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

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2025

OR

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

For the transition period from _____ to _____

Commission file number: **001-41106**

Incannex Healthcare Inc.
(Exact name of registrant as specified in its charter)

Delaware	**93-2403210**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
Suite 105, 8 Century Circuit Norwest, NSW 2153 Australia	**Not applicable**
(Address of principal executive offices)	(Zip Code)

+61 409 840 786
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant computed by reference to the closing price of $2.12 of the common stock on the Nasdaq Global Market as of December 31, 2024, was approximately $29.1 million. The calculation of the aggregate market value of the common stock held by non-affiliates of the registrant excludes shares of common stock held by each officer, director and stockholder that the registrant concluded were affiliates on that date. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of September 28, 2025, there were 347,705,507 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from certain filed portions of the registrant's definitive Proxy Statement for the 2025 Annual Meeting of Stockholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this Form 10-K.

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Trademarks

We own or have rights to trademarks and trade names that we use in connection with the operation of our business, including our corporate name, logos, product names and website names. Solely for your convenience, some of the trademarks and trade names referred to in this annual report on Form 10-K for the fiscal year ended June 30, 2025 ("Annual Report") are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names.

Statistical and Other Industry and Market Data

This Annual Report includes statistical and other industry and market data and contains estimates and information concerning our industry and our business, including estimated market size and projected growth rates of the markets for our drug candidates. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This information involves a number of assumptions and limitations. Although we are responsible for all of the disclosures contained in this Annual Report and we believe the third-party market position, market opportunity and market size data included in this Annual Report are reliable, we have not independently verified the accuracy or completeness of this third-party data. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in these publications and reports.

Special Note Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") adopted pursuant to the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties, other factors and assumptions, including the risks described in "Risk Factors" and elsewhere in this Annual Report, regarding, among other things:

- our ability to implement our product development and business strategies, including our ability to continue to pursue development pathways and regulatory strategies for IHL-42X, PSX-001, and IHL-675A and any of our other drug candidates;
- estimates regarding market size and related future growth rates;
- our research and development ("R&D") activities, including clinical testing and manufacturing and the related costs and timing;
- the possibility that we may be required to conduct additional clinical studies or trials for our drug candidates and the consequences resulting from the delay in obtaining necessary regulatory approvals;
- the timing, scope or likelihood of regulatory filings and approvals and our ability to obtain and maintain regulatory approvals for our drug candidates for any indication;
- the pricing, coverage and reimbursement of our drug candidates, if approved and commercialized;
- the rate and degree of market acceptance and clinical utility of our drug candidates;
- our ability to compete with other drugs or therapies currently marketed or in development for our target indications;
- our expectations around feedback from and discussions with regulators, regulatory development paths and with respect to Controlled Substances Act designation;

- our ability to obtain or maintain effective patent rights and other intellectual property protection for our drug candidates, and to prevent competitors from using technologies we consider important to the successful development and commercialization of our drug candidates;
- our estimates regarding expenses, revenues, financial performance and capital requirements, including the length of time our capital resources will sustain our operations;
- our ability to commercialize drug candidates and to generate revenues;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our drug candidates;
- our ability to retain and attract qualified employees, directors, consultants and advisors;
- our ability to continue to comply with applicable privacy laws and protect confidential information from security breaches;
- how recent and potential future changes in healthcare policy could negatively impact our business and financial condition;
- the extent to which global economic and political developments, including existing regional conflicts, pandemics, natural disasters, and the indirect and/or long-term impact of inflation, will affect our business operations, clinical trials, or financial condition; and
- any statement of assumptions underlying any of the foregoing.

These risks are not exhaustive. Other sections of this Annual Report may include additional factors that could harm our business and financial performance.

You should not rely on forward-looking statements as predictions of future events. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

We qualify all our forward-looking statements by these cautionary statements.

As used in this Annual Report, unless otherwise stated or the context otherwise indicates, references to "Incannex," the "Company," "we," "our," "us" or similar terms refer to Incannex Healthcare Inc., and our wholly-owned subsidiaries.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to developing innovative medicines for patients living with serious chronic diseases and significant unmet needs.

IHL-42X, our drug candidate in a pivotal Phase 2/3 clinical trial for the treatment of obstructive sleep apnea ("OSA") is an oral fixed-dose combination of dronabinol and acetazolamide designed to act synergistically by targeting two different physiological pathways associated with the intermittent hypoxia and hypercapnia that characterize OSA. In a proof-of-concept study conducted in Australia, as well as in the Phase 2 portion of our RePOSA clinical trial, we observed that IHL-42X reduced apnea hypopnea index ("AHI") and was well-tolerated in OSA patients.

In the Phase 2 portion of the RePOSA clinical trial investigating, IHL-42X maximum reductions in AHI were observed at up to 83% for the high-dose group and up to 79% for the low-dose group. Notably, 33.3% of patients in the low-dose group and 41.2% of patients in the high-dose group achieved a greater than 30% reduction in AHI, while 13.9% (low-dose) and 14.7% (high-dose) experienced reductions exceeding 50%. Significant clinical improvement was observed across multiple secondary endpoints. Observed treatment-emergent adverse effects ("TEAEs") were infrequent, with the majority being mild or moderate in severity. The low-dose and high-dose IHL-42X groups achieved a statistically significant reduction in percent change in AHI from baseline compared to placebo ($p<0.05$), the primary measure of OSA severity. Based on these results, we are finalizing arrangements for our End of Phase meeting with the U.S. Food and Drug Administration (the "FDA") to obtain guidance on planned next steps, including a pivotal Phase 3 trial design.

PSX-001, our drug candidate in Phase 2 clinical development, is an oral synthetic psilocybin treatment, administered in combination with psychological therapy for patients with moderate-to-severe generalized anxiety disorder ("GAD"). We completed a Phase 2 clinical trial, known as PsiGAD1, in the results of which we observed that the combination of synthetic psilocybin with psychotherapy significantly reduced anxiety scores and was well-tolerated in GAD patients. In this trial, statistically meaningful reductions in Hamilton Anxiety Rating Scores ("HAM-A scores") were observed, with subjects in the investigational arm achieving an average 12.8-point reduction from baseline that was sustained for an 11-week follow up period. A greater than 50% reduction in HAM-A scores was observed in 44.1% of subjects receiving the experimental treatment and 24% of subjects in the treatment arm achieved full disease remission, a number five times higher than placebo. Improvements were also observed in secondary endpoint measures. PSX-001 was observed to be well-tolerated with no serious adverse events reported. The majority of TEAEs were transient, mild to moderate in nature and consistent with the expected pharmacological effects of psilocybin. No signs of increased suicidality, psychosis, or prolonged psychological distress, concerns often cited with psychedelic treatments, were observed. We have a cleared Investigational New Drug ("IND") application with the FDA and are preparing to initiate a multi-jurisdiction Phase 2 clinical trial in 2026.

IHL-675A is our drug candidate for the treatment of inflammatory conditions, with an initial focus on rheumatoid arthritis. IHL-675A is an oral fixed-dose combination of cannabidiol ("CBD") and hydroxychloroquine sulfate designed to target two different pathways, acting synergistically to alleviate inflammation. In our Phase 1 clinical trial, IHL-675A was observed to be well-tolerated and bioavailable. In preclinical studies, IHL-675A was observed to reduce inflammatory markers and disease scores across multiple animal inflammatory disease models and in vitro assays. This candidate was being developed in an Australian Phase 2 trial investigating the safety and efficacy of IHL-675A in rheumatoid arthritis patients, but we encountered patient recruitment challenges and this Phase 2 clinical trial was terminated. Insufficient data was collected to make any conclusions on safety or efficacy of IHL-675A. We now are developing a strategy for an IND opening study investigating the safety and efficacy of IHL-675A in patients diagnosed with rheumatoid arthritis to be conducted in the United States.

Each of these programs represents a potential new approach to treating serious conditions that currently have limited, inadequate, or no approved pharmaceutical options.

Our Strategy

Our mission is to advance novel therapies, leveraging evidence-based innovation, with the potential to transform the lives of people suffering from serious, chronic conditions and unmet medical needs. Our three lead programs were created internally and prioritized based on their potential to offer new therapeutic approaches and long-term patient benefits.

We aim to maximize value to our stockholders and to provide important new treatment options to patients in need of new therapeutic options. Key elements of our strategy include:

- **Advance our novel investigational drug candidates through pivotal and registrational clinical development programs**. We are pursuing approval from the FDA through the submission of New Drug Applications ("NDAs") for all our three lead drug candidates. We plan to seek market authorization in the United States for our drug candidates and following U.S. approval, we plan to strategically expand into the European Union, United Kingdom, Japan, Australia, and Canada. These regions represent significant opportunities due to their large healthcare systems, established regulatory frameworks, and high market demand for innovative therapies. By securing approvals in these key regions, we aim to maximize the global commercial potential of our drug candidates.

- **Seek streamlined regulatory pathways for our drug candidates**. We and our consultants and advisors believe that each of our lead drug candidates may be eligible to qualify for one or more FDA expedited review programs (e.g. breakthrough therapy designation, accelerated approval, priority review and/or Fast Track designation). Each of these programs target conditions that currently have limited, inadequate, or no approved pharmaceutical treatment options. FDA expedited review programs may facilitate the development and potentially expedite review of drugs to treat serious conditions and fill an unmet medical need. Where appropriate, we also intend to pursue the FDA's 505(b)(2) pathway, enabling more efficient approval by leveraging existing data from approved products and established active ingredients.

- **Maintain a strong intellectual property portfolio**. We believe we have developed a global intellectual property strategy to support our development and ultimate global commercial objectives. We are monitoring the results of our R&D programs to identify new intellectual property and intend to pursue protection in the United States, Europe, Japan, Israel, and other key global markets.

- **Maximize the value of our pipeline and drug candidates**. We are actively pursuing FDA registration for our lead drug candidates currently in development. Our approach focuses on advancing novel, scientifically validated therapies with strong clinical potential. Simultaneously, we will retain the flexibility to explore strategic partnerships, licensing agreements, and collaboration opportunities as they arise, with the objective of maximizing the value of our pipeline and approved drug candidates. These efforts are aligned with our commitment to delivering long-term value for our stockholders.

Lead Drug Candidates

Obstructive Sleep Apnea

IHL-42X	RePOSA	Ph 2/3 Safety and Efficacy Trial	• 560 Patient, randomized, double-blind safety and efficacy study • Phase 2 data released July 2025
	BABE	Bioavailability Trial	• Data released Jan 2025
	POC	Proof of Concept Ph2 Trial	• Proof of concept, cross-over safety and efficacy study (Study completed)

Generalized Anxiety Disorder

PSX-001	PsiGAD2	Ph2 Dose Comparison	• 94 patient, double-blind, safety and efficacy study • Dosing expected to begin 2026
	PsiGAD1	Proof of Concept Ph2 Trial	• 73 patient, double-blind, safety and efficacy study • Dosing completed Jan 2024

Rheumatoid Arthritis

IHL-675A	Phase 2	Ph2 Safety and Efficacy Study	• 128 Patient, double-sided, safety and efficacy study • Strategy for IND opening clinical trial being developed
	Phase 1	Ph1 Safety and PK Study	• 36 patient, Phase 1 safety and PK study • Study completed

The estimated addressable global market opportunity for OSA medical devices is approximately US$8.2 billion, with an estimated compound annual growth rate ("CAGR") of 7.33% from 2024 to 2029. Sales for GAD treatments in the United States reached approximately US$21 billion in 2023. The rheumatoid arthritis market in the United States reached US$25.37 billion in 2023 and is expected to exceed US$31.58 billion by 2033. We believe our drug candidate, IHL-675A, also has potential applications in other inflammatory conditions, such as inflammatory bowel disease, chronic obstructive pulmonary disease ("COPD"), and asthma. Sales for these other inflammatory conditions in the United States totaled US$3.6 billion in 2022.

Clinical Approach

Through our internal research and collaborations with leading medical institutions in Australia, we identified significant opportunities to pursue combination drug strategies targeting synthetic cannabinoids and psychedelic agents to address unmet medical needs. Combination therapy allows for lower doses than monotherapy, which may reduce the likelihood of unwanted side effects while enhancing efficacy.

- IHL-42X and IHL-675A: In these programs, we are developing oral fixed-dose combinations in which the active agents target different components of disease pathophysiology. Having two drugs with independent mechanisms of action increases the likelihood of synergistic benefit beyond what either drug could achieve alone. Clinical data supports these synergistic advantages.

- PSX-001: Our psilocybin treatment comprises administration of PSX-001 with psychological support from trained therapists. Evidence suggests psilocybin may have beneficial effects across several mental health conditions, and the combination with structured therapy is designed to optimize outcomes and safety.

- Regulatory strategy: The development path for our cannabinoid programs enables pursuit of the FDA's 505(b)(2) pathway. This approach may substantially reduce time from drug concept to in-human trials by leveraging existing nonclinical toxicology data for the individual agents.

- Geographic execution: Initial preclinical and early-stage clinical development was conducted primarily in Australia, providing cost efficiency and access to the Australian R&D rebate program. With this foundation, we believe we are well positioned for development with the FDA. We may continue to conduct certain smaller studies in Australia to generate supportive data while advancing pivotal trials under U.S. INDs.

IHL-42X

Obstructive Sleep Apnea

IHL-42X	**RePOSA**	**Ph 2/3 Safety and Efficacy Trial**	• 560 Patient, randomized, double-blind safety and efficacy study • Phase 2 data released July 2025
	BABE	**Bioavailability Trial**	• Data released Jan 2025
	POC	**Proof of Concept Ph2 Trial**	• Proof of concept, cross-over safety and efficacy study (Study completed)

Obstructive Sleep Apnea or "OSA"

OSA is a disease of sleep disordered breathing characterized by a narrowing or collapse of the upper airway during sleep, which interferes with breathing and reduces sleep quality. Presentation of OSA often includes snoring and waking up gasping for air. Though OSA is recognized as a relatively common and chronic disorder, it remains underdiagnosed and inadequately treated. Untreated OSA is associated with a wide range of serious long-term outcomes, including cardiovascular disease, cognitive impairments such as memory loss, poor concentration and judgment, depression and increased risk of death or injury due to traffic accidents resulting from excessive daytime sleepiness. The substantial patient and society costs related to undiagnosed and diagnosed obstructive OSA include increased healthcare usage, reduced productivity, and diminished quality of life.

