUDITED

	Mezzanine equity					Common shares		Accumulated other comprehensive (loss)/income	Accumulated deficit	Total shareholders' deficit
	Series seed 1 convertible preferred stock		Series seed 2 convertible preferred stock		Advance subscription agreement					
	Shares	Amount	Shares	Amount	Amount	Shares	Amount			
Balance, January 1, 2025	452,625	\$ 600,000	1,941,582	\$ 1,042,515	\$ —	6,500,000	\$ 65	\$ (148,506)	\$ (2,457,288)	\$ (2,605,729)
Drawdowns received	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(233,830)	(233,830)
Foreign currency translation adjustments	—	—	—	—	—	—	—	(32,731)	—	(32,731)
Change in fair value	—	—	—	—	—	—	—	—	—	—
Balance, June 30, 2025	452,625	\$ 600,000	1,941,582	\$ 1,042,515	\$ —	6,500,000	\$ 65	\$ (181,237)	\$ (2,691,118)	\$ (2,872,290)
	Mezzanine equity					Common shares		Accumulated other comprehensive (loss)/income	Accumulated deficit	Total shareholders' deficit
	Series seed 1 convertible preferred stock		Series seed 2 convertible preferred stock		Advance subscription agreement					
	Shares	Amount	Shares	Amount	Amount	Shares	Amount			
Balance, January 1, 2026	452,625	\$ 600,000	1,941,582	\$ 1,042,515	\$ —	6,500,000	\$ 65	\$ (212,901)	\$ (3,922,982)	\$ (4,135,818)
Drawdowns received	—	—	—	—	950,000	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(3,233,369)	(3,233,369)
Foreign currency translation adjustments	—	—	—	—	—	—	—	19,630	—	19,630
Change in fair value	—	—	—	—	(228,007)	—	—	—	—	—
Balance, June 30, 2026	452,625	\$ 600,000	1,941,582	\$ 1,042,515	\$ 721,993	6,500,000	\$ 65	\$ (193,271)	\$ (7,156,351)	\$ (7,349,557)

See accompanying notes to unaudited condensed consolidated financial statements.

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CY BIOPHARMA GROUP
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
UNAUDITED

	Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities		
Net loss	\$ (3,233,369)	\$ (233,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of SAFE liabilities	417,924	(50,419)
Change in fair value of Advanced Subscription Agreement	(228,007)	-
Net foreign currency transaction (gains) / losses	12,640	(93,538)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	86,915	395
Accounts payable and accrued expenses	1,472,140	(7,864)
Net cash used in operating activities	(1,471,757)	(385,256)
Cash flows from investing activities		
Net cash used in investing activities	—	—
Cash flows from financing activities		
Issuance of 2026 Loan Notes	5,677,691	—
Proceeds from advance subscription agreement	950,000	—
Net cash provided by financing activities	6,627,691	—
Increase/(decrease) in cash	5,155,934	(385,256)
Effect of exchange rate changes	2,843	(93,996)
Cash at beginning of year	638,591	500,080
Cash at end of year	\$ 5,797,368	\$ 20,828
Supplemental non-cash investing and financing activities:		
Conversion of SAFE liabilities into Series Seed convertible preferred stock	\$ —	\$ —

CY BIOPHARMA GROUP
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of business

Cy Biopharma Group (the “Company” or “Cy”) is a biopharmaceutical company focused on the development of treatments for chronic pain, operating through wholly owned subsidiaries in the United States, Switzerland, the United Kingdom, and Ireland. The Group’s parent company is incorporated and domiciled in the U.S. and registered in Delaware. For the purposes of these unaudited condensed financial statements, the Company refers to the Group and does not represent a separate legal entity.

2. Basis of presentation and summary of significant accounting policies

Basis of presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted in these interim financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for the periods presented. These interim financial statements should be read in conjunction with the Company’s audited annual financial statements and related notes for the year ended December 31, 2025, from which the accompanying balance sheet as of December 31, 2025 has been derived. As a private company, the Company has not previously filed annual reports or other periodic reports with the U.S. Securities and Exchange Commission.

In the opinion of management, these condensed consolidated financial statements include all adjustments necessary for the fair presentation of the Company’s financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

The condensed consolidated financial statements are presented in U.S. dollars, which is the reporting and functional currency of the Company.

The condensed consolidated financial information comprises the financial statements of Cy Biopharma Group and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated on consolidation.

Going concern

The Company has prepared its condensed financial statements on the basis that it will continue as a going concern. In accordance with the Financial Accounting Standards Board (“FASB”), Accounting Standards Update (“ASU”) 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern.

The Company has incurred losses from inception and anticipates that it will continue to incur losses for the foreseeable future, and had an accumulated deficit of \$7,156,351, and a working capital surplus of \$3,295,337 as of June 30, 2026. The Company has funded these losses through a combination of private equity and debt financings, and it expects it will continue to do so until such time as it can generate significant revenue from product sales, or other commercial revenues, if ever, or through licensing and/or collaboration agreements for its chronic pain product candidates.

On February 11, 2026, the Company entered into an Advance Subscription Agreement with an investor under which the investor committed to provide \$950,000 of advance subscription funds, of which \$950,000 has been received through the date the financial statements were available to be issued. See Note 9.

The Company has the ability to obtain additional funding through equity and debt financings, however, the Company may not be able to raise capital on terms acceptable to the Company. Without additional funds, it may be forced to delay, scale back or eliminate some of its operations. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of estimates

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting periods.

The most significant estimates in the Company’s consolidated financial statements relate to research and development costs and clinical trial accruals, as well as the fair value measurement of SAFE liabilities.

Management does not consider other estimates used in the preparation of the condensed consolidated financial statements to be critical, as they do not involve a significant degree of judgment, subjectivity, or estimation uncertainty.

3. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2026	December 31, 2025
Prepaid research and development services	\$ 27,069	\$ 89,266
Other prepaid expenses and current assets	—	169
Total	<u>\$ 27,069</u>	<u>\$ 89,435</u>

As of June 30, 2026 and December 31, 2025, the Company did not have any material operating or finance leases in relation to the security deposits. Accordingly, no right-of-use assets or lease liabilities were recorded on the consolidated balance sheet as of year-end.

4. Other current liabilities

Other current liabilities consist of the following:

	June 30, 2026	December 31, 2025
Tax payable	\$ 2,352	\$ 2,447
Other current liabilities	20,698	1,422
Total	<u>\$ 23,050</u>	<u>\$ 3,869</u>

5. Accrued expenses

Accrued expenses consist of the following:

	June 30, 2026	December 31, 2025
Accrued professional fees/litigation	\$ —	\$ 746,301
Accrued interest	76,909	72,274
Other interest expense	9,361	457
Total	<u>\$ 86,270</u>	<u>\$ 819,032</u>

Accrued expenses primarily consist of litigation-related accruals and professional fees. Refer to Note 11 for more details on the litigation-related accruals.

The remaining balance within accrued expenses relates to professional fees, including audit fees and consultancy fees for external professional services.

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6. Fair value measurement

The following table summarizes the Company's financial liabilities measured at fair value on a recurring basis as of June 30, 2026 and December 31, 2025:

	As of June 30, 2026			
	Total	Level 1	Level 2	Level 3
Financial liabilities				
SAFE liabilities	\$ 1,502,695	—	—	\$ 1,502,695
Instruments classified as temporary equity				
Advance Subscription Agreement	721,993	—	—	721,993
	As of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Financial liabilities				
SAFE liabilities	\$ 1,084,771	—	—	\$ 1,084,771
Instruments classified as temporary equity				
Advance Subscription Agreement	—	—	—	—

The SAFE liabilities and Advanced Subscription Agreement are classified within Level 3 of the fair value hierarchy because they are not traded in active markets and their valuation requires the use of significant unobservable inputs, including the probability and timing of future financing, liquidity and dissolution scenarios, market-participant discount rates, credit spreads, guideline public company volatility and equity value assumptions.

There were no transfers between levels of the fair value hierarchy during the six months ended June 30, 2026 and 2025.

7. Convertible loan notes

Throughout 2024 and 2025, the Company issued a series of convertible promissory loan notes (the "2024/2025 Loan Notes"), with an aggregate principal amount of \$1,100,000. During the six months ended June 30, 2026, the Company issued additional convertible loan notes (the "2026 Loan Notes", and together the "Loan Notes") with an aggregate principal amount of \$5,677,691, bringing total principal outstanding to \$6,777,691 as of June 30, 2026. The notes were issued in accordance with the terms and conditions set out in the financing agreement and represent unsecured obligations of the Company.

The Loan Notes represent unsecured obligations of the Company and accrue simple, non-compounding interest at a rate of 4% per annum from the date of issuance until repayment or conversion.

The conversion terms of the Loan Notes vary by issuance. The 2024/2025 Loan Notes contain conversion features based on valuation-cap and capitalization-based conversion mechanics. The 2026 Loan Notes are convertible upon the occurrence of specified financing and liquidity events, including a Qualified Financing, Reverse Merger Transaction, certain Change of Control transactions, or other conversion events agreed by the parties. The conversion price of the 2026 Loan Notes is determined by reference to the terms of the applicable future transaction, including the price per share established in the relevant financing or corporate transaction. As a result, the number of shares issuable upon conversion of the Loan Notes is not fixed and will be determined based on the contractual terms applicable at the date of conversion.

Unless earlier converted, all unpaid principal, accrued but unpaid interest, and any other amounts payable under the Loan Note become due and payable upon the earliest of:

- (i) ninety (90) days following a demand by the holder, which demand may not be made earlier than thirty-six (36) months from the effective date (the "Final Maturity Date");
- (ii) the occurrence of a Change of Control; or
- (iii) the occurrence of an Event of Default, each as defined in the agreement.

As none of the embedded features required separate recognition, the Loan Notes were initially recorded at their stated principal amount. Subsequently, the debt is measured at amortized cost, with interest accreted to maturity using the effective interest method.

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The conversion price and the number of shares to be issued upon conversion are not fixed and may change based on future events, including the timing and terms of a

Qualified Financing (an equity financing meeting minimum proceeds specified in the SAFE), the Company's fully diluted capitalization at the conversion date, and any Company election to issue a new series of preferred stock. These terms may result in different conversion prices or share quantities at the date of conversion. The variability in these terms becomes effective only upon a Qualified Financing or the Final Maturity Date, as applicable.

The Company's convertible loan notes mature 90 days after a repayment demand, which cannot be made earlier than 36 months from the July 29, 2024 effective date. Accordingly, the notes are scheduled to mature in 2027 unless earlier converted. There are no sinking-fund requirements associated with these notes.

The carrying amount of the convertible debt instrument consists of the following:

	June 30, 2026	December 31, 2025
Principal 2024/2025 Loan Notes	\$ 1,100,000	\$ 1,100,000
Principal – 2026 Loan Notes	5,677,691	-
Total Principal	6,777,691	1,100,000
Accrued interest	76,909	72,274
Total	\$ 6,854,600	\$ 1,172,274

The Company recognized interest expense of \$4,630 and \$17,936 in relation to the Loan Notes in the consolidated statements of operations and comprehensive loss for the six months ended June 30, 2026 and 2025, respectively.