A 2019 article published by *The Lancet* premised on literature-based analysis of 17 studies across 16 countries, estimated that OSA affects some 936 million adults worldwide. This alarming statistic is thought to be increasing due to the growing prevalence of obesity and an aging global population. Many people with OSA develop high blood pressure (hypertension), which can increase the risk of cardiovascular disease. OSA is considered a serious medical condition; the more severe the OSA, the greater the risk of coronary artery disease, heart attack, heart failure, stroke and shortened life span.

There are limited drug treatment options for OSA. Certain drug products containing tirzepatide, a GLP-1 agonist, are approved for treatment of OSA in obese patients. Tirzepatide is also approved to treat obesity, reducing body mass index. There is a well-established link between obesity and OSA risk, and one of the consequences of reducing body mass index in obese patients with OSA is improvement of OSA severity. However, tirzepatide does not treat the pathophysiological mechanisms of OSA outside of obesity and is not an available option for non-obese OSA patients, which is estimated to be greater than 67% of the OSA patient population.

Available non-pharmacological treatment options for OSA include: the standard of care, positive airway pressure ("PAP"), including continuous positive airway pressure ("CPAP"), in which an external device pneumatically splints the airway open to prevent disruptions in breathing; oral appliances to advance the mandible or to retain the tongue, putting the mouth in a position more conducive to breathing; surgery to remove physical obstructions to airflow; and implantable electronic stimulators to activate muscles at the base of the tongue, opening the airway in synchrony with respiration. An estimated 50% of patients discontinue CPAP treatment within one year. Patient compliance to PAP devices is low due to discomfort and claustrophobia resulting from pressurized air being pumped into the patient's nose and/or mouth via a mask or nasal pillow during sleep. These available treatment options, in many cases, are poorly tolerated, inadequate, expensive, and for implantable stimulators and surgery, invasive.

Despite these discomforts, the global annual market for sleep apnea devices is over US$8.2 billion and growing. The estimated compound annual growth rate for the global market of OSA devices from 2024 to 2029 is 7.33%.

IHL-42X in OSA

IHL-42X is an oral fixed-dose combination of acetazolamide, a carbonic anhydrase inhibitor approved for various indications, and dronabinol, a synthetic form of delta-9-tetrahydrocannabinol ("THC") approved for the treatment of nausea, vomiting and loss of appetite. Both agents have been shown in clinical studies to reduce the AHI. We believe that the activity of dronabinol on cannabinoid receptors causes dilation of the airway, and acetazolamide induces modest metabolic acidosis, signaling to the body that there is excess CO2 in the blood, thus increasing respiration. By combining two agents with mechanisms known to reduce AHI in one pharmaceutical formulation, we believe IHL-42X may have therapeutic benefit at lower doses of each constituent drug that are safe and tolerable.

Phase 2 Clinical Trial for IHL-42X for OSA

We completed a Phase 2 clinical trial in Australia to investigate the safety and efficacy of IHL-42X for the treatment of OSA. This study established proof-of-concept, the combination reduced AHI in patients with OSA.

The primary endpoint of this Australian Phase 2 clinical trial was the change in AHI relative to baseline, and the secondary endpoints included change in oxygen desaturation index ("ODI"), daytime somnolence measured by the Epworth Sleepiness Scale ("ESS"), improvement in mood as measured by the Profile of Moods State ("POMS"), and well-being as measured by the Short Form 36. Safety of the IHL-42X combination was assessed through adverse event monitoring. Participants completed a single-blind placebo treatment period followed by three double-blind IHL-42X treatment periods, each with a different dose strength of IHL-42X. Each treatment period was seven days with an overnight sleep study on night seven to determine AHI and other secondary endpoint data. Blood samples were collected the morning after the sleep study and analyzed for THC content.

In the final analysis of data from this trial, IHL-42X was observed to reduce AHI at all three dose strengths (2.5 mg dronabinol + 125 mg acetazolamide, 5 mg dronabinol + 250 mg acetazolamide, and 10 mg dronabinol + 500 mg acetazolamide). The lowest dose (2.5 mg dronabinol + 125 mg acetazolamide) was observed to be the most effective, reducing AHI by an average of 50.7 % relative to baseline, with 25% of subjects' AHI reduced by >80%. With low-dose IHL-42X, THC was cleared below the common threshold for impaired driving (1 ng/mL) by the morning after dosing. Subjects also reported improved sleep quality during IHL-42X treatment periods compared to placebo.

IHL-42X was observed to be generally well-tolerated with no serious adverse events observed at any dosage level. Adverse events were recorded from the time the subjects enrolled in the trial until their end-of-study visit. After recording TEAEs, the study team, including investigators and medical monitors, reviewed the TEAEs to determine whether they were likely related to the drug candidate. Of the 11 subjects studied, TEAEs deemed to be possibly, probably, or related to study treatment occurred at a higher incidence at the higher doses on dronabinol/acetazolamide (5 mg dronabinol plus 250 mg acetazolamide and 10 mg dronabinol plus 500 mg acetazolamide) compared to the low (2.5 mg dronabinol plus 125 mg acetazolamide) dose and placebo treatment periods.

Low dose IHL-42X had a similar proportion of subjects reporting TEAEs and a lower number of total TEAEs than the placebo. This indicated that low-dose IHL-42X was well-tolerated.

This Phase 2 clinical trial both supported our FDA IND submission and informed the design of the ongoing Phase 2/3 clinical trial (or the RePOSA Study, as discussed below).

Formulation Development and Manufacturing of IHL-42X

We engaged Procaps Group, S.A. ("Procaps") for the manufacture of a specific oral fixed-dose formulation of IHL-42X for our clinical trials.

Bioavailability/Bioequivalence Clinical Trial

We conducted a bioequivalence/bioavailability ("BA/BE") clinical trial for IHL-42X. The BA/BE study focused on assessing the pharmacokinetics ("PK") and tolerability of IHL-42X's active pharmaceutical ingredients ("APIs"), dronabinol (a synthetic form of THC) and acetazolamide, in comparison to FDA reference listed drugs Marinol (dronabinol) and acetazolamide oral tablets manufactured by Taro Pharmaceutical Industries. The trial also investigated the effect of food on IHL-42X tolerability and PK. The BA/BE study was designed to evaluate the concentrations of APIs and metabolites in blood samples over 48 hours, and to adhere to FDA recommendations for bioequivalence studies. In January 2025, we announced positive topline results from this trial. These topline results confirmed bioavailability of IHL-42X, demonstrating delivery of both dronabinol and acetazolamide. The PK profile of IHL-42X was similar to those observed for the respective reference listed drugs, including equivalent total exposure levels ("AUCinf") observed for the drug molecules. Furthermore, administration of IHL-42X with food, in contrast to fasted conditions, indicated no substantial food effect on overall exposure to acetazolamide. Consistent with what is known for the reference listed drugs, an increase in overall exposure to THC was observed when IHL-42X was administered with food compared to fasted state. No serious adverse events were reported during the trial. TEAEs were generally observed to be mild to moderate. The proportion of subjects reporting at least one TEAE on the IHL-42X fasted period (57.4%) was similar to the dronabinol fasted period (52.1%). Fewer subjects reported TEAEs during the acetazolamide fasted treatment period (37.8%). Food did not have a substantial effect on the number of subjects reporting TEAEs for IHL-42X, with 57.4% fasted vs 58.8% fed.

We expect the outcomes of the BA/BE trial will serve as a bridging mechanism to the reference listed drugs, potentially facilitating regulatory approval via the FDA 505(b)(2) regulatory pathway.

Phase 2/3 Clinical Trial Investigating IHL-42X in Patients with OSA (the "RePOSA Study")

The RePOSA Study is a randomized, double-blind Phase 2/3 clinical trial, investigating the effect of IHL-42X in patients with OSA who are non-compliant, intolerant or naïve to PAP devices, such as CPAP, to determine the safety and efficacy of the drug candidate. The RePOSA study is being conducted in accordance with an IND cleared by the FDA.

The primary endpoint of the RePOSA Study is a change in AHI as compared to baseline. Key secondary endpoints include a change in patient sleep quality, sleep related impairments and fatigue. Other secondary endpoints include a change in oxygen saturation index, hypoxic burden and sleepiness. Exploratory endpoints are change in sleep architecture, cognitive function, blood pressure and other biomarkers identified for those at risk for OSA. The Phase 2 portion of the RePOSA Study was a four-week, dose ranging, three-arm (IHL-42X low dose (2.5 mg dronabinol + 125 mg acetazolamide), IHL-42X high dose (5 mg dronabinol + 250 mg acetazolamide) and placebo) trial designed to determine the optimal dose of IHL-42X based on safety and efficacy in OSA patients. The Phase 3 portion of the trial is a 52-week, four-arm (IHL-42X, dronabinol, acetazolamide and placebo), factorial trial that will compare the optimal dose of IHL-42X to the component APIs, dronabinol and acetazolamide, at equivalent doses, as well as placebo. The endpoints, inclusion criteria and study procedures are similar across both component studies, which is designed to streamline the transition process from Phase 2 to Phase 3.

The Phase 2 portion of the RePOSA Study was completed in July 2025 and demonstrated statistically and clinically significant improvements across multiple key endpoints for patients receiving IHL-42X compared to placebo, highlighting its potential to reduce OSA severity and enhance patient quality of life:

- *AHI*: The low-dose and high-dose IHL-42X groups achieved a statistically significant reduction in percent change in AHI from baseline compared to placebo ($p<0.05$), the primary measure of OSA severity. Maximum reductions in AHI were observed at up to 83% for the high-dose group and up to 79% for the low-dose group. Notably, 33.3% of patients in the low-dose group and 41.2% in the high-dose group achieved a greater than 30% reduction in AHI, while 13.9% (low-dose) and 14.7% (high-dose) experienced reductions exceeding 50% —demonstrating a strong therapeutic response in a substantial subset of the population.

- *Patient Global Impression of Change ("PGI-C") Sleep Related Impairment*: The low-dose IHL-42X group showed statistically significant improvement ($p<0.05$) in PGI-C, reflecting meaningful patient-perceived benefits.

- *PGI-C Fatigue*: Statistically significant improvement in PGI-C Fatigue was observed in the low-dose group, suggesting enhanced daytime alertness and reduced fatigue.

- *ODI*: Both low- and high-dose groups demonstrated statistically significant improvements in ODI, indicating better oxygenation during sleep.

- *Patient-Reported Outcomes*: IHL-42X led to clinically significant improvements in patient-reported outcome measures, including the Functional Outcomes of Sleep Questionnaire-10, Patient-Reported Outcomes Measurement Information System ("PROMIS") Sleep-Related Impairment 8a, PROMIS Fatigue 7a, and ESS in both low- and high-dose groups, demonstrating enhanced sleep quality, reduced daytime fatigue, and improved daily functioning for patients with OSA.

- *Polysomnography ("PSG") Metrics*: IHL-42X drastically improved objective sleep parameters as measured by PSG.

- *Wake After Sleep Onset:* Reduced by 29.8% in the high-dose arm, meaning patients spent less time awake during the night.

- *AHI During Supine Sleep*: Decreased by 30.3% in the high-dose arm, a critical improvement given supine sleep exacerbates apneic events.

- *Rapid Eye Movement ("REM")* Sleep: IHL-42X did not reduce the proportion of time spent in REM sleep, as measured in the PSGs. This distinguishes IHL-42X from many drugs that are approved for other sleep indications, which are known to reduce the amount of time spent in REM sleep. REM is an important stage of sleep that contributes to memory consolidation, emotional regulation and brain health.

IHL-42X was also observed to be well-tolerated across both low- and high-dose cohorts. No serious adverse events were reported during the treatment period, and TEAEs were infrequent, with the majority being mild or moderate in severity.

We are finalizing arrangements for our End of Phase 2 meeting with the FDA to get feedback on planned next steps, including a pivotal Phase 3 trial design.

General Anxiety Disorder

Generalized Anxiety Disorder

PSX-001	PsiGAD2	Ph2 Dose Comparison	• 94 patient, double-blind, safety and efficacy study • Dosing expected to begin 2026
	PsiGAD1	Proof of Concept Ph2 Trial	• 73 patient, double-blind, safety and efficacy study • Dosing completed Jan 2024

Generalized Anxiety Disorder or "GAD"

GAD is a chronic, often debilitating mental health disorder that affects approximately 10% of U.S. adults in their lifetimes. Symptoms of GAD include excessive anxiety and worry that persist for over six months, which can lead to significant impairments in social, occupational and other functioning, according to the National Institute of Mental Health. GAD is the most common anxiety disorder seen in primary care settings. An estimated 6.8 million adults are diagnosed with GAD in a given year in the United States.

Existing Treatments

There is a significant unmet need for new therapies in GAD. Current recommendations for GAD treatment include selective serotonin reuptake inhibitors ("SSRIs"), serotonin and noradrenaline reuptake inhibitors ("SNRIs"), and pregabalin as first-line options, with benzodiazepines as second-line options. GAD is also treated with psychotherapy alone or in combination with pharmacotherapies. However, these treatments have significant limitations, including a delayed onset of action, poor therapy adherence rates and substantial treatment side effects. In particular, the side effects associated with long-term use of these pharmacotherapies include emotional numbness, reduced positivity, weight gain, sexual dysfunction, and suicidal thoughts.

Psychedelic-Assisted Psychotherapy as a Treatment in Mental Health

Psychedelic-assisted psychotherapy may provide rapid, significant, and lasting benefits in treating unipolar depression, depression and anxiety symptoms associated with a terminal illness, and substance misuse. Psilocybin is a psychoactive molecule that occurs naturally in several genera of mushrooms, which primarily acts on the serotonin receptor system, and can modulate states of consciousness, cognition, perception, and mood.

Over the past decade, there has been an accumulating body of evidence that psilocybin may have beneficial effects in anxiety, depression, and other mental health conditions. In these studies, administration of psilocybin with psychological support from trained therapists provided a rapid reduction in anxiety and depression symptoms on the day of administration with generally maintained treatment effects at follow-up assessments many months later. These studies have shown psilocybin to be generally well-tolerated. Most studies do not report serious adverse events.

Two psilocybin third-party research programs for depression have received breakthrough therapy designation from the FDA. A small number of other psilocybin treatment development programs are underway globally. Should the results from any of these research programs be positive, approval of psilocybin-assisted psychotherapy as a prescription treatment could occur within the next five years.