8. SAFE liabilities

The Company has issued various SAFEs as part of its financing activities. These instruments comprise three principal cohorts outstanding during the periods presented:

- (i) an earlier 2021 and 2022 SAFE cohort comprised SAFEs issued to third-party investors for total funding of \$1.15 million, with standard Y Combinator post-money valuation cap terms, including no discount, a \$5.0 million valuation cap, automatic conversion in an equity financing, liquidity protection based on the greater of the cash-out amount or conversion amount, and only minimal recovery in a dissolution scenario.
- (ii) a 2024 SAFE cohort comprised multiple arm's-length issuances to third-party investors, including five individuals and Token Ventures Ltd., with total funding of \$390,000 and standard Y Combinator SAFE terms covering equity financing, liquidity events and dissolution.
- (iii) a 2025 SAFE provided \$750,000 of funding with a \$50.0 million post-money valuation cap and, because it was issued to an existing shareholder, was not an arm's-length transaction.

The SAFE liabilities are measured at fair value on a recurring basis, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss as a component of net loss. The SAFE liabilities are derecognized upon settlement, generally through conversion into equity securities in connection with equity financing or another specified event.

Settlement of the SAFEs is determined by the contractual trigger events (equity financing, liquidity event, or dissolution); the Company does not control the settlement outcome. The SAFEs will settle for a variable number of shares. Changes in the Company's equity value directly affect both (i) the fair value of the liabilities and (ii) the expected number of shares issuable upon conversion. The contracts do not impose any maximum limit on either the potential cash settlement amount or the number of shares that could be issued.

The 2021 and 2022 cohort of Simple Agreements for Future Equity ("SAFES") converted into convertible preferred shares on August 23, 2024. The SAFE cohorts issued in 2025 and 2024 remained outstanding for the six months ended June 30, 2025 and year ended December 31, 2024.

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The following table presents a reconciliation of the beginning and ending balances of the SAFE liabilities:

	SAFE liabilities	
	June 30, 2026	December 31, 2025
Balance at beginning of year	\$ 1,084,771	\$ 430,257
Issuances	—	750,000
Change in fair value	417,924	(95,486)
Balance at end of year	\$ 1,502,695	\$ 1,084,771

The table below presents the fair value of the SAFE liabilities, disaggregated by cohort:

	June 30, 2026	December 31, 2025
2024 SAFE	\$ 450,883	\$ 421,630
2025 SAFE	1,051,812	663,141
Total	\$ 1,502,695	\$ 1,084,771

The SAFE liabilities were valued using a scenario-weighted model that considered equity financing, liquidity, and dissolution outcomes.

Significant unobservable inputs included the Company's equity value, the expected timing and probability of future events, discount rates, a CCC-equivalent credit spread, volatility, and the specific contractual terms of each SAFE cohort, including valuation caps, discount features, liquidity protections, and conversion mechanics. Because the fair value measurement relies on significant unobservable inputs, it is inherently subjective and could change materially in future periods as those assumptions change.

The Company also has an Advance Subscription Agreement classified as temporary equity. See Note 9.

9. Advance Subscription Agreement

On February 11, 2026, the Company entered into an Advance Subscription Agreement (the "ASA") with an existing shareholder, and, as such, the ASA was not an arm's-length transaction (see Note 12). During the six months ended June 30, 2026, the Company received drawdowns totaling \$950,000.

The ASA is non-interest-bearing and does not require the Company to settle in cash. Upon a Conversion Event, as defined in the ASA, the aggregate drawdowns convert into the same class of securities issued in that transaction.

The discount and valuation cap features are measured at fair value on a recurring basis within Level 3 of the fair value hierarchy, using a scenario-weighted model.

Significant unobservable inputs include the probability and timing of a Conversion Event, the Company's equity value and discount rates.

The table below presents the changes in the carrying amount of the ASA:

	Advance Subscription Agreement
	June 30, 2026
Balance at January 1, 2026	\$ —
Drawdowns received	950,000
Conversions	—
Change in fair value	(228,007)
Balance at June 30, 2026	\$ 721,993

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10. Shareholders' Equity

As of June 30, 2026, the Company is authorized to issue 13,264,904 shares, consisting of 10,870,697 shares of Common Shares and 2,394,207 shares of convertible preferred shares (including 452,625 Series Seed-1 Convertible preferred and 1,941,582 Series Seed-2 Convertible preferred shares).

Common Shares

Holders of Common Shares are entitled to one vote per share, with no cumulative voting. Their rights are subordinated to the rights and preferences of Convertible preferred Shares.

Convertible preferred Shares

On a liquidation, dissolution, winding up, or Deemed Liquidation Event, before any distribution to Common Shareholders, preferred shareholders receive the greater of (i) the Original Issue Price plus unpaid declared dividends, or (ii) the amount payable assuming conversion into Common Shares immediately prior to the event. If insufficient assets exist, Convertible preferred holders share ratably.

The Convertible preferred Shares are not callable and not subject to any sinking-fund or similar mandatory redemption provisions, and therefore there is no aggregate or per-share amount at which the Convertible preferred Shares may be redeemed.

Convertible preferred holders are entitled to receive any declared but unpaid dividends before Common Shareholders. The shares are convertible into Common Shares at the holder's option at the stated conversion rate, with conversion resulting in share settlement. The number of Common Shares issuable varies based on the conversion formula within the underlying agreement.

Reserves

Shares are reserved for Convertible preferred Share conversion, equity incentive plans, and other convertible instruments. The Company did not grant any equity awards and did not recognize any stock-based compensation expense during the six months ended June 30, 2026 or 2025.

11. Commitments and contingencies

Legal proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. As of June 30, 2026 and December 31, 2025, the Company was involved in certain legal matters for which accruals have been recorded as described below and in Note 5.

The Company was involved in a legal matter with its former Chief Executive Officer, which was settled in May 2026. In connection with this matter, the Company has recorded an accrual of \$75,000 for the year ended December 31, 2025. No accrual was recorded as of June 30, 2026.

The Company was also involved in a legal matter relating to the former Chief Executive Officer of its Swiss subsidiary. The claim was raised during the year ended December 31, 2025 and was settled in May for 220,000 Swiss Francs. In connection with this matter, the Company has recorded an accrual of \$371,724 for the year ended December 31, 2025. No accrual was recorded as of June 30, 2026.