PSX-001 for GAD

Our oral psilocybin lead candidate, PSX-001 is designed to be used in combination with psychological therapy from trained therapists that has been specifically designed for patients diagnosed with GAD. The therapy is designed to optimize patient safety and therapeutic outcomes in GAD with specific support before, during and after PSX-001 dosing sessions.

Our psilocybin treatment includes administration of two therapeutic doses of our drug candidate, PSX-001, with psychological support from trained therapists before, during and after each dose session. The psychotherapy comprises three distinct phases:

- Preparation psychotherapy: conducted following full enrollment and prior to the first dosing session with a key focus on explaining the concept of the trial and principles of the psychotherapy program to the patient, gaining and understanding of the patient's presenting problem(s), establishing a safety plan and dosing day plan and conducting experiential exercises.

- Dosing sessions: the patients will be administered PSX-001 orally. Prior to dosing, the safety and dosing day plan are reviewed. Once the patient is deemed ready for dosing the dose will be administered and the study team will provide support for navigating the experience.

- Integration psychotherapy: conducted following the dosing sessions, with a key focus on reviewing the dosing session, identifying and exploring experiential avoidance that emerged in the dosing session and values-based actions.

Phase 2 Exploratory Proof-of-Concept Clinical Trial

We conducted an Australian Phase 2 exploratory, proof-of-concept clinical trial, known as PsiGAD1, pursuant to an approval from the Human Research Ethics Committee.

The trial was a Phase 2 randomized triple-blind active-placebo-controlled trial to assess the safety and efficacy of psilocybin-assisted psychotherapy for GAD. Participants experienced two psilocybin or active-placebo dosing sessions and up to 11 non-drug, specialist psychotherapy sessions over a period of ten weeks.

Primary outcomes were safety, efficacy and tolerability, and secondary outcomes included quality of life, functional impairment, and comorbidities. Safety was assessed by monitoring adverse events including but not limited to liver function tests and scores on the Ultra Brief Checklist of Suicidality. Efficacy was assessed by comparing the change in HAM-A scores from baseline between the placebo and treatment group. Tolerability was assessed by comparing the proportion of participants who complete both dosing sessions in the placebo and treatment groups. Secondary endpoints were assessed by monitoring disability, comorbidity, productivity and quality of life using patient reported outcome measures.

In August 2025, we reported full results which demonstrated that the trial met its primary endpoint, supporting a clinical effect in the psilocybin treatment group compared to the placebo group. Statistically meaningful reductions in HAM-A scores were observed, with patients being treated with PSX-001 achieving an average 12.8-point reduction from baseline that was sustained for an 11-week follow-up period. A greater than 50% reduction in HAM-A scores was observed in 44.1% of patients receiving treatment, and 24% of patients receiving treatment achieved full disease remission, a number five times higher than placebo. Improvements were also observed in secondary endpoint measures including, (i) an average 7.4-point reduction in Generalized Anxiety Disorder 7-item scale scores, compared to a 3.5-point reduction for placebo ($p<0.0004$), (ii) a 6.0-point reduction in Sheehan Disability Scale scores, versus 1.3 points in the placebo group ($p<0.007$), (iii) a 3.9-point reduction in Patient Health Questionnaire-9 scores compared to just 0.3 points in the placebo group ($p<0.005$), and (iv) an improvement in Personal Wellbeing Index, also known as "quality of life," by an average of 10.6 points in the Psi-GAD group versus 2.7 points for placebo—a statistically significant difference ($p<0.002$). PSX-001, within the context of psychotherapy, was observed to be well-tolerated with no serious adverse events reported. The majority of TEAEs were transient, mild to moderate in nature and consistent with the expected pharmacological effects of psilocybin. Only one of the 73 participants withdrew from the trial during the 7-week treatment program. No signs of increased suicidality, psychosis, or prolonged psychological distress, concerns often cited with psychedelic treatments, were observed.

Next Steps in PSX-001 Clinical Development

The FDA has completed its review of and cleared our IND and gave its authorization for us to proceed with a Phase 2b clinical trial investigating PSX-001 in patients diagnosed with GAD. We are preparing to initiate this trial in 2026. This Phase 2b trial is expected to include approximately 94 subjects (including those currently treated with SSRIs who meet the study inclusion and exclusion criteria), evaluate change in the HAM-A anxiety score and other measures of efficacy and be conducted at multiple sites in the United States and the United Kingdom. The required review of the trial dossier by the UK's Medicines and Healthcare products Regulatory Agency ("MHRA") has also been completed. We have designed the follow-up Phase 2b clinical trial with the assistance of Clerkenwell Health, a UK-based contract research organization ("CRO") specializing in psychiatry and central nervous system treatments.

Development and Manufacture of Current Good Manufacturing Practices ("cGMP") Psilocybin Drug Product

We have engaged Ardena US LLC (formerly Catalent Pharma Solutions LLC) for the development and cGMP manufacture of Incannex's oral psilocybin drug candidate, PSX-001. This drug candidate will be used in our planned clinical trials.

Model Mental Health Clinic for Psychedelic-Assisted Psychotherapy

On June 17, 2025, we announced our 50:50 joint venture with Mind Medicine Australia ("MMA") to operate a psychedelic-assisted therapies services clinic in Melbourne, Australia. The new entity, MMA Clinics, represents a strategic advancement in our commercialization model. The joint venture will deliver a fully integrated suite of services including clinical operations, governance, medicine supply, medical oversight, and marketing support to a growing network of aligned authorized prescribers across Australia.

IHL-675A

Rheumatoid Arthritis

IHL-675A	**Phase 2**	**Ph2 Safety and Efficacy Study**	• 128 Patient, double-sided, safety and efficacy study • Strategy for IND opening clinical trial being developed
	Phase 1	**Ph1 Safety and PK Study**	• 36 patient, Phase 1 safety and PK study • Study completed

We are developing IHL-675A, an oral fixed-dose combination drug candidate that contains synthetic CBD and hydroxychloroquine sulphate ("HCQ") for the treatment of inflammatory conditions, with an initial focus on rheumatoid arthritis. Inflammatory conditions occur when the body's immune system attacks its own tissues and organs causing inflammation, pain, discomfort, and damage to the affected tissues.

IHL-675A comprises a combination of hydroxychloroquine sulphate, an approved anti-rheumatic drug, and synthetic CBD. HCQ is a disease modifying antirheumatic drug that regulates the activity of the immune system, which may be overactive in some conditions. HCQ can modify the underlying disease process, rather than simply treating the symptoms. In our in vitro studies and disease model experiments, we demonstrated that IHL-675A components, CBD and HCQ, act synergistically to inhibit production of key inflammatory cytokines as well as other key measures of disease severity. Based on the results of these experiments, we believe IHL-675A also has the potential for use in rheumatoid arthritis and other inflammatory conditions, such as acute respiratory distress syndrome, COPD, asthma, bronchitis and inflammatory bowel diseases, e.g. colitis and Crohn's disease. The rheumatoid arthritis market in the United States is growing rapidly with sales for rheumatoid arthritis treatments reaching US$25.37 billion in 2023. This market is expected to exceed US$31.58 billion by 2033.

Manufacturing Arrangements

We engaged Procaps for the manufacture of a specific oral, fixed-dose formulation of IHL-675A for our clinical trials.

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory disorder that can affect joints, skin, eyes, lungs, heart and blood vessels. As an autoimmune disorder, rheumatoid arthritis is caused by attacks to body tissues by one's immune system. Unlike the wear-and-tear damage caused by osteoarthritis, rheumatoid arthritis causes a painful swelling that can eventually result in bone erosion and joint deformity. HCQ is approved for treatment of rheumatoid arthritis in the form of hydroxychloroquine sulphate and marketed as Plaquenil and generic equivalents.

Phase 1 Clinical Trial for IHL-675A

We have completed a Phase 1 clinical trial to assess the safety and PK of IHL-675A in healthy volunteers, the results of which will form part of our planned FDA IND for rheumatoid arthritis, and potentially lung inflammation and inflammatory bowel disease. The key endpoints of the trial were the adverse events reported and the plasma levels of the APIs, CBD and HCQ, and their major metabolites over a 28-day period. Three cohorts of 12 participants (n = 36) received either IHL-675A, Epidiolex (CBD) or Plaquenil (HCQ) and the assessments were identical across the three arms of the trial. The trial measured the safety, tolerability, and PK profiles of IHL-675A compared to the reference listed drugs, Epidiolex (CBD) and Plaquenil (HCQ).

CBD and HCQ have historically been used independently in treating rheumatoid arthritis and other inflammatory disorders. However, as with any pharmaceuticals, there were risks involved when evaluating as a combination. Part of the strategy in the design of IHL-675A was that the combination of CBD with HCQ permitted a reduction in HCQ, which reduced the known risks associated with cumulative HCQ dose, without sacrificing efficacy. Results from the in vitro preclinical studies we conducted prior to the trial led to the hypothesis that a lower cumulative dose of HCQ, when combined with CBD, would also reduce disease severity scores in IHL-675A's target indications in humans. Nonetheless, there was always the potential for the two drugs to interact and exacerbate minor concerns that exist when used alone or lead to new safety concerns. Demonstrating that a combination drug containing CBD and HCQ had a similar safety profile to the component drugs was an important step in the development program and was a requirement set out by regulatory agencies. Safety assessments in this trial included cardiac monitoring via 24-hour Holter monitor and electrocardiogram, and blood biomarkers, serum liver enzyme levels, blood cell counts and biochemistry, monitoring of vital signs and mental health questionnaires.

The other component of this trial was monitoring the PK of the API of IHL-675A, CBD and HCQ, and comparing them to their respective reference listed drugs Epidiolex and Plaquenil. Study participants were dosed with either IHL-675A, Epidiolex or Plaquenil with equivalent amounts of the respective API. Blood samples were drawn at predetermined intervals over a 48-hour period, as well as seven, 14, 21 and 28 days post dosing, and analyzed for levels of CBD and HCQ as well as their major metabolites. For each molecule the maximum concentration ("Cmax"), time to maximum concentration ("Tmax") and AUCinf were determined. The PK parameters for IHL-675A, Epidiolex and Plaquenil were compared to determine whether the APIs in IHL-675A were bioequivalent to the reference listed drugs. Bioequivalence is an important component of the FDA 505(b)2 approval pathway that Incannex is targeting with IHL-675A.

Based on final available study results, IHL-675A was observed to be well-tolerated and both the APIs were bioavailable. The results of this study were published in a peer reviewed journal in 2025 (Mbogo, George Williams, et al. "An open-label phase I comparator-controlled clinical trial to assess tolerability and PKs of IHL-675A a fixed-dose combination of CBD plus hydroxychloroquine in healthy volunteers." Scientific Reports 15.1 (2025): 19357.).

CBD PK Results

Comparison of the average PK of CBD in participants administered IHL-675A compared to those administered Epidiolex revealed that the CBD was taken up from IHL-675A more quickly and reached a higher Cmax than from Epidiolex. The average Cmax of CBD from IHL-675A was 1.57 times higher than for Epidiolex. The Tmax was 26% faster for IHL-675A than Epidiolex. CBD administered in IHL-675A was also cleared more quickly than Epidiolex. The half-life (t1/2) of CBD from IHL-675A was 13% faster than Epidiolex. The AUCinf was similar for CBD administered as IHL-675A and Epidiolex. These patterns are trends at this point ($p > 0.05$). Similar results were observed for CBD metabolites 7-COOH-CBD and 7-OH-CBD.

Hydroxychloroquine PK Results

A comparison of the average PK of HCQ in participants administered IHL-675A compared to those administered Plaquenil revealed that HCQ was taken up more slowly from IHL-675A than from Plaquenil. However, the two drugs had a similar maximum plasma concentration. The Tmax for HCQ administered as IHL-675A was 46% slower than for Plaquenil. The hydroxychloroquine clearance and total exposure were similar for the two drugs. These patterns are trends at this point ($p > 0.05$). Plasma concentrations of hydroxychloroquine of HCQ metabolites desethylhydroxychloroquine, bisdesethylhydroxychloroquine and desethylchloroquine were detected only at low levels (<2 ng/mL) at all points in the study.

Tolerance

IHL-675A was observed to be well-tolerated, with no serious adverse events reported. The same number of treatment related TEAEs were reported for IHL-675A as for Epidiolex. Fewer treatment related TEAEs were reported for Plaquenil. All treatment related TEAEs were minor, with the exception of one incidence of moderate severity abdominal cramps, which was resolved soon after onset.

Interpretation of the Results from the Phase 1 Clinical Trial

Both APIs, CBD and HCQ, were absorbed from IHL-675A. Trends in PK profiles indicated that the uptake of CBD may be more rapid for IHL-675A than Epidiolex and uptake of HCQ may be slower for IHL-675A than Plaquenil. This could be advantageous for IHL-675A. Clinical evidence suggests that CBD provides immediate relief for inflammation and pain, whereas HCQ is a slower acting molecule and provides extended relief.

Phase 2 Clinical Trial Assessing the Effects of IHL-675A on Pain and Function in Patients with Rheumatoid Arthritis

We planned to conduct a Phase 2 clinical trial in Australia to assess the safety and efficacy of IHL-675A on pain and function in patients with rheumatoid arthritis. The trial was planned to include approximately 128 subjects who met the eligibility criteria and who upon enrollment would have been be randomized according to one of four arms: either IHL-675A, CBD alone, HCQ alone or placebo. The treatments were to be double blinded, meaning neither the investigators nor patients would have known which treatment an individual was receiving.

The primary endpoint for the Phase 2 trial was pain and function relative to baseline determined via the score on the RAPID3 assessment at 24 weeks. Per the protocol, participants were to record their pain and function outcomes daily, by completing questionnaires on pain, fatigue, joint stiffness and quality of life, using an electronic patient reported outcomes device (similar to completing a questionnaire on an electronic tablet). The participants also attended monthly visits at the clinical trial site, where blood tests, and physical examinations were to monitor additional safety and efficacy outcomes, including inflammatory biomarkers. This study was terminated prior to completion due to challenges with patient recruitment. Insufficient data was collected to make any conclusions on safety or efficacy of IHL-675A.