12. Related party transactions

The Company considers its directors, executive officers, significant shareholders, and entities controlled or influenced by such parties to be related parties. The Company also evaluates transactions with entities in which its directors or officers serve in key management roles.

Skye Biopharma SAS/Estudio Podesta

During the six months ended June 30, 2026, and 2025, the Company entered into transactions with a third party service provider, Estudio Podestá, a legal services firm in Uruguay that provided research related activities on the procurement of regulatory licenses associated with the production of psilocybin-based products. Skye Biopharma SAS was an entity used within these research activities and is an entity under common director ownership and therefore considered a related party. These expenditures represent related party transactions, as the activities performed by the third-party service provider, using Skye Biopharma SAS, provided research for the Group.

For the six months ended June 30, 2026, and 2025, total payments to Estudio Podestá amounted to nil and \$25,000 respectively. These amounts were recognized as operating expenses in the consolidated statement of operations and comprehensive loss. No amounts were due to or from Skye Biopharma SAS or the third party service provider as of June 30, 2026, or December 31, 2025.

13. Subsequent events

The Company evaluated subsequent events from the balance sheet date through to the date the unaudited condensed consolidated financial statements were issued.

On August 6, 2026, the Company completed a stock-for-stock merger with Ensysce Biosciences, Inc. ("Ensysce"), a Nasdaq-listed clinical-stage company, under which all outstanding equity interests of the Company were exchanged, at a fixed exchange ratio, for an aggregate of 282,122 shares of Ensysce Series C non-voting convertible preferred stock. Prior to the merger, the Company completed a convertible note financing with total proceeds of \$17.1 million, of which \$5.7 million was received as of June 30, 2026 (see Note 7) and the remaining \$11.4 million was received in July 2026. The merger was completed after June 30, 2026 and is not reflected in these condensed consolidated financial statements.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Introduction

On August 5, 2026, Ensysce Biosciences, Inc. (“Ensysce” or the “Company”) acquired Cy Biopharma, Inc. (“Cy”), pursuant to the terms of an Agreement and Plan of Merger, dated August 5, 2026 (the “Merger Agreement”), by and among Ensysce, PHRMA Merger Sub I, Inc. (“First Sub”), PHRMA Merger Sub II, LLC (“Second Sub”), and Cy.

Pursuant to the Merger Agreement, First Sub merged with and into Cy, with Cy surviving the merger as a wholly owned subsidiary of Ensysce (the “First Merger”). Immediately following the First Merger, Cy merged with and into Second Sub, with Second Sub surviving as a wholly owned subsidiary of Ensysce (the “Second Merger,” and together with the First Merger, the “Merger”). The surviving entity was subsequently renamed Cy Biopharma, LLC and remains a wholly owned subsidiary of Ensysce.

At the closing of the Merger on August 5, 2026 (the “Closing”), Ensysce issued to the former equity holders of Cy an aggregate of 282,122 shares of Ensysce Series C Non-Voting Convertible Preferred Stock (the “Series C Preferred Stock”) in exchange for the outstanding shares of Cy capital stock immediately prior to the First Merger.

Each share of Series C Preferred Stock is convertible into 1,000 shares of Ensysce common stock following receipt of the requisite stockholder approval, subject to certain beneficial ownership limitations and the terms and limitations set forth in the Series C Certificate of Designation.

PIPE Financing

On August 5, 2026, concurrently with the Merger, Ensysce entered into a Securities Purchase Agreement with certain investors (the “PIPE Investors”), pursuant to which Ensysce agreed to issue and sell an aggregate of 120,260 shares of Series C Preferred Stock for potential aggregate gross proceeds of approximately \$43.0 million (the “PIPE Financing”) in two tranches.

At the initial closing of the PIPE Financing on August 5, 2026 (the “Initial Closing”), Ensysce issued 66,811 shares of Series C Preferred Stock at a purchase price of \$321.79 per share, or \$0.32179 per share on an as-converted basis, resulting in gross proceeds of approximately \$21.5 million.

Subject to achievement of a specified clinical trial milestone, Ensysce has agreed to issue an additional 53,449 shares of Series C Preferred Stock at a purchase price of \$402.24 per share, or \$0.40224 per share on an as-converted basis (the “Milestone Closing”), which would provide additional gross proceeds of approximately \$21.5 million.

Upon achievement of the same clinical trial milestone, Ensysce has also agreed to issue an additional 22,166 shares of Series C Preferred Stock at a purchase price of \$402.24 per share, or \$0.40224 per share on an as-converted basis (the “Cy Milestone Closing”), to certain former Cy equity holders that previously held convertible notes, which would result in additional gross proceeds of approximately \$8.9 million.

Other Transactions

In connection with the Merger, Ensysce also entered into an Omnibus Amendment and Termination Agreement (the “3i Agreement”) with 3i, LP (“3i”), pursuant to which the parties agreed to terminate certain existing financing arrangements. All outstanding shares of Ensysce Series B Preferred Stock, all of which were held by 3i, were converted into an aggregate of 3,229,276 shares of Ensysce common stock, and all common stock warrants held by 3i were converted into 7,183 shares of Series C Preferred Stock. Ensysce also agreed to make a \$250,000 cash payment to 3i.

Separately, to satisfy an existing contractual obligation with a research and development vendor, Galephar Pharmaceutical Research (“Galephar”), Ensysce issued 2,176 shares of Series C Preferred Stock to Galephar.

The Merger, PIPE Financing and related other transactions are collectively referred to herein as the “Transactions.”

On August 6, 2026, Ensysce publicly announced the completion of the Merger and the related PIPE Financing and filed a Current Report on Form 8-K reporting the Transactions and attaching the Merger Agreement, Securities Purchase Agreement and related transaction documents. In connection with the announcement, the Company stated that the Transactions are expected to provide funding to advance Cy’s lead product candidate, CY200, a clinical-stage neuroplastic therapy for the treatment of Complex Regional Pain Syndrome (“CRPS”) Type 1 that has received Orphan Drug Designation from the U.S. Food and Drug Administration. The Company expects the available financing to support CY200 through key clinical milestones, including topline data from a randomized Phase 2 clinical trial evaluating the efficacy, safety and tolerability of CY200 in patients with CRPS Type 1, and to support preparation for registrational development.

Unaudited Pro Forma Condensed Combined Financial Information

The unaudited pro forma condensed combined financial information has been prepared by Ensysce in accordance with Regulation S-X Article 11, Pro Forma Financial Information, as amended by the final rule, Amendments to Financial Disclosures About Acquired and Disposed Businesses, as adopted by the SEC on May 20, 2020 (“Article 11”). The following unaudited pro forma condensed combined financial information gives effect to the acquisition of Cy and the other related Transactions.

The unaudited pro forma condensed combined balance sheet as of June 30, 2026, combines the historical balance sheet of Cy as of June 30, 2026, and the historical balance sheet of Ensysce as of June 30, 2026, and depicts the accounting for the Transactions (“pro forma balance sheet transaction accounting adjustments”) as if they had occurred on June 30, 2026. The unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2026, and for the year ended December 31, 2025, combine the historical results of Ensysce and Cy and depict the pro forma balance sheet transaction accounting adjustments for the Transactions assuming that those adjustments were made as of January 1, 2025 (“pro forma statements of operations transaction accounting adjustments”). Collectively, pro forma balance sheet transaction accounting adjustments and pro forma statements of operations transaction accounting adjustments are referred to as “transaction accounting adjustments.” These unaudited pro forma condensed combined financial information for the six months ended June 30, 2026, and year ended December 31, 2025, and related notes have been derived from and should be read in conjunction with:

- the historical audited consolidated financial statements of Ensysce and the related notes, and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in Ensysce’s annual report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the SEC on March 30, 2026, and incorporated herein by reference;
- the historical unaudited interim financial statements of Ensysce and the related notes, and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in Ensysce’s quarterly report on Form 10-Q for the six months ended and as of June 30, 2026, as filed with the SEC on August 13, 2026, and incorporated herein by reference;
- the historical audited financial statements of Cy as of and for the year ended December 31, 2025, included herein; and
- the historical unaudited interim financial statements of Cy and the related notes as of and for the six months ended June 30, 2026, included herein.

Cy’s historical financial information has been included for purposes of preparing the unaudited pro forma condensed combined financial information. The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations and financial

position would have been had the Transactions occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position. The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may result from the Transactions.

The transaction accounting adjustments to the unaudited pro forma condensed combined financial information are based on the assumptions described in the accompanying notes. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Ensysce and Cy been a combined organization during the specified periods.

**UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
AS OF JUNE 30, 2026**

	Historical		PIPE		Accounting		Transaction		Pro Forma
	Ensysce	Cy	Financing		Adjustments		Adjustments		Combined
Assets									
Current assets:									
Cash and cash equivalents	\$ 676,704	\$ 5,797,368	\$ 21,499,112	2(a)	\$ -	\$ 11,433,711	6(a)	\$ 39,406,895	
Unbilled receivable	416,811	-	-		-	-		416,811	
Prepaid expenses and other current assets	1,752,695	27,069	-		-	(60,368)	6(f)	1,719,396	
Total current assets	2,846,210	\$ 5,824,437	\$ 21,499,112		\$ -	\$ 11,373,343		\$ 41,543,102	
Property and equipment, net	111,063	-	-		-	-		111,063	
Total assets	\$ 2,957,273	\$ 5,824,437	\$ 21,499,112		\$ -	\$ 11,373,343		\$ 41,654,165	
Liabilities and stockholders' equity									
Current liabilities:									
Accounts payable	\$ 1,977,629	\$ 2,419,780	\$ -		\$ -	\$ (2,202,275)	6(b)	\$ 2,195,134	
Accrued expenses and other liabilities	1,893,635	86,270	1,903,591	2(a)	23,050	9(a)	(600,000)	6(c)	8,813,925
						250,000	6(d)		
						(76,909)	6(e)		
						3,334,288	6(f)		
						2,000,000	6(b)		
Notes payable and accrued interest	196,842	-	-		-	-		196,842	
Other current liabilities	-	23,050	-		(23,050)	9(a)	-	-	
Total current liabilities	4,068,106	\$ 2,529,100	\$ 1,903,591		\$ -	\$ 2,705,104		\$ 11,205,901	
Convertible loan notes	-	6,777,691	-		-	(6,777,691)	6(e)	-	
SAFE liabilities	-	1,502,695	-		-	(1,502,695)	6(e)	-	
Total liabilities	\$ 4,068,106	\$ 10,809,486	\$ 1,903,591		\$ -	\$ (5,575,282)		\$ 11,205,901	
Mezzanine equity									
Cy series seed 1 convertible preferred stock	\$ -	\$ 600,000	\$ -		\$ -	\$ (600,000)	6(g)	\$ -	
Cy series seed 2 convertible preferred stock	-	1,042,515	-		-	(1,042,515)	6(g)	-	
Advance subscription agreement	-	721,993	-		-	(721,993)	6(e)	-	
Total mezzanine equity	\$ -	\$ 2,364,508	\$ -		\$ -	\$ (2,364,508)		\$ -	
Stockholders' equity (deficit)									
Ensysce common stock	\$ 1,624	\$ -	\$ -		\$ -	\$ 323	6(d)	\$ 1,947	
Ensysce preferred stock	-	-	21,499,112	2(a)	-	90,784,038	6(g)	113,391,192	
			(1,903,591)	2(a)		700,215	6(c)		
						2,311,418	6(d)		
Cy common stock	-	65	-		-	(65)	6(g)	-	
Additional paid-in capital	145,063,802	-	-		-	(2,561,740)	6(d)	142,502,062	
Accumulated deficit	(145,847,123)	(7,156,351)	-		-	(79,170,463)	6(h)	(225,117,801)	
						7,156,349	6(g)		
						(100,215)	6(c)		
Accumulated other comprehensive loss	-	(193,271)	-		-	193,271	6(g)	-	
Total Ensysce stockholders' equity (deficit)	(781,697)	(7,349,557)	19,595,521		-	19,313,133		30,777,400	
Minority interest	(329,136)	-	-		-	-		(329,136)	
Total stockholders' equity	\$ (1,110,833)	\$ (7,349,557)	\$ 19,595,521		\$ -	\$ 19,313,133		\$ 30,448,264	
Total liabilities, mezzanine equity, and stockholders' equity (deficit)	\$ 2,957,273	\$ 5,824,437	\$ 21,499,112		\$ -	\$ 11,373,343		\$ 41,654,165	