FDA Development

We have completed pre-IND meetings with the FDA to discuss the regulatory pathway for the development of IHL-675A for rheumatoid arthritis and inflammatory lung conditions in the United States and plan to initially open an IND for a Phase 2 trial for rheumatoid arthritis. The FDA provided guidance on the requirements for 505(b)(2) NDA submissions, as was proposed for IHL-675A, that rely on the FDA's finding of safety and/or effectiveness for listed drugs. In the pre-IND meeting for use of IHL-675A for treatment of rheumatoid arthritis, the FDA confirmed that no further non-clinical studies are needed to open an IND and provided guidance on the proposed clinical development plan for IHL-675A in rheumatoid arthritis. We are currently building on the feedback from FDA to design an IND opening study to investigate the safety and efficacy of IHL-675A in patients diagnosed with rheumatoid arthritis.

Secondary Assets and Additional Opportunities

While we are focusing our available resources on the continued development of our three lead drug candidates in the above indications, we are also exploring the development of 25 other secondary assets where we believe proof-of-concept has been established in either preclinical studies, Phase 1 clinical trials or Phase 2 clinical trials.

These secondary drug candidates target a variety of potentially high-value indications, including topical cannabinoid candidates for various skin conditions (estimated global market size US$1.8 billion in 2021), a chewable candidate for smoking cessation (estimated global market size US$28.9 billion in 2024 with estimated 9.2% CAGR) and a candidate for the treatment of opioid addiction (estimated global market size of $4.59 billion in 2021). We also believe our lead drug candidate, IHL-675A, may be able to treat inflammatory bowel disease (estimated U.S. market size US$21 billion in 2021) and pulmonary inflammatory diseases such as COPD and asthma (estimated combined U.S. market size US$36.7 billion in 2022).

Intellectual Property

We strive to protect the proprietary know-how and technology that we believe is important to our business, including seeking and maintaining patents intended to cover our drug candidates and compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business. In addition to pursuing patent protection for all our assets, we rely on unpatented trade secrets, know-how and other confidential information as well as proprietary technological innovation and expertise that are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants.

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of use, treatment and patient selection, formulations and manufacturing processes created or identified from our ongoing development of our drug candidates. We have two primary patent families in our lead drug candidates, including IHL-42X and IHL-675A. Our IHL-42X patent portfolio consists of 12 pending applications, and our IHL-675A patent portfolio consists of 16 pending applications. If granted, the patent applications in the IHL-42X patent portfolio are expected to expire as far out as 2041 to 2043, and the patent applications in the IHL-675A patent portfolio are expected to expire as far out as 2041 to 2042 (in each case, subject to any patent term disclaimers, adjustments, or extensions). Patent applications in each of these families are active in multiple jurisdictions, including, the United States, Australia, Canada, Colombia, European Patent Organization, Israel, New Zealand, and Japan. We are currently exploring potential patent protection strategies for our lead drug candidate, PSX-001.

Product/Technology	Number of Applications	Type of Patent Protection	Applicable jurisdictions
IHL-42X/Compositions and methods for the treatment of obstructive sleep apnoea (OSA)	12	Standard/utility	AU, CA, CO, EP, IL, JP, NZ, US
IHL-675A/Compositions and methods for the treatment of an inflammatory conditions	16	Standard/utility	AU, CA, CO, EP, IL, JP, NZ, US

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of use, treatment and patient selection, formulations and manufacturing processes created or identified from our ongoing development of our drug candidates. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing, or may in the future pursue, will issue as patents in any particular jurisdiction or whether the claims of any issued patents will be enforceable or provide sufficient protection from competitors.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by our issued patents, our pending patent applications or of patent applications we may file in the future. Moreover, we may have to participate in interference proceedings or derivation proceedings declared by the U.S. Patent and Trademark Office (“USPTO”), or similar proceedings outside the United States, to determine priority of invention.

We also own trademark registrations in Australia and the United States to distinguish and/or protect our brand, including our company name and logo.

Competition

We are targeting indications that have limited, inadequate, or no approved pharmaceutical treatment options. The table below outlines existing drugs and therapies used to treat the illnesses we aim to treat with our drug candidates and what believe are some of the associated pitfalls for patients with these existing drugs and therapies.

IHL Drug Candidate	Indication	Existing Drugs and Therapies	Existing Drug and Therapy Pitfalls
IHL-42X	Obstructive Sleep Apnea	- PAP device, dental device, surgery, Zepbound (tirzepatide)	- Noisy mechanical device worn during sleep. - Potential poor patient compliance due to discomfort. - Surgery is invasive -Tirzepatide is only approved for the treatment of obese OSA patients, and these obese patients represent approximately 33% of all OSA patients worldwide.
IHL-675A	Rheumatoid Arthritis	- Corticosteroids - DMARDS - Biologic agents	- High expense, significant side effect profiles. - Lack of efficacy or tolerability in certain patient cohorts.
IHL-675A	Lung Inflammation	- Corticosteroids - Ventilator	- Corticosteroids reduce immune system activity. - Ventilators are associated with a high rate of mortality.
IHL-675A	Inflammatory Bowel Disease	- Corticosteroids - Immune system suppressors (ISSs) - Biologic agents	- Corticosteroids can reduce immune system activity. - ISSs can damage the digestive tract lining.
PSX-001	Generalized Anxiety Disorder	- Antidepressants (SSRI/SNRI classes)	- Non-curative, poor side effect profile. - Some patients become treatment resistant.

However, the biopharmaceuticals industry is highly competitive. While we believe that our investigational synthetic cannabinoid-combination and psychedelic-assisted treatments represent a fundamental shift in the treatment paradigm relative to other treatments for these serious, chronic diseases, we face or may face potential competition from many different sources, including major pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and medical research organizations. Many of our competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Accordingly, our potential competitors may succeed in obtaining FDA or other regulatory approval for alternative or superior products. Any drug candidates that we successfully develop will compete with the standard of care and new therapies that may become available in the future.

Our competitors also may compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs. In addition, competitors may have higher name recognition and more extensive collaborative relationships. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of competitors. Smaller or emerging earlier stage companies may also prove to be significant competitors, particularly if they have collaborations with larger, established companies. Competitors in the OSA drug development space include Apnimed, Inc. and Mineralys Therapeutics. In particular, Apnimed's lead product candidate for OSA, AD109, has completed both Phase 2b and Phase 3 trials with topline results from its Phase 3 trials announced in May and July 2025. A number of companies are developing drug candidates intended for the treatment of GAD, including Cybin Inc., Otsuka Pharmaceutical Development & Commercialization, Inc., Sunovion Pharmaceuticals Inc., Mind Medicine Inc., and others. Competitors working on novel biopharmaceuticals focused on modulation of the serotonin and dopamine systems include Atai Life Sciences N.V., Compass Pathways plc, GH Research plc and others. There are a large number of existing pharmaceutical companies marketing drugs for the treatment of rheumatoid arthritis, including Pfizer Inc., Abbvie Inc., Amgen Inc., Novartis AG, Boehringer Ingelheim International GmbH, Eli Lilly and Company, F. Hoffmann-La Roche AG, Bristol Myers Squibb, AstraZeneca PLC, and Merck & Co., Inc. While we believe we have identified the potential for IHL-675A to more effectively reduce pain and increase quality of life in addition to or over these existing therapies and standard of care, IHL-675A will compete with or complement these other therapeutic options.

We are further aware that there are non-FDA approved cannabinoid preparations being made available from companies in the medical marijuana industry, which might compete with our drug candidates. While federal law prohibits the sale and distribution of most marijuana products not approved or authorized by FDA, the vast majority of states and the District of Columbia have legalized either cannabinoids or marijuana for either recreational or medical use, or both, and congressional efforts related to legalization of marijuana continue. Further, under the U.S. Farm Bill, enacted in late 2018, certain extracts and other material derived from cannabis are no longer controlled under the federal Controlled Substances Act of 1970 ("CSA"). However, the marketing of such products as a food, dietary supplement, or for medical purposes remains subject to FDA requirements. With respect to the marketing of CBD as a food or dietary supplement, in January 2023, the FDA concluded that the existing regulatory frameworks for foods and supplements were not appropriate for CBD products and denied three citizen petitions that had asked the agency to conduct rulemaking to allow the marketing of CBD products as dietary supplements. In addition, following receipt of a scientific and medical evaluation of marijuana from the Department of Health and Human Services ("HHS") recommending that the substance be moved from Schedule I to Schedule III, the U.S. Drug Enforcement Administration ("DEA") issued a notice of proposed rulemaking in May 2024 to effectuate such rescheduling. The public comment period on the proposed rule ended in mid-2024 and a public hearing on the proposal was scheduled by DEA for January 2025. The DEA hearing was postponed indefinitely by the presiding administrative law judge, and as of September 2025, the rulemaking appears stalled and marijuana remains a Schedule I substance. However, President Trump has expressed interest in rescheduling marijuana and his administration is continuing to evaluate the Schedule III proposal. Although our business is distinct from that of entities marketing FDA-unapproved marijuana and CBD-containing dietary supplements, future enacted legislation or federal government action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana or CBD products could increase competition for and adversely affect our ability to generate sales from our drug candidates.

We are also aware that a number of companies are increasing their efforts in discovery of non-traditional alternative compounds including psychedelics. A number of for-profit biotechnology companies or institutions are specifically pursuing the development of psilocybin to treat mental health illnesses. There are also other organizations or institutions evaluating the use of psilocybin in mental health and neurocognitive conditions. In August 2025, the DEA forwarded to HHS a citizen petition proposing that the agencies reschedule psilocybin from Schedule I to Schedule II under the federal CSA. Moving psilocybin to Schedule II would remove some of the onerous restrictions to which Schedule I controlled substances are subject, including limitations on manufacturing and research. In addition, there are various companies exploring other psychedelic compounds for the treatment of mental health and neurocognitive conditions.

Regulatory Authorities

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing, sales, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval and post-approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our drug candidates.

United States

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, which govern, among other things, pharmaceutical product quality, safety, efficacy, development, manufacturing, testing, packaging, labeling, storage, recordkeeping, advertising and promotion. In addition, controlled substances, like synthetic cannabidiol, THC, and psilocybin, as well as security, recordkeeping, storage, manufacturing, distribution, and importation, among other things, are regulated by the DEA.

The process of obtaining required authorizations from FDA or DEA and achieving and maintaining compliance with applicable laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with applicable FDA or other requirements may result in refusal to approve pending applications, imposition of clinical holds on ongoing trials, warning letters, civil or criminal penalties, recall or seizure of products, partial or total suspension of production or distribution, or withdrawal of the product from the market. FDA approval is required before any new drug, including any new indication for a previously approved drug, can be marketed in the United States.

The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive preclinical laboratory tests, potentially including animal studies, and formulation studies in accordance with the FDA's good laboratory practice ("GLP") regulations and other applicable regulations;

- submission to the FDA of an IND to support human clinical testing, which must become effective before human clinical trials may begin;

- approval from the DEA prior to commencement of any clinical trials in the United States that involve the use of Schedule I controlled substances, which would include our lead drug candidates, IHL-42X, PSX-001 and IHL- 675A;

- authorization from an independent institutional review board ("IRB") or ethics committee at each clinical trial site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice ("GCP") requirements, and other clinical-trial related regulations to establish the safety and efficacy of the investigational drug for each proposed indication;

- submission to the FDA of an NDA for marketing approval, including payment of application user fees;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced and tested to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- potential FDA audit of the clinical trial sites to assure compliance with IND regulations and GCP requirements and to assure the integrity of the clinical data submitted in support of the NDA;

- satisfactory completion of an FDA advisory committee review, if applicable; and

- FDA review and approval of the NDA/Biologics Licensing Application and DEA scheduling (for a controlled substance) prior to any commercial marketing or sale of the drug in the United States.

Clinical Development

Before any drug candidate may be tested in humans, it must undergo rigorous preclinical testing. Preclinical tests generally include laboratory evaluations of a drug candidate's chemical and biological activities, formulation and stability, as well as studies to evaluate toxicity and potential for other adverse events, which support subsequent clinical testing and rationale for therapeutic use.

The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended both the FDCA and Public Health Service Act to specify that nonclinical testing for drugs and biologics, respectively, may, but is not required to, include *in vivo* animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or *in vivo* animal tests.

The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. A 30-day waiting period after the submission of each IND is required before commencement of clinical testing in humans. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds may also be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance.

A clinical trial involves the administration of the investigational drug candidate to patients under the supervision of qualified investigators following GCP standards, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial (unless the consent requirement has been waived by an IRB) along with the requirement to ensure that the data and results reported from the clinical trials are credible and accurate. GCP requirements are meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. A clinical trial is conducted under a protocol that details, among other things, the objectives of the trial, the criteria for determining subject eligibility, the dosing plan, the parameters to be used in monitoring safety, the procedure for timely reporting of adverse events, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Further, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and re-approve the trial at least annually until completion. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health ("NIH"), for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's complementary policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement against clinical trial sponsors that fail to comply with such requirements.

For purposes of supporting NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1: Trials are initially conducted in a limited population of healthy human subjects to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution, and excretion of the investigational product, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to identify possible adverse side effects and safety risks and to evaluate the preliminary efficacy, optimal dosages and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The investigational product is administered to an expanded patient population in adequate and well-controlled studies to further evaluate dosage, clinical efficacy and safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the investigational product and to provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

- Phase 4: Additional trials may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, sponsors usually complete additional nonclinical studies and must also develop additional information about the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop and validate methods for testing the identity, strength, quality and purity of the final product. Moreover, appropriate packaging must be selected and tested, and stability studies must be conducted to assure product integrity and demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Congress recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. As of the time of this filing, there is uncertainty as to what the specific requirements pertaining to a diversity action plan may be. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor's proposed diversity action plan, it may delay trial initiation.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Application Submission and FDA Review

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with the information relating to the product's chemistry, manufacturing and controls and proposed labeling, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. The NDA must contain proof of the drug candidate's safety and substantial evidence of effectiveness for its proposed indication or indications in the form of relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. In particular, a marketing application must demonstrate that the manufacturing methods and quality controls used to produce the drug product are adequate to preserve the drug's identity, strength, quality, and purity. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. FDA approval of an NDA must be obtained before the corresponding drug may be marketed in the United States.

Under the Prescription Drug User Fee Act ("PDUFA"), each NDA submission is subject to a substantial application user fee, and the sponsor of an approved NDA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. The application user fee must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

The FDA reviews all NDAs submitted to determine if they are substantially complete before it accepts them for filing and may request additional information rather than accepting a submission for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt and must inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may refuse to file any submission that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the marketing application must be resubmitted with the additional information requested by the agency. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once an NDA is accepted for filing, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application meets the criteria for "priority review," six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification after the NDA has been accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

During the review process, the FDA reviews the NDA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued strength, quality, and purity. The FDA may refer any NDA, including applications for novel drug candidates which present difficult questions of safety or efficacy to an advisory committee to provide clinical insight on application review questions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews and evaluates the application and provides a recommendation as to whether it should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making final decisions on approval.

The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require the development of a risk evaluation and mitigation strategy ("REMS"), if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve an NDA without a REMS, if required.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent manufacture of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies as part of the review process and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Under the Pediatric Research Equity Act (the "PREA"), amendments to the FDCA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and efficacy of the drug candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires a sponsor that is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early-phase clinical trials or other clinical development programs.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the NDA addressing all of the deficiencies identified in the letter or withdraw the application. If and 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 response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Priority Review, and Breakthrough Therapy Designations

A sponsor may seek approval of its drug candidate under programs designed to accelerate the FDA's review and approval of new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept the sections and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. A fast track designated drug candidate may also qualify for accelerated approval (described below) or priority review, under which the FDA sets the target date for FDA action on an NDA at six months after the FDA accepts the application for filing.

Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after FDA accepts the application for filing.

In addition, a sponsor may seek FDA designation of its drug candidate as a breakthrough therapy if the drug candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review and regulatory staff in a proactive, collaborative, cross-disciplinary review, where appropriate. A drug designated as breakthrough therapy is also eligible for accelerated approval if the relevant criteria are met.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Fast track, priority review and breakthrough therapy designations do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or approval process.

Accelerated Approval

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when it has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity and mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug candidate's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the product. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs or biologics previously granted accelerated approval. Under such act's amendments to the FDCA, the FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for drug candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Post-Approval Requirements

After approval, the manufacturer and the approved drug product are subject to extensive continuing regulation by the FDA, which includes, among other things, obligations to manufacture the product in accordance with cGMP, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with FDA promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label uses") and limitations on industry-sponsored scientific and educational activities. The manufacturer and its products are also subject to similar post-approval requirements by regulatory authorities comparable to FDA in jurisdictions outside of the United States where the products are approved. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or a supplement to an NDA, which may require the applicant to develop additional data or conduct additional nonclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our drug candidates must meet applicable cGMP requirements to the FDA's or comparable international regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our candidates in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. 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 prescheduled or 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. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturing organizations ("CMOs") that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including voluntary recall and regulatory sanctions as described below.

Once an approval or clearance of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or other enforcement-related letters, or clinical holds on post-approval clinical trials;
- Refusal of the FDA to approve pending marketing applications or supplements to approved marketing authorizations, or suspension or revocation of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Injunctions or the imposition of civil or criminal penalties;
- Consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and/or
- Mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act ("DSCSA") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a ten-year period, which culminated in November 2023. However, the FDA announced a one-year "stabilization period" until November 2024, followed by trading partner-specific exemptions through specified dates in 2025, to accommodate additional time that trading partners in the pharmaceutical supply chain needed in order to fully implement DSCSA requirements for electronic drug tracing at the package level.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is often impossible to predict whether further legislative or regulatory changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes, if any, may be.

Regulation of Controlled Substances

Our drug candidates contain active substances derived from the cannabis plant and psilocybe mushrooms (or that are synthesized versions of such substances), which are classified as controlled substances, as defined in the CSA. The CSA and its implementing regulations establish a "closed system" of distribution for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, labeling, importation, exportation, disposal and other requirements under the oversight of the DEA, the federal agency responsible for regulating controlled substances. The DEA requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the applicable requirements to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules - Schedule I, II, III, IV, or V - with varying qualifications for listing in each schedule. Schedule I substances have a high potential for abuse, have no currently "accepted medical use" in treatment in the United States and lack accepted safety for use under medical supervision. They may be used only in federally approved research programs and may not be marketed or sold for dispensing to patients in the United States. THC, along with other substances derived from the cannabis plant, and psilocybin are Schedule I controlled substances under the CSA. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence and Schedule V substances the lowest relative risk for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III-V substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, and cannot be refilled.

Following FDA approval of a drug containing a Schedule I controlled substance, that substance must be rescheduled as a Schedule II, III, IV or V substance before it can be marketed. For example, products approved for medical use in the United States that contain THC, other cannabis plant extracts, or synthetic versions of such substances must be placed in one of Schedules II-V as approval by the FDA satisfies the "acceptable medical use" requirement. In November 2015, the Improving Regulatory Transparency for New Medical Therapies Act, which law removed uncertainty associated with timing of the DEA rescheduling process after FDA approval, was signed into law. Specifically, the law requires the DEA to issue an "interim final rule," pursuant to which a manufacturer may market its product within 90 days of FDA approval. The law also preserves the period of orphan marketing exclusivity for the full seven years such that this period only begins after DEA scheduling.

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substances utilized. For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes the registrant to handle controlled substances within specific schedules. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the registered manufacturer that produces them.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting, handling and compliance with other DEA regulatory requirements prior to issuing a controlled substance registration and periodically thereafter to ensure continued compliance. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer (not a dosage form manufacturer or a repacker/relabeler) for a Schedule I or II substance must be published in the Federal Register and remain open for 30 days to permit interested persons to submit comments, objections, or requests for a hearing. A copy of the notice of the Federal Register publication is forwarded by the DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance.

Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses and must obtain authorization to dispose of controlled substances. As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I or II substance a Schedule III, IV or V narcotic, a specially designated Schedule III non-narcotic, or a Schedule IV or V narcotic controlled in Schedule I or II by the Convention on Psychotropic Substances and submit import or export declarations for a Schedule III, IV or V non-narcotic.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. This limited aggregate amount of cannabis or psilocybin that the DEA allows to be produced in the United States each year is allocated among individual companies, which, in turn, must annually apply to the DEA for individual manufacturing and procurement quotas. The quotas apply equally to the manufacturing of the API and the production of dosage forms. The DEA may adjust aggregate production quotas and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

State governments also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances within the state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Following receipt of a scientific and medical evaluation of marijuana from HHS recommending that the substance be moved from Schedule I to Schedule III, the DEA issued a notice of proposed rulemaking in May 2024 to effectuate such rescheduling. The DEA scheduled a public hearing on the proposal for January 2025, but the hearing was postponed indefinitely by the presiding administrative law judge. As of September 2025, the rulemaking appears stalled and marijuana remains a Schedule I substance. However, President Trump has expressed interest in rescheduling marijuana and his administration is continuing to evaluate the Schedule III proposal.

In May 2024, the DEA published a notice of proposed rulemaking to reschedule marijuana (the cannabis plant and the various compounds, manufactures, salts, derivatives, mixtures, or preparations from it) from Schedule I to Schedule III. Additionally, in August 2025, the DEA forwarded to HHS a citizen petition proposing that the agencies reschedule psilocybin from Schedule I to Schedule II. After receiving the petition, HHS will conduct a scientific and medical review of the proposed rescheduling and supporting data and, once completed, will issue a recommendation to the DEA. However, it is uncertain whether DEA will issue a final rule to implement the rescheduling of either substance. Even if a final rule is issued in either case, it will likely be subject to continued political opposition or possible legal challenges in federal court.

We will be subject to DEA approval to conduct our clinical trials and manufacturing activities in the United States. All parties engaged for our projects, including but not limited to formulation development, manufacturing, preclinical and clinical research, involving controlled substances in the United States must have the appropriate registrations with and permits from the DEA as well as licenses from applicable state authorities. We may also decide to develop, manufacture or commercialize our drug candidates in additional countries. As a result, we will be subject to controlled substance laws and regulations from the Australian Therapeutic Goods Administration ("TGA"), Health Canada's Office of Controlled Substances, the Drugs & Firearms Unit (Home Office) of the National Drug Control System in the United Kingdom, and from other regulatory agencies in other countries where we develop, manufacture or commercialize, if approved, each drug asset in the future.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our drug candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the drug candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of the NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug candidate is eligible for the extension and the application for extension must be made 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. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Abbreviated NDAs for Generic Drugs

In 1984, with passage of the Hatch-Waxman Act, which established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. To obtain approval of a generic drug, an applicant must submit an Abbreviated New Drug Application ("ANDA") to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

In contrast, Section 505(b)(2) 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. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant as applicable.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, an NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (described below), in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for an NDA, 505(b)(2) NDA or supplement thereto if one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. The three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed by the original applicant;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

If the follow-on 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 follow-on application in question has been accepted for filing 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 after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

Other U.S. Healthcare Laws and Regulations

If our drug candidates are approved in the United States, we will have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. These laws include:

- The federal Anti-Kickback Statute (the "AKS") prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Centers for Medicare and Medicaid Services ("CMS") information related to payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, such physicians, non-physician healthcare practitioners, and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and international laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers.

The majority of state governments have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. State and international laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Due to the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Data Privacy and Security in the United States

We are subject to laws and regulations governing data privacy and the protection of personal information including health information in the United States. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy of health and personal information and federal and state consumer protections laws that regulate the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties. Our customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA and state health information privacy laws. If we knowingly obtain health information that is protected under HIPAA, called "protected health information," our customers or research collaborators may be subject to enforcement, and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

State laws protecting health and personal information are becoming increasingly stringent. For example, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. The California Consumer Privacy Act ("CCPA") mirrors a number of the key provisions of the General Data Protection Regulation ("GDPR") described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The California Consumer Rights Act ("CPRA") became effective on January 1, 2023, strengthening elements of the CCPA. Since passage of the CCPA, several other states (e.g., Connecticut, Colorado, Virginia, Delaware, Florida, Iowa, Montana, Oregon, Tennessee, Texas and Utah) have also enacted comprehensive consumer privacy laws that include key differences from California's law, further complicating compliance by industry and other stakeholders. Other states in the United States are considering privacy laws similar to the CCPA.

International Regulation

In addition to regulations in the United States, we are subject to a variety of international regulations governing clinical trials and the commercial sales and distribution of our drug candidates. Whether or not we obtain FDA approval for a drug product, we must obtain approval of such product by the comparable regulatory authorities of international countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. In addition, the requirements governing the conduct of clinical trials vary greatly from country to country.

European Union and United Kingdom

In the European Economic Area ("EEA"), which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining marketing authorization from the European Medicines Agency ("EMA"). Under EU regulatory systems, we must submit and obtain authorization for a clinical trial application in each member state in which we intend to conduct a clinical trial. When conducting clinical trials in the European Union, we must adhere to the provisions of the European Union Clinical Trials Directive (Directive 2001/20/EC) and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial. In 2014, the new Clinical Trials Regulation, (EU) No 536/2014, Clinical Trials Regulation, was adopted and it became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all of the EU Member States, as it repealed the Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation became applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation became applicable (i.e., beyond January 30, 2025), the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal" or Clinical Trial Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

After we have completed our clinical trials, we must obtain marketing authorization before we can market our drug products in the European Union. We may submit Marketing Authorization Applications ("MAA") under the centralized procedure or one of the national authorization procedures.

The EMA is a body of the European Union located in Amsterdam. The EMA is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. The EMA is involved in the scientific evaluation of medicines that fall within the scope of the centralized procedure. Like the FDA, there is a harmonization between regulators and the EMA may inspect and audit the development facilities, planned production facilities, clinical trial sites and laboratory facilities. Additionally, after the product is approved and marketed, the EMA uses various mechanisms for assuring that firms adhere to the terms and conditions of approval described in the application and that the product is manufactured in a consistent and controlled manner.

Centralized Procedure

The centralized procedure provides for the grant of a single marketing authorization by the European Commission, through the EMA, that is valid throughout the EEA. This marketing authorization process is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where either the product contains a new active substance indicated for the treatment of diseases other than those on the mandatory list, or where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation, or for which a centralized process is in the interest of public health.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), which is the EMA's committee that is responsible for human medicines, established at the EMA is responsible for conducting the assessment of whether a medicine meets the required quality, safety and efficacy requirements, and whether it has a positive benefit/risk profile. The maximum timeframe for the evaluation of a MAA is 210 days from the receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, which makes the final decision to grant a marketing authorization. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major interest to the public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe for assessment is 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard review timeframe for the centralized procedure if it determines that the MAA is no longer appropriate to conduct an accelerated assessment.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Under the above-described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

PRIME Scheme

EMA offers a scheme that is intended to reinforce early dialogue with, and regulatory support from, EMA in order to stimulate innovation, optimize development and enable accelerated assessment of PRIority MEdicines ("PRIME"). It is intended to build upon the scientific advice scheme and accelerated assessment procedure offered by EMA. The program is voluntary and eligibility criteria must be met for a medicine to qualify for PRIME.

The PRIME scheme is open to medicines under development and for which the applicant intends to apply for an initial marketing authorization application through the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods or therapy or improving existing ones. Applicants will typically be at the exploratory clinical trial phase of development and will have preliminary clinical evidence in patients to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need. In exceptional cases, applicants from the academic sector or small and medium sized enterprises may submit an eligibility request at an earlier stage of development if compelling nonclinical data in a relevant model provide early evidence of promising activity, and first in man studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.

If a medicine is selected for the PRIME scheme, EMA:

- appoints a rapporteur from the CHMP or from the Committee for Advanced Therapies to provide continuous support and to build up knowledge of the medicine in advance of the filing of a marketing authorization application;
- issues guidance on the applicant's overall development plan and regulatory strategy;
- organizes a kick-off meeting with the rapporteur and experts from relevant EMA committees and working groups;
- provides a dedicated EMA contact person; and
- provides scientific advice at key development milestones, involving additional stakeholders, such as health technology assessment bodies and patients, as needed.

Medicines that are selected for PRIME designation are also expected to benefit from EMA's accelerated assessment procedure at the time of application for marketing authorization. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Regulatory Data Protection in the European Union

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon grant of a marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No. 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents generic and biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a marketing authorization for a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity period. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EEA market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate ("SPC"), may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each EU Member State and the granted certificates are valid only in the granting Member State. An application must be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product, and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six-month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all EU Member States.

Controlled Drugs Classification

The position in the member states of the European Union is not harmonized. Member states have implemented the relevant United Nations Conventions (the Single Convention on Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971) into their national legislation, which has led to differences in how controlled substances are regulated in different countries of the European Union. It is therefore important to determine at a national level whether a substance is controlled and to comply with the applicable legal requirements.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product.