The accompanying notes are an integral part of the unaudited pro forma condensed combined financial information.

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS AND OTHER COMPREHENSIVE LOSS
FOR THE SIX MONTHS ENDED JUNE 30, 2026**

	Historical		Transaction		Pro Forma
	Ensysce	Cy	Accounting		Combined
			Adjustments		
Federal grants	\$ 2,125,313	\$ -	\$ -		\$ 2,125,313
Operating expenses:					
Research and development	5,818,633	439,310	-		6,257,943

General and administrative	2,445,299	2,583,207	-	5,028,506
Total operating expenses	8,263,932	3,022,517	-	11,286,449
Loss from operations	(6,138,619)	(3,022,517)	-	(9,161,136)
Other income (expense):				
Changes in the fair value of SAFE Liabilities	-	(417,924)	417,924	7(a) -
Change in fair value of Advanced Subscription Agreement	-	228,007	(228,007)	7(a) -
Interest expense	(4,243)	(4,630)	4,630	7(a) (4,243)
Other income and expense, net	15,572	-	-	15,572
Foreign currency transaction (loss)/gain, net	-	(16,305)	-	(16,305)
Total other income/(expenses), net	11,329	(210,852)	194,547	(4,976)
Net loss	\$ (6,127,290)	(3,233,369)	194,547	(9,166,112)
Net loss attributable to noncontrolling interests	(166)	-	-	(166)
Deemed dividend	-	-	-	-
Net loss attributable to common stockholders	<u>\$ (6,127,124)</u>	<u>\$ (3,233,369)</u>	<u>\$ 194,547</u>	<u>\$ (9,165,946)</u>
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	-	19,630	-	19,630
Total comprehensive loss	<u>\$ (6,127,124)</u>	<u>\$ (3,213,739)</u>	<u>\$ 194,547</u>	<u>\$ (9,146,316)</u>
Net loss per basic and diluted share:				
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.62)			\$ (0.70)
Weighted average common shares outstanding, basic and diluted	<u>9,954,626</u>			<u>13,183,902</u>

The accompanying notes are an integral part of the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS AND OTHER COMPREHENSIVE LOSS FOR THE YEAR ENDED DECEMBER 31, 2025

	Historical		Transaction	Pro Forma
	Ensysce	Cy	Accounting	Combined
			Adjustments	
Federal grants	\$ 5,066,650	\$ -	\$ -	\$ 5,066,650
Operating expenses:				
Research and development	10,376,895	473,380	79,170,463	7(b) 90,020,738
General and administrative	4,930,701	1,075,268	-	6,005,969
Total operating expenses	15,307,596	1,548,648	79,170,463	96,026,707
Loss from operations	(10,240,946)	(1,548,648)	(79,170,463)	(90,960,057)
Other income (expense):				
Change in fair value of liability classified warrants	10,096	-	-	10,096
Changes in the fair value of financial instruments	-	95,486	(95,486)	7(a) -
Interest expense	(18,767)	(54,228)	53,978	7(a) (19,017)
Interest income	-	7	-	7
Other income and expense, net	73,430	-	-	73,430
Foreign currency transaction (loss)/gain, net	-	41,689	-	41,689
Total other income/(expenses), net	64,759	82,954	(41,508)	106,205
Net loss	\$ (10,176,187)	\$ (1,465,694)	\$ (79,211,971)	\$ (90,853,852)
Net loss attributable to noncontrolling interests	(487)	-	-	(487)
Deemed dividend	-	-	708,514	7(c) 708,514
Net loss attributable to common stockholders	<u>\$ (10,175,700)</u>	<u>\$ (1,465,694)</u>	<u>\$ (79,920,485)</u>	<u>\$ (91,561,879)</u>
Other comprehensive (loss)/income – Foreign currency translation adjustments, net of tax	-	(64,395)	-	(64,395)
Total comprehensive loss	<u>\$ (10,175,700)</u>	<u>\$ (1,530,089)</u>	<u>\$ (79,920,485)</u>	<u>\$ (91,626,274)</u>
Net loss per basic and diluted share:				
Net loss per share attributable to common stockholders, basic and diluted	\$ (3.98)			\$ (15.82)
Weighted average common shares outstanding, basic and diluted	<u>2,557,377</u>			<u>5,786,653</u>

The accompanying notes are an integral part of the unaudited pro forma condensed combined financial information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Merger

On August 5, 2026, Ensysce, First Sub, Second Sub and Cy entered into the Merger Agreement, pursuant to which Ensysce acquired Cy. Pursuant to the Merger Agreement, First Sub merged with and into Cy, with Cy surviving as a wholly owned subsidiary of Ensysce. Immediately following the First Merger, Cy merged with and into Second Sub, with Second Sub surviving as a wholly owned subsidiary of Ensysce and the Second Sub changing its name to “Cy Biopharma, LLC”.

Upon the Closing, Ensysce acquired all outstanding equity interests of Cy. In exchange for all outstanding shares of Cy stock immediately prior to the effective time of the First Merger, Ensysce issued to the former equity holders of Cy the right to receive an aggregate of 282,122 shares of Ensysce Series C Preferred Stock.

Each share of Series C Preferred Stock is convertible into 1,000 shares of Ensysce common stock, par value \$0.0001 per share, following receipt of the requisite stockholder approval and subject to the terms, conditions and beneficial ownership limitations set forth in the applicable Certificate of Designation. The estimated fair value of the Series C

Preferred Stock issued as consideration in the Merger was approximately \$90.8 million.

2. Concurrent Private Placement

On August 5, 2026, in connection with the Merger, Ensysce entered into a Securities Purchase Agreement with PIPE Investors, pursuant to which Ensysce agreed to issue and sell an aggregate of 120,260 shares of Series C Preferred Stock for aggregate gross proceeds of approximately \$43.0 million in two tranches.

At the Initial Closing, Ensysce issued 66,811 shares of Series C Preferred Stock at a purchase price of \$321.79 per share, or \$0.32179 per share on an as-converted basis, resulting in gross proceeds of approximately \$21.5 million.

Subject to achievement of a specified clinical trial milestone, Ensysce has agreed to issue an additional 53,449 shares of Series C Preferred Stock at a purchase price of \$402.24 per share, or \$0.40224 per share on an as-converted basis, which would result in additional gross proceeds of approximately \$21.5 million.

Upon achievement of the same specified clinical trial milestone, Ensysce has also agreed to issue an additional 22,166 shares of Series C Preferred Stock at a purchase price of \$402.24 per share, or \$0.40224 per share on an as-converted basis, to certain former Cy equity holders that previously held convertible notes, which would result in additional gross proceeds of approximately \$8.9 million.

Each share of Series C Preferred Stock issued pursuant to the PIPE Financing is convertible into 1,000 shares of Common Stock, subject to the terms and limitations set forth in the Certificate of Designation.

The unaudited pro forma condensed combined financial information reflects the Initial Closing of the PIPE Financing and related transaction accounting adjustments. The potential proceeds and issuance of securities associated with the Milestone Closing have not been reflected in the unaudited pro forma condensed combined financial information because the applicable clinical trial milestone had not been achieved as of the Closing.

- a) To reflect the Initial Closing of approximately \$21.5 million in upfront gross proceeds from the issuance of 66,811 shares of Series C Preferred Stock at a purchase price of \$321.79 per share, less issuance costs of approximately \$1.9 million.

The potential issuance of an additional 53,449 shares of Series C Preferred Stock and receipt of approximately \$21.5 million of additional gross proceeds upon achievement of the specified clinical trial milestone are not reflected because the milestone condition had not been achieved as of the Closing.

3. Other Related Transactions

On August 5, 2026, Ensysce and 3i entered into an agreement pursuant to which Ensysce and 3i agreed to terminate certain existing agreements between Ensysce and 3i.

Pursuant to the 3i Agreement, all outstanding shares of Ensysce Series B Preferred Stock were converted into an aggregate of 3,229,276 shares of common stock, of which 910,905 shares were issued directly to 3i and 2,318,371 shares were issued to a financial institution to be held in an abeyance account. In addition, outstanding warrants held by 3i were converted into 7,183 shares of Series C Preferred Stock. Ensysce also agreed to make a cash payment of \$250,000 to 3i.

Separately, in connection with the Company's research agreement with Galephar, Ensysce settled its outstanding obligation to issue 2,175,368 shares of common stock by issuing 2,176 shares of Series C Preferred Stock to Galephar.

4. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information has been prepared by management in accordance with Article 11 of Regulation S-X and is presented in U.S. dollars. The transaction accounting adjustments have been identified and presented to provide relevant information necessary to understand the effects of the Transactions on Ensysce.

The unaudited pro forma condensed combined balance sheet as of June 30, 2026, gives effect to the Transactions as if they had occurred on June 30, 2026. The unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2026, and the year ended December 31, 2025, give effect to the Transactions as if they had occurred on January 1, 2025.

The unaudited pro forma condensed combined financial information was prepared using the historical financial information of Ensysce and Cy and gives effect to the transaction accounting adjustments described in these notes. Certain historical amounts of Cy have been reclassified to conform to Ensysce's financial statement presentation and accounting policies, as applicable.

5. Accounting Treatment for the Merger

The Merger is accounted for as an asset acquisition in accordance with Accounting Standards Codification Topic 805, Business Combinations ("ASC 805"), because substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable in-process research and development ("IPR&D") asset related to the CY200 program. Ensysce is the accounting acquirer and, upon consummation of the Merger, Cy became a wholly owned subsidiary of Ensysce.

Under the asset acquisition method, the cost of the acquisition, including qualifying transaction costs, is allocated to the assets acquired based on their relative fair values, after consideration of the liabilities assumed. No goodwill is recognized in an asset acquisition. Acquired IPR&D that has no alternative future use is expensed as of the acquisition date.

The preliminary acquisition accounting reflected in the unaudited pro forma condensed combined financial information is based on currently available information, the terms of the Merger Agreement and related transaction documents, and assumptions that management believes are reasonable under the circumstances. Cash, prepaid expenses and other acquired assets and assumed liabilities are reflected based on preliminary estimates of their acquisition-date amounts. Substantially all of the value of the acquired assets is attributable to the CY200 IPR&D program. Accordingly, after allocation of the acquisition cost to the other identifiable assets acquired based on their relative fair values, substantially all of the remaining acquisition cost is allocated to acquired IPR&D. Because the acquired IPR&D has no alternative future use as of the acquisition date, the amount allocated to IPR&D is expensed immediately upon acquisition.