These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

In addition, all new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

Furthermore, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with applicable cGMP requirements, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products, are strictly regulated in the European Union under Directive 2001/83/EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the European Union, or in the United Kingdom under the Human Medicines Regulations 2021. Although general requirements for advertising and promotion of medicinal products are established under EU Directive 2001/83/EC as amended, the details are governed by regulations in each European Union member state (as well as Iceland, Norway and Liechtenstein) and can differ from one country to another.

United Kingdom

As of January 1, 2021, European Union law no longer directly applies in the United Kingdom. The United Kingdom has adopted existing European Union medicines regulation as standalone United Kingdom legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions.

The MHRA, is responsible for regulating the United Kingdom medicinal products market (Great Britain and Northern Ireland). An MHRA authorization must be obtained for each medicine to be marketed in the regions that comprise the United Kingdom. On January 1, 2021, all European Union marketing authorizations were converted to United Kingdom marketing authorizations subject to a manufacturer opt-out. The United Kingdom has introduced separate, specific processes for regulatory submissions and medicinal product marketing authorization, and MHRA guidance states that the United Kingdom will have the power to take into account marketing authorizations made under the European Union decentralized and mutual recognition procedures. On January 1, 2024, the MHRA launched the International Recognition Procedure ("IRP"), which provides for an expedited authorization procedure for products that have received positive marketing authorization decisions from trusted partner agencies, such as the EMA or the FDA. There are two available routes for assessment and recognition under the IRP:

- Recognition Route A - 60 days from validation of submission
    - Application must be based on a Reference Regulatory ("RR"), marketing authorization within the previous two years
    - Any significant differences from the quality dossier approved by the RR marketing authorization requires assessment under Recognition Route
    - Evidence of cGMP compliance for manufacturing sites should be provided with submission
    - None of the Recognition Route B criteria are met
- Recognition Route B - 110 days from validation of submission with one planned clock stop (up to 60 days) at day 70 to allow applicant to respond to issues identified during review
    - Application must be based on a RR marketing authorization within the previous 10 years
    - Criteria requiring Recognition Route B include, among other things:

      The RR marketing authorization granted a conditional or exceptional circumstances marketing authorization

      Additional manufacturing sites included in the application were not assessed by the RR marketing authorization or a manufacturing site is not cGMP certified

      There are substantial changes to the manufacturing process compared to the process approved by the RR marketing authorization

      Certain product types (e.g., advanced therapy medicinal products, orphan medicines, over-the-counter medicines)

      A RMP was not assessed under the RR marketing authorization

      The RR marketing authorization required one or more post-authorization safety studies for the product

      A companion diagnostic is necessary for correct use of the product

United Kingdom medicines legislation is subject to future regulatory change under the Medicines and Medical Devices Act 2021. This act sets out a framework for the adoption of medicines regulation.

Different rules apply in Northern Ireland following implementation of the Northern Ireland Protocol, under which European Union central marketing applications continue to apply there. However, in March 2023, the United Kingdom government and the European Commission reached agreement on a regulatory framework to replace the Northern Ireland Protocol, referred to as the Windsor Framework. Effective as of January 1, 2025, the Windsor Framework introduced new rules for the regulation of pharmaceutical products in the United Kingdom. Specifically, the MHRA is responsible for approving all medicines intended to be marketed in the United Kingdom (including Northern Ireland), and the EMA is no longer involved in approving medicines intended for sale in Northern Ireland.

The Trade and Cooperation Agreement, which sets forth a framework for partnership between the European Union and the United Kingdom, became effective as of January 1, 2021. The Trade and Cooperation Agreement between the European Union and the United Kingdom contains an Annex in relation to medicinal products with the objective of facilitating availability of medicines, promotion of public health and consumer protection in respect of medicinal products. The Annex provides for mutual recognition of cGMP inspections and certificates, meaning that manufacturing facilities do not need to undergo duplicate inspections for the two markets. The Annex establishes a Working Group on Medicinal Products to deal with matters under the Trade and Cooperation Agreement, facilitate co-operation and for the carrying out of technical discussions. It is expected that further bilateral discussions will continue with respect to regulatory areas not the subject of the Trade and Cooperation Agreement, including pharmacovigilance. The Trade and Cooperation Agreement also does not include reciprocal arrangements for the recognition of batch testing certification. However, the United Kingdom has listed approved countries, including the EEA which will enable United Kingdom importers and wholesales to recognize certain certification and regulatory standards. The European Commission has not adopted such recognition procedures.

It is expected that the establishment of a separate United Kingdom authorization system, albeit with transitional recognition procedures in the United Kingdom, will lead to additional regulatory costs. In addition, additional regulatory costs may be incurred with respect to the lack of mutual recognition of batch testing and related regulatory measures.

Data Privacy and Security in the European Union and the United Kingdom

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union's GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the European Union to the United States - the EU-US Data Privacy Framework, which provides individuals in the European Union with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised by the Court of Justice of the European Union ("CJEU") in its decision on a case known as *Schrems II*, which invalidated the previous EU-US Privacy Shield. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of European Union data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Following the United Kingdom's withdrawal from the European Union, the GDPR has been implemented in the United Kingdom (as the "UK GDPR"). The UK GDPR sits alongside the amended United Kingdom Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the UK GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or to monitor their behavior will be subject to the UK GDPR - the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of annual global revenues. On June 28, 2021, the European Commission issued a decision that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the European Union to the United Kingdom. In June of 2021, the European Commission issued a decision, which will sunset on June 27, 2025 without further action, that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom. The Parliament of the United Kingdom is currently considering the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, UK GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework.

Australia

In Australia, the relevant regulatory body responsible for the pharmaceutical industry is the TGA. As with the EMA and FDA there is a harmonization and collaboration between regulatory authorities. The TGA requires notification of all clinical trials via an electronic submission of a Clinical Trial Notification prior to commencing the clinical trial.

Third-Party Payer Coverage and Reimbursement

Although our drug candidates have not been commercialized for any indication, if they are approved for marketing, the commercial success of our drug candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels.

In the United States and internationally, sales of any product that we market in the future, and our ability to generate revenues from such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as government healthcare programs, such as Medicare and Medicaid, managed care providers, private insurance plans and other organizations.

Third-party payors are increasingly challenging the price of medical products and services and have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the cost-effectiveness of our drug candidates for formulary coverage and reimbursement, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Even with such studies, our drug candidates may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our drug candidates, in whole or in part.

In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our drug candidates that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted to potentially impact reimbursement rates for the drug candidates we are developing and may develop in the future and could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of drug candidates that, if successfully developed, we bring to market. Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our future business.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some Member States provide that products may be marketed only after a reimbursement price has been agreed, whereas other Member States may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but the competent authorities in such Member States monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required for medicinal products, and such efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by such countries. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Future legislation, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which reimbursement for the costs of our drug candidates and related treatments will be available in the United States and worldwide from government and health administration authorities, private health insurers and other organizations. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. The adoption of certain proposals could limit the prices we are able to charge for our drug candidates, the amounts of reimbursement available for our drug candidates, and limit the acceptance and availability of our drug candidates. Therefore, substantial uncertainty exists as to the reimbursement status of newly approved healthcare products by third-party payors.

Healthcare Reform and Potential Changes to Healthcare Laws

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA"), which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Legislative and regulatory changes under the ACA are possible, but it is unknown what form any such changes or any law would take and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Notably, the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94), which became law on December 20, 2019, includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 ("IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump administration, may impact the IRA drug price negotiation program. For example, the One Big Beautiful Bill Act, which President Trump signed into law in July 2025, modified the IRA's exclusion protecting orphan drugs designated for a single rare disease indication from required pricing negotiations by expanding it to apply to drugs designated for multiple rare diseases and by prohibiting Medicare price negotiations until seven years after an orphan drug, or 11 years after an orphan biologic, is approved for a non-orphan indication, which will significantly delay pricing negotiations for certain high-priced and widely used drugs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers ("PBMs"), and other members of the healthcare and pharmaceutical supply chain, an important decision that has led to more aggressive efforts by states in this area. The Federal Trade Commission ("FTC") in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Numerous PBM reforms are being considered in both the Senate and the House of Representatives, including diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical developers like us. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products, and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the European Union and the United Kingdom, similar political, economic and regulatory developments may affect our ability to profitably commercialize any of our drug candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments in the United Kingdom or at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most member states and the United Kingdom have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, including prescription pharmaceuticals.

Environmental, Health and Safety Regulation

We are subject to numerous federal, state and local environmental, health and safety ("EHS") laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our partner research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development and manufacturing activities may involve, from time to time, use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure that EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been material to date, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

United States Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities. Importantly, United States authorities deem most healthcare professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public healthcare and/or public education systems to be "foreign officials" under the FCPA. When we interact with foreign healthcare professionals and researchers in testing and marketing our products abroad, should any of our product candidates receive foreign regulatory approval in the future, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Inflation and Seasonality

Management believes inflation has not had a material impact on our operations or financial condition. Management further believes that our operations are not currently subject to seasonal influences due to our current lack of marketed products. Moreover, the targets of our drug candidates are not seasonal diseases. Accordingly, should any of our drug candidates be approved, management does not expect that our business would be subject to seasonal influences.

Manufacturing and Raw Materials

We have no manufacturing capabilities and, as noted above, are dependent on third parties for the cost effective manufacture and manufacturing process development of our drug candidates. Problems with third-party manufacturers or the manufacturing process as such may delay or jeopardize clinical trials and commercialization of our drug candidates. We or our third-party manufacturers may also experience delays due to the DEA's limitations on controlled substances discussed above.

Human Capital Resources

As of June 30, 2025, we had a total of twelve employees, all of which are full time. Of these employees, eight were employed in R&D and four were employed in general management and administration.

Each of our full-time employees has entered into an employment agreement with an unlimited term. We may only terminate the employment of any of our employees in accordance with the relevant employee contract of employment.

Our standard contract of employment for full-time employees provides that we can terminate the employment of an employee without notice for serious misconduct or with between one to six months' notice without cause (as set out in the relevant employee's contract of employment).

Information About Our Directors and Executive Officers

The following persons currently serve as our directors and executive officers:

Directors and Executive Officers	Position
Executive Officers	
Joel Latham	President, Chief Executive Officer and Director
Joseph Swan	Chief Financial Officer and Corporate Secretary
Lou Barbato, M.D.	Chief Medical Officer
Lekhram Changoer	Chief Technology Officer
Directors	
Troy Valentine	Director/Co-Founder, Alignment Capital Pty Ltd
Peter Widdows	Board Chair and Non-Executive Director, Youi Insurance Non-Executive Chaiman, Sunny Queens Australia
George Anastassov, M.D.	Doctor, Maxillofacial Surgery Services
Robert Clark	Vice President, Regulatory Affairs, Novo Nordisk A/S

Corporate Information

Incannex Healthcare Inc., was incorporated in Delaware in July 2023. On November 28, 2023, the redomiciliation of Incannex Healthcare Limited, an Australian corporation ("Incannex Australia"), was implemented under Australian law in accordance with the Scheme Implementation Deed, as amended and restated on September 13, 2023, between Incannex Australia and the Company. As a result of the redomiciliation, Incannex Australia became a wholly-owned subsidiary of Incannex Healthcare Inc., which is the new ultimate parent company of the subsidiaries listed in the section entitled "Organizational Structure" below.

Our principal office is located at Suite 105, 8 Century Circuit, Norwest 2153, NSW Australia and our telephone number is +61 409 840 786. We currently intend to relocate our principal office to Dubai sometime over the coming months. Our address on the Internet is www.incannex.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

The information on, or accessible through, our website is not part of this Annual Report. We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and amendments to those reports with the Securities and Exchange Commission ("SEC"). Our filings with the SEC are available free of charge on the SEC's website and on the "Investors" section of our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Organizational Structure

Below is a list of our significant wholly-owned subsidiaries, date of formation and jurisdiction. These subsidiaries were established to allow us to conduct commercial and clinical operations in Europe and the United States and expand our operations in Australia.

Subsidiary	Date of Formation/Acquisition	Jurisdiction
Incannex Healthcare Limited (now Incannex Healthcare Pty Ltd)	November 30, 2023	Victoria, Australia
Incannex Pty Ltd	November 30, 2018	Victoria, Australia
Psychennex Pty Ltd	November 20, 2020	Victoria, Australia
APIRx Pharmaceutical USA, LLC	August 5, 2022	Delaware
Clarion Clinics Group Pty Ltd	March 3, 2023	Victoria, Australia
Clarion Model Clinic Pty Ltd	March 2, 2023	Victoria, Australia
Psychennex Licensing and Franchising Pty Ltd	March 2, 2023	Victoria, Australia

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including our financial statements and related notes included elsewhere in this Annual Report and in the section titled "Management's Discussion and Analysis *of Financial Condition and Results of Operations" before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business, financial condition, results of operations and prospects.*

Summary Risk Factors

We are subject to a number of risks that if realized could affect our business, financial condition, results of operations and cash flows. As a clinical-stage biopharmaceutical company, certain elements of risk are inherent to our business. Accordingly, we encounter risks as part of the normal course of our business. Some of the more significant challenges and risks include the following:

Risks Related to Our Financial Condition and Capital Requirements

- We have a history of operating losses and may not achieve or maintain profitability in the future. Our ability to achieve profitability depends on the successful development of our drug candidates.
- We rely on R&D tax incentives to provide resources to conduct our business operations. If the amount of R&D tax incentives decreases, our results of operations and cash resources may be materially affected.
- We expect that we will need substantial additional funding to continue the development of our drug candidates. If we are unable to raise capital when needed or to do so on terms that are favorable to us, we could be forced to again delay, reduce or eliminate our development programs or commercialization efforts or reduce or scale back our operations.
- We may be unable to maintain the listing of our shares of common stock on the Nasdaq Capital Market.

Risks Related to the Development and Regulatory Approval of Our Drug Candidates

- If we do not obtain the necessary regulatory approvals, we will be unable to commercialize our drug candidates.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes. The results of earlier preclinical studies or trials may not be predictive of the results of later clinical trials. Clinical trials are difficult to design and implement, and any of our clinical trials could produce unsuccessful results or fail at any stage in the process.
- Topline, interim or preliminary data from our trials may not be representative of final results.
- We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

Risks Related to Commercialization of Our Drug Candidates

- Even if we receive marketing approval of a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

- Our drug candidates will be subject to controlled substance laws and regulations. Failure to receive necessary approvals may delay the launch of our drug candidates and failure to comply with these laws and regulations may adversely affect the results of our business operations.