The accounting for the Transactions is preliminary and may be revised as additional information becomes available and management completes its analysis of the assets acquired, liabilities assumed, consideration transferred and other transaction-related matters. The final accounting and allocation of the acquisition cost will be determined after the final consideration is determined and any valuations, studies or other analyses deemed necessary are completed. Accordingly, the final amounts may differ materially from those reflected in the unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information is presented for illustrative purposes only and does not necessarily reflect the financial position or results of operations that would have occurred had the Transactions been completed on the dates assumed, nor is it necessarily indicative of the future financial position or results of operations of Ensysce following the Transactions. The unaudited pro forma condensed combined financial information does not give effect to anticipated synergies, operating efficiencies, tax savings or cost savings that may result from the Transactions and should be read in conjunction with the accompanying notes.

6. Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet

The transaction accounting adjustments included in the unaudited pro forma condensed combined balance sheet as of June 30, 2026, are based on preliminary estimates that could change materially as additional information becomes available.

- a) To reflect the receipt of \$11.4 million from the issuance of Cy convertible notes in July 2026.
- b) To reflect the payment by Ensysce of certain Cy transaction costs recorded in accounts payable, including the effect of a \$0.2 million negotiated reduction in legal fees.
- c) To reflect the issuance of Series C Preferred Stock in satisfaction of an existing contractual obligation associated with the Galephar transaction and the corresponding elimination of the related \$0.6 million historical liability.
- d) To reflect the settlement of outstanding 3i holdings in connection with the Transactions, including the conversion of Series B Preferred Stock into Common Stock, the conversion of outstanding warrants into Series C Preferred Stock, and a \$0.25 million cash payment.
- e) To reflect the conversion, settlement or extinguishment of Cy's outstanding convertible notes and SAFE instruments in connection with the Transactions, including the elimination of the related historical liability balances and accrued interest.
- f) To reflect approximately \$3.4 million of estimated acquisition-related legal and advisory costs incurred or expected to be incurred in connection with the Merger that were either not reflected in the historical balance sheets to be accrued or reclassified out of deferred financing costs.
- g) To reflect the asset acquisition accounting resulting from the Merger, including the issuance of 282,122 shares of Series C Preferred Stock as purchase consideration and the elimination of Cy's historical equity balances.
- h) To reflect the immediate expensing of acquired IPR&D upon consummation of the Merger, as the acquired IPR&D has no alternative future use.

7. Adjustments to Unaudited Pro Forma Condensed Combined Statements of Operations

The transaction accounting adjustments included in the unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2026, and the year ended December 31, 2025, reflect the Transactions as if they had occurred on January 1, 2025.

- a) To reflect the elimination of historical interest expense, changes in fair value and other income or expense associated with Cy's convertible notes and SAFE instruments that were converted, settled or extinguished in connection with the Transactions, as if such conversion, settlement or extinguishment had occurred on January 1, 2025.
- b) To reflect the immediate expensing of approximately \$79 million of acquired IPR&D with no alternative future use upon consummation of the Merger.

The adjustment is based on the preliminary allocation of the asset acquisition cost to Cy's acquired assets based on their relative fair values. The amount allocated to acquired IPR&D is reflected as acquired in-process research and development expense in the unaudited pro forma condensed combined statement of operations. The adjustment is nonrecurring and is presented as though the Merger had occurred on January 1, 2025.

- c) Reflects a deemed dividend recognized in connection with the settlement of 3i's holdings. The deemed dividend is included in determining pro forma net loss available to common stockholders for purposes of calculating pro forma net loss per share, as the settlement is assumed to have occurred as of January 1, 2025.

8. Net Loss Per Share

Pro forma basic and diluted net loss per share attributable to common stockholders has been adjusted to reflect the Transactions, including Common Stock issued pursuant to settlement of 3i's holdings, as if the applicable Transactions had occurred on January 1, 2025.

Because Ensysce and the pro forma combined company reported net losses for the periods presented, potentially dilutive securities are excluded from the computation of diluted net loss per share when their inclusion would be anti-dilutive. The shares of common stock underlying the Series C Preferred Stock have been excluded from the calculation of pro forma basic and diluted net loss per share. The Series C Preferred Stock is not convertible until receipt of the requisite stockholder approval, at which time it will automatically convert into common stock, subject to certain beneficial ownership limitations. As the approval had not occurred as of the applicable pro forma periods, the underlying shares were excluded from basic net loss per share and were excluded from diluted net loss per share as their effect would be anti-dilutive.

The pro forma weighted-average shares outstanding are calculated as follows:

	For the Six Months Ended June 30, 2026	For the Year Ended December 31, 2025
	Basic and Diluted	Basic and Diluted
Pro forma net loss	\$ (9,165,946)	\$ (91,561,879)
Historical weighted-average common shares outstanding	9,954,626	2,557,377
Common shares issued in connection with settlement of 3i Series B preferred stock	3,229,276	3,229,276
Pro forma weighted average number of common shares	13,183,902	5,786,653
Pro forma net loss per share, basic and diluted	\$ (0.70)	\$ (15.82)

The following table reflects the outstanding dilutive potential shares that are excluded from the calculation of diluted net loss per share due to their anti-dilutive effect.

	For the Six Months Ended June 30, 2026	For the Year Ended December 31, 2025
Stock options	93,281	87,048
Warrants	1,260,291	2,440,527
Convertible notes	2,844	9,187

Conversions from Series C Preferred Stock	358,292,000	358,292,000
Performance-Based RSUs expected to be granted upon closing of the Merger	4,140,285	4,140,285
Total	363,788,701	364,969,047

9. Reclassifications

Certain amounts in the historical consolidated financial statements of Cy have been reclassified within the “Historical Cy” column of the unaudited pro forma condensed combined financial information to conform to the Company’s financial statement presentation. These reclassifications primarily relate to the presentation of other current liabilities, and had no impact on Cy’s previously reported total assets, total liabilities, stockholders’ equity, or net loss.

- a) Reflects the reclassification of certain historical Cy balances, primarily relating to other current liabilities, to conform to Ensysce’s financial statement presentation. These adjustments have no impact on total assets, total liabilities, stockholders’ equity, or net loss.