- The production and sale of our drug candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may have consequences for the legality of investments from international jurisdictions.

- The markets for the target indications for our drug candidates are competitive and certain of our competitors have more advanced candidates in their respective pipelines. While we believe our drug candidates have expected benefits that may overcome these advantages, our efforts to prevail as compared to our competitors may not be successful.

Risks Related to Our Business Operations

- Our R&D efforts will be jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

- Our business is subject to complex and evolving U.S. federal and state, and international laws and regulations, imposing obligations on how we collect, use, disclose, store and process personal data. We are also subject to information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal data. The actual or perceived failure by us or vendors to comply with these laws and regulations, policies and contractual obligations could harm our business and/or reputation, and subject us to significant fines and liability.

- We are exposed to fluctuations in exchange rates which may adversely affect our operating results.

Risks Related to Intellectual Property

- Our success depends on our ability to protect our intellectual property and our proprietary technology, and we may not be able to protect our intellectual property rights throughout the world.

- If we are unable to obtain and maintain patent protection for any drug candidates, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any drug candidates we may develop, and our technology may be adversely affected. We are currently exploring a patent protection strategy for our candidate PSX-001. If these efforts are unsuccessful, we may not be able to obtain intellectual property protection for this candidate.

Risks Related to Investing in Our Securities

- The price of our common stock has been and may continue to be highly volatile, which may make it difficult for stockholders to sell our common stock when desired or at attractive prices.

- Our common stock could be further diluted as the result of the issuance of additional shares of common stock, warrants, options or other convertible securities. Future sales of shares of our common stock in the public market, or the perception that such sales could occur, has in the past and could in the future cause our stock price to fall.

- We are and may continue to be subject to short-selling strategies.

Risks Related to Our Financial Condition and Capital Requirements

We have a history of operating losses and may not achieve or maintain profitability in the future. Our ability to achieve profitability depends on the successful development of our drug candidates.

We are a clinical-stage biopharmaceutical company, and the success of our drug candidates is therefore uncertain. None of our drug candidates has been approved for commercial sale in any jurisdiction, and we expect it to be several years before any of them may be approved, if ever. We will not be able to generate product revenue unless and until our drug candidates, alone or with future partners, successfully complete clinical trials, receive regulatory approval and are successfully commercialized. Although we have entered into a joint venture with respect to PSX-001 and may again seek to obtain revenue from collaboration or licensing agreements with third parties, these agreements and joint ventures may not provide us with material or ongoing revenues.

We have experienced significant recurring operating losses and negative cash flows from operating activities since inception. For example, for the fiscal years ended June 2024 and 2025, we had total comprehensive losses of $46.7 million and $18.5 million, respectively, and we had negative cash flows from operating activities of $12.5 million and $5.8 million, respectively. As of June 30, 2025, we had accumulated comprehensive losses of $157.6 million.

We expect to continue to incur losses from operations for the foreseeable future and expect the costs of drug development to increase in the future as more patients are recruited for our clinical trials. Because of the numerous risks and uncertainties associated with the research, development and manufacturing of our drug candidates, we may experience larger than expected future losses and, particularly if we fail to successfully develop one or more of our drug candidates, we may never become profitable or if we become profitable, main profitability.

We rely on R&D tax incentives to provide resources to conduct our business operations. If the amount of R&D tax incentives decreases, our results of operations and cash resources may be materially affected.

In fiscal 2024 and 2025, respectively, we received $1.7 million and $11.4 million in R&D tax incentives from the Australian government as a result of the clinical trials activities conducted in Australia. In Australia, entities are entitled to either (i) a 48.5% refundable tax offset for eligible companies with an aggregated turnover of less than A$20 million per annum or (ii) a non-refundable 38.5% tax offset for all other eligible companies. Our aggregated turnover is less than A$20 million and not controlled by one or more income tax exempt entities. We anticipate being entitled to a claim of 48.5% refundable tax offset for costs relating to eligible R&D activities during the year. Such incentives provide material resources to conduct our business operations.

However, we have no control on the rate of R&D tax incentives or on the conditions to receive these incentives. Certain R&D costs that we incur in the future may be ineligible for cash incentives. For example, costs incurred outside Australia in connection with our future clinical trials are generally not eligible for cash incentives. In addition, the federal government of Australia and the Australian Taxation Office ("ATO") could change the rules of the regulatory regime or amend past tax returns and, as a result, amounts paid to us may become repayable to the ATO, including the amount of tax incentives in respect to our fiscal year ended June 30, 2024, which is included as current receivables in our consolidated financial statements. Any rule changes made to reduce the amount we are able to claim currently or in the future and any retrospective changes that reduce the incentives that we have claimed in past tax years could harm our business, financial condition and results of operations.

We expect that we will need substantial additional funding to continue the development of our drug candidates. If we are unable to raise capital when needed or to do so on terms that are favorable to us, we could again be forced to delay, reduce or eliminate our development programs or commercialization efforts or reduce or scale back our operations.

To date, we have not generated any revenue from product sales to customers and none of our drug candidates have been approved for commercialization by any regulatory body. We do not expect to receive any material revenue from any drug candidates that we develop, including IHL-42X, PSX-001, and IHL-675A, unless and until we obtain regulatory approval for these candidates. Our future net losses will depend, in large part, on our success in developing our drug candidates. Correspondingly, the amount of our future net losses will depend, in part, on the rate of our future expenditures.

We anticipate that our expenses will increase substantially for the foreseeable future if, and as, we:

- continue our research and preclinical and clinical development of our drug candidates;
- expand the scope of our current proposed clinical studies for our drug candidates;
- initiate additional preclinical, clinical or other studies for our drug candidates;
- change or add manufacturers or suppliers;
- seek regulatory and marketing approvals for our drug candidates that successfully complete clinical studies;
- seek to identify and validate additional drug candidates;
- acquire or in-license other drug candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a publicly quoted company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

We will need to obtain additional funding in connection with the further development of our drug candidates.

Any additional equity fundraising in the capital markets may be dilutive for our stockholders. To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, completing acquisitions or declaring or paying dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our drug candidates or future revenue streams or grant licenses on terms that are not favorable to us.

As noted above, we also have historically received, and may receive in the future, tax incentives for R&D. These tax incentives have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth above this section in the risk factor titled "*We rely on R&D tax incentives to provide resources to conduct our business operations. If the amount of R&D tax incentives decreases our business operations may be materially affected.*" Although we might apply for additional tax incentives, government contracts or grants in the future, we cannot assure that we will be successful in obtaining these for any drug candidates or programs.

Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. As such, additional financing may not be available to us when needed, on acceptable terms, or at all. In addition, disruptions and volatility in recent years in the financial markets have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. During the past year, we delayed the development of our drug candidate IHL-675A due to a lack of financial resources. If we are again unable to secure sufficient capital to fund our operations, then we may be required to again delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Moreover, we could also have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us.

In addition, securing additional financing requires a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our drug candidates. Any of these circumstances or the failure to obtain funding, when and as needed, and on favorable terms would adversely affect our business, results of operations, R&D efforts, prospects and potentially the value of our common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC require annual management assessments of the effectiveness of our internal control over financial reporting. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud.

Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Our internal controls over financial reporting may not prevent or detect all misstatements because of inherent limitations. Additionally, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with our policies and procedures.

Any failure to design and implement an effective system of internal controls may reveal deficiencies in our internal controls that are deemed to be material weaknesses. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Management has concluded that we did not maintain effective disclosure controls and procedures due to the material weakness in internal control over financial reporting which existed as of June 30, 2025, relating to the documentation of accounting policies and procedures, particularly relating to the correct application of complex accounting measures. The measures that we are undertaking to remediate the material weakness in internal control over financial reporting have and will include: (i) hiring qualified internal control personnel or consultants to manage the implementation of internal control policies, procedures and improvement of the internal audit function, as applicable; (ii) developing and implementing written policies and procedures for accounting and financial reporting that meet the standards applied to public companies listed in the United States; and (iii) conducting internal control training to management, key operations personnel and the accounting department, so that management and relevant personnel understand the requirements and elements of internal control over financial reporting mandated by the U.S. securities laws.

This material weakness will not be considered remediated until we have completed implementing the necessary additional applicable controls and operate with these controls for a sufficient period of time to allow management and our auditors to conclude that these controls are operating effectively.

While we believe we have made progress in accordance with our remediation plan, we cannot determine when our remediation plan will be fully completed, and we cannot provide any assurance that these remediation efforts will be successful or that our internal control over financial reporting will be effective as a result of these efforts. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

If we are unable to maintain or regain compliance with the requirements of the Nasdaq Stock Market ("Nasdaq"), this could result in the delisting of our common stock. A delisting of our common stock from Nasdaq could adversely affect our ability to raise additional capital through the public or private sale of equity securities, the ability of investors to dispose shares of our common stock or obtain accurate quotations as to the market value of our common stock and the price and value of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. The requirements for all Nasdaq market tiers, including the Nasdaq Capital Market, impose a minimum $1.00 per share bid price requirement. To comply with this requirement, the closing price for our common stock must not fall below $1.00 for a 30 consecutive trading day period. Since early March of 2025, the closing bid price for our common stock has consistently been below $1.00 per share, and on April 23, 2025, we received a written notice (the "Notice") from the Listing Qualifications Department (the "Staff") of Nasdaq notifying the us that, because the closing bid price for our common stock, closed below $1.00 per share for 30 consecutive trading days, we no longer met the minimum bid price requirement for continued inclusion on Nasdaq pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). The Staff provided us with an initial grace period expiring on October 20, 2025. To regain compliance the closing price of our common stock must exceed a minimum of $1.00 per share for at least 10 consecutive trading days and potentially 20 consecutive trading days in the discretion of the Staff. On or following October 20, 2025, the Staff may provide us with an additional 180-day compliance period in which we may seek to regain compliance with the Minium Bid Price Rule, but there can be no guarantee that such an additional compliance period will be granted or that we will regain compliance within this additional 180-day compliance period.

In the event of a delisting notice, we would typically have an opportunity to appeal such decision to the Nasdaq Hearing Panel or take other measures to preserve the listing of our common stock on Nasdaq, but these measures and any appeal may not be successful. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock.

In the event we are delisted from Nasdaq, the only established trading market for our common stock would be eliminated, and we would be forced to list our shares on the OTC Markets or another quotation medium, depending on our ability to meet the specific listing requirements of those quotation systems. As a result, an investor would likely find it more difficult to trade or obtain accurate price quotations for our shares. Delisting would likely also reduce the visibility, liquidity, and value of our common stock, reduce institutional investor interest in our company, and may increase the volatility of our common stock. Delisting could also cause a loss of confidence of potential industry partners, lenders, and employees, which could further harm our business and our future prospects.

Unless our common stock is listed on a national securities exchange, such as Nasdaq, our common stock may also be subject to the regulations and restrictions regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. These penny stock requirements and regulations could severely limit the liquidity of our common stock in the secondary market because fewer brokers or dealers would likely to be willing to undertake related compliance activities to trade in our common stock. If our common stock is not listed on a national securities exchange, the rules and restrictions regarding penny stock transactions may limit an investor's ability to sell to a third-party and our trading activity in the secondary market may be reduced. Delisting from Nasdaq would also likely limit the range and attractiveness of strategic alternatives that we are able to consider, adversely affect our ability to raise additional capital through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities, and/or negatively affect the value and liquidity of our common stock.

We cannot guarantee that our share repurchase program will be utilized to the full value approved, if at all, or that it will enhance long-term stockholder value. Any repurchases we consummate could increase the volatility of the price of our common stock and could have a negative impact on our available cash balance.

Our board of directors authorized a share repurchase program pursuant to which we may repurchase up to $20 million of our common stock. The manner, timing and amount of any share repurchases may fluctuate and will be determined by us based on a variety of factors, including the market price of our common stock, our priorities for the use of cash to support our business operations and plans, general business and market conditions, tax laws, and alternative investment opportunities. The share repurchase program authorization does not obligate us to acquire any specific number or dollar value of shares. Further, our share repurchases could have an impact on our share trading prices, increase the volatility of the price of our common stock, or reduce our available cash balance such that we will be required to seek financing to support our operations. Our share repurchase program may be modified, suspended, or terminated at any time, which may result in a decrease in the trading prices of our common stock. Even if our share repurchase program is fully implemented, it may not enhance long-term stockholder value. Additionally, repurchases are subject to the 1% share repurchase excise tax enacted by the IRA, which may be offset by shares newly issued during that fiscal year. We have and will continue to take the share repurchase excise tax into account with respect to our decisions to repurchase shares.

Risks Related to the Development and Regulatory Approval of Our Drug Candidates

If we do not obtain the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

We are not permitted to market our drug candidates in the United States until we receive FDA approval of an NDA, or in any other jurisdiction until we receive the requisite approval from the respective regulatory authorities in such jurisdictions. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the drug candidate. The standards that the FDA and its international counterparts use when regulating companies such as ours are not always applied predictably or uniformly and can change. Any analysis we perform of data from chemistry, manufacturing and controls, preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also again encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or international regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenues from the particular drug candidate for which we are seeking approval.

Furthermore, obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a drug candidate, similar international regulatory authorities must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for drug candidates is also subject to approval. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full target market potential of our drug candidates will be harmed.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes. The results of earlier preclinical studies or trials may not be predictive of the results of later clinical trials. Clinical trials are difficult to design and implement, and any of our clinical trials could produce unsuccessful results or fail at any stage in the process.

Clinical trials conducted on humans are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the process. Additionally, any positive results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the results of later stage clinical trials, such that drug candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and early-stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier phases of the trials. Therefore, the results of any ongoing or future clinical trials we conduct may not be successful.

Our ongoing or planned clinical trials may also again be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable international regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay in reaching, or failure to reach, agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable volunteers or patients to participate in a trial such as occurred in our prior trial investigating IHL-675A;
- delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis;
- failure of trial participants to complete a trial or return for post-treatment follow-up;
- inability to monitor trial participants adequately during or after treatment;
- clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable international regulatory authority due to observed safety findings or other reasons;
- negative or inconclusive results in our clinical trials, and our decision to or regulators' requirement that we conduct additional non-clinical studies, clinical trials or that we abandon one or more of our product development programs; or
- inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials.

We rely and plan to continue to rely on third-party CROs, CMOs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have and expect that we will continue to have agreements in place with CROs and CMOs governing their contracted activities and conduct, we have limited influence over their actual performance. As a result, we ultimately do not and will not have control over a CRO's or CMO's compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements or its adherence to agreed-upon time schedules and deadlines, and a future CRO's or CMO's failure to perform those obligations could subject any of our clinical trials to delays or failure.

Further, we may also again encounter delays if a clinical trial is suspended or terminated by us, by any IRB or ethics committee, or by the FDA, EMA, MHRA, or other regulatory authority. A suspension or termination may occur due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA, MHRA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate or changes in governmental regulations or administrative actions. We cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our drug candidates.

If we experience additional delays in the commencement or completion of, or suspension or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be harmed, and our ability to generate product revenues from the drug candidate may be delayed or eliminated. In addition, any additional delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize regulatory approval of our drug candidates and our ability to commence sales and generate revenues. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects.

We have in the past and may in the future find it difficult to enroll patients in our clinical trials and patients could discontinue their participation in our clinical trials, which could delay or prevent our current and any future clinical trials of our drug candidates and make those trials more expensive to undertake.

The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of research participants who remain in the trial until its conclusion. Our Phase 2 clinical trial in Australia to assess the safety and efficacy of IHL-675A was terminated prior to completion due to challenges with patient recruitment. Insufficient data was collected to make any conclusions on safety or efficacy of IHL-675A We may again encounter delays in enrolling, or be unable to enroll, a sufficient number of individuals to complete any of our clinical trials, and even once enrolled we may again be unable to retain a sufficient number of participants to complete any of our trials. Subject enrollment and retention in clinical trials depends on many factors, including:

- the eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the proximity of potential subjects to clinical sites;
- the existing body of safety and efficacy data with respect to the drug candidate;
- side effects or adverse events caused by our drug candidates;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies;
- competing clinical trials being conducted by other companies or institutions;
- the risk that participants enrolled in clinical trials will drop out of the trials before completion;
- the occurrence of epidemics or pandemics and other similar events; and
- the operational efficiency of trial sites, including sufficient staffing.

In addition, the U.S. Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. We or our licensing partners must submit a diversity action plan to the FDA by the time a Phase 3 trial, or pivotal study, protocol is submitted to the agency for review, unless we or our licensing partners are able to obtain a waiver for some or all of the requirements for a diversity action plan. Initiation of such trials may be delayed if the FDA objects to a proposed diversity action plans for any future Phase 3 trial of our drug candidates, and we or our licensing partners may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

Furthermore, any negative results we may report in clinical trials may make it difficult or impossible to recruit and retain subjects in other clinical trials of that same drug candidate. Delays or failures in planned enrollment or retention of clinical trial subjects may again result in increased costs or program delays, which could have a harmful effect on our ability to develop a drug candidate or could render further development impossible.

The ongoing and future clinical trials of our drug candidates may not show sufficient safety and efficacy to obtain requisite regulatory approvals for commercial sale.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale in any jurisdiction. Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety and to understand the drug candidate's side effects at various doses and schedules. Further, Phase 3 clinical trials may not show sufficient safety or efficacy to obtain regulatory approval for marketing. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could require that the clinical trial be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the drug candidate involved, as well as other factors. If we suffer any additional significant delays, quality issues, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue the development of our drug candidates or generate revenue and our business may be severely harmed.

Our drug candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit their commercial potential, or result in significant negative consequences following marketing approval, if marketing approval is obtained.

Undesirable side effects caused by our drug candidates could cause us or the FDA, EMA, MHRA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities of our drug candidates. In the event that our clinical trials produce undesirable side effects, our trials could be suspended or terminated and the FDA, EMA or MHRA or comparable international regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. In addition to this, any drug-candidate-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our drug candidates receive marketing approval, and we or others identify undesirable side effects caused by these drug candidates (or any other similar products) after this approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of our drug candidates;
- regulatory authorities may require the addition of labeling statements, specific warnings or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, or we may be required to implement a REMS in the United States or a comparable risk mitigation plan in other jurisdictions to ensure that the benefits of the drug candidate outweigh the risks;
- we may be required to change the way the drug candidates are distributed or administered, or change the labeling of the drug candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable international regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidate;
- we may decide to recall or withdraw drug candidates from the marketplace after they are approved;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; and
- our reputation may suffer.

In addition, adverse side effects caused by any drugs that may be similar in nature to our drug candidates could delay or prevent regulatory approval of our drug candidates, limit the commercial profile of an approved label for our drug candidates, or result in significant negative consequences for our drug candidates following and assuming marketing authorization.

If a drug candidate is approved, any of these events could prevent us from achieving or maintaining market acceptance of the affected drug candidates and could substantially increase the costs of commercializing our drug candidates, and significantly impact our or a partner's ability to successfully commercialize drug candidates and generate revenues.

Topline, interim or preliminary data from our trials may not be representative of final results.

From time to time, we have published and may again publish or report topline, interim or preliminary data from our clinical trials. Topline, interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Topline, interim or preliminary 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 the final data are available.

Because we rely on third-party manufacturing and supply partners, our supply of R&D, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality. If we are able to commercialize any of our drug candidates, our third-party manufacturers may be unable to scale or fail to comply with their supply obligations to us.

We do not currently have the ability to manufacture our drug candidates without the use of third parties. We rely, and expect to continue to rely, on third-party supply and manufacturing partners, such as Procaps and Ardena, to manufacture and supply the materials for our R&D and preclinical and clinical trial supplies, including those needed for our lead drug candidates. This reliance on third-party manufacturers may expose us to more risk than if we were to manufacture our drug candidates ourselves. We do not control the manufacturing processes of our CMOs, and we are dependent on these CMOs for the production of our drug candidates in accordance with cGMP, DEA and other relevant applicable regulations.

In complying with the manufacturing regulations of the FDA, DEA and other comparable international regulatory authorities, we and our third-party manufacturers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the drug candidates meet applicable specifications and other regulatory requirements. As previously discussed, our drug candidates are also subject to more stringent regulation and quotas due to the current status of certain ingredients as Schedule I controlled substances pursuant to the CSA and applicable DEA regulations. If either we or our CMOs fail to comply with any of these requirements, we may be subject to regulatory enforcement action, including the seizure of drug candidates and shutting down of production.

We or our third-party manufacturers may also encounter shortages in the raw materials or APIs necessary to produce our drug candidates in the quantities needed for our clinical trials or, if our drug candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of demands from competing businesses, quota restrictions, capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or APIs by our competitors or others. The failure by us or our third-party manufacturers to obtain the raw materials or APIs necessary to manufacture sufficient quantities of our drug candidates would likely delay and significantly harm our clinical trials and related R&D efforts.

Our third-party manufacturers are subject to inspection and approval by regulatory authorities, including before we can commence the manufacture and sale of any of our drug candidates, and thereafter are subject to ongoing inspection from time to time. Our third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements in or outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of notices of inspectional observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or commercial products (if any), operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and, as applicable, commercialize our drug candidates could suffer significant interruptions.

If our candidates are approved, we would likely need to rapidly scale our manufacturing capabilities, including any capability we may have through our CMOs. If our CMOs fail to scale as needed, our commercialization efforts, or the commercialization efforts of any partner we may have, would likely be impaired.

Any disruption effecting our CMOs, such as a fire, natural disaster, labor shortage or strike, supply chain disruption, pandemic, accident, political conflict, hazard, theft, attack or vandalism at our CMOs, or any impacts on our CMOs due to such matters, could significantly interrupt our R&D capability, and, as applicable, our or a partner's commercialization efforts. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we would have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to CMOs occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our drug candidates and any of our drugs that may obtain approval. Any such changes could require the conduct of bridging studies and regulatory approval before we can use any materials produced at new facilities or under new processes in clinical trials or, for any candidates reaching approval, in our commercial supply. For these reasons, a significant disruptive event of any CMOs could have drastic consequences, including placing our ability to continue operations at risk.

If our third-party manufacturers fail to provide supplies of our drugs or drug candidates when and as needed for any reason, our business, results of operations and prospects may be materially and adversely harmed.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We are, and may continue to be, reliant on other parties for the successful development and commercialization of many of our drug candidates. We rely upon CROs and clinical investigators for the conduct of our clinical trials and may rely upon contract laboratories for execution of our preclinical studies, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs or collaboration partners does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our nonclinical studies in accordance with GLP and requirements with respect to animal welfare. We and our CROs or collaboration or licensing partners are required to comply with GCP, which are regulations and guidelines enforced by the FDA, EMA, MHRA and comparable international regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP regulations, and other regulations applicable to clinical trials and investigational drug products, through periodic inspections of trial sponsors, CROs, principal investigators and trial sites. If we or any of our CROs or partners fail to comply with applicable GCP regulations or other clinical trial regulations, the data generated in our clinical trials may be deemed unreliable and the FDA, EMA, MHPA or comparable international regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that upon inspection by a given regulatory authority that such regulatory authority will determine that any of our clinical trials comply with GCP requirements or other applicable regulations. In addition, our clinical trials must be conducted with product manufactured under cGMP requirements. Failure to comply with these regulations may require us to repeat nonclinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs and other contractors or collaborators are not our employees, and except for remedies available to us under such agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going or future clinical or nonclinical programs, as applicable. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, then our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Entering into arrangements with alternative CROs, clinical trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drug candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

In addition, we are obligated under our contracts with CROs to reimburse these CROs for certain expenses incurred by them in the performance of the services they provide to us. The precise timing and amounts of these expenses and our corresponding reimbursement obligations are and may continue to be uncertain and outside of our control. We incur the costs for these reimbursement obligations when invoiced by the CRO. We often receive invoices long after the CRO has performed the services that are the subject of the invoice. As a result, our related operating expenses have and may continue to vary significantly period-to-period and are not necessarily indicative of the expenses associated with the activities of the CRO conducted during the period covered by the periodic report in which these expenses are disclosed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

A potential breakthrough therapy designation by the FDA for our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will receive marketing approval.

We may seek a breakthrough therapy designation from the FDA for one or more of our drug candidates. A breakthrough therapy is defined as a drug product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drug products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of a clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drug products designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval, compared to drugs considered for approval under conventional or other accelerated FDA procedures and does not ensure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify and are designated as a breakthrough therapy, the FDA may later decide that the drug products no longer meet the conditions for designation and the designation may be rescinded.

We may seek Fast Track designation for one or more of our other drug candidates in the future. Even if we apply for Fast Track designation in the future, we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a drug candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may request an FDA Fast Track designation from the FDA. If we seek Fast Track designation for a drug candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We expect to utilize the FDA's Section 505(b)(2) pathway for certain of our drug candidates and if that pathway is not available, the development of our drug candidates will likely take significantly longer, cost significantly more and entail significantly greater complexity and risk than currently anticipated, and, in any case, may not be successful.

We plan to seek approval to use the FDA's Section 505(b)(2) pathway for certain of our drug candidates. However, if the FDA subsequently determines that we may not use this regulatory pathway, then we would need to seek regulatory approval for the drug candidates via a "full" or "stand-alone" NDA under Section 505(b)(1) of the FDCA. This would require us to conduct additional clinical trials, provide additional safety and efficacy data and other information, and meet additional standards for regulatory approval including possibly nonclinical data. If this were to occur, the time and financial resources required to obtain FDA approval, as well as the development complexity and risk associated with these programs, would likely substantially increase, which could have a material adverse effect on our business and financial condition.

The Drug Price Competition and Patent Term Restoration Act of 1984, informally known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies and information that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite our development programs relative to seeking approval under the 505(b)(1) regulatory pathway.

Notwithstanding the approval of an increasing number of products by the FDA under Section 505(b)(2) over the last decade, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, or Congress were to amend the statute to alter the currently available regulatory pathway, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA. Even if we are able to utilize the Section 505(b)(2) regulatory pathway for one or more of our drug candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, any delay resulting from our inability to pursue the FDA's 505(b)(2) pathway could result in new competitive products reaching the market more quickly than our drug candidates, which may have a material adverse impact our competitive position and prospects. Even if we are allowed to pursue the FDA's 505(b)(2) pathway, we cannot assure you that our drug candidates will receive the requisite approvals for commercialization.

We may use our financial and human resources to pursue a particular research program or drug candidate and fail to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with certain programs or drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future R&D programs and future drug candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential drug candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We have conducted, and intend to conduct, clinical trials for certain of our drug candidates at sites outside of the United States, and the U.S. regulatory agencies may not accept data from trials conducted in such locations.

As noted above, we have conducted trials for our drug candidates pursuant to Australian law and intend to conduct future and current trials for these candidates pursuant to FDA regulations in an effort to obtain FDA approval. The FDA's acceptance of data from clinical trials conducted outside the United States may be subject to certain conditions or may not be accepted at all, and other comparable non-U.S. regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their respective jurisdictions. In cases where data from clinical trials conducted wholly outside of the United States are intended to serve as the basis for marketing approval in the United States, the FDA will generally not accept such non-U.S. trial data unless (i) the data are determined to be applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the FDA is able to validate the data through an onsite inspection or other appropriate means, if necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Furthermore, even where the non-U.S. trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many comparable non-U.S. regulatory authorities have similar approval requirements.

In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept future data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct or have conducted outside the United States, it would likely result in the need for additional trials that would be costly and time-consuming and delay or permanently halt the development of a drug candidate.

Conducting clinical trials outside the United States may also expose us to additional risks, including risks associated with the following, among other things: additional international regulatory requirements; international exchange fluctuations; compliance with international manufacturing, customs, shipment and storage requirements; the failure of enrolled subjects in international countries to adhere to clinical protocol as a result of differences in standard-of-care; cultural differences in medical practice and clinical research; diminished protection of intellectual property rights; and compliance with general local legal requirements.

Risks Related to Commercialization of Our Drug Candidates

Even if we receive marketing approval of a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

Any marketing authorization that we receive for any current or future drug candidate may be subject to limitations on the authorized indicated uses for which the product may be marketed or the conditions of authorization or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product. The FDA or comparable international regulatory authorities may also require a REMS or a comparable international strategy, as a condition of approval of any drug candidate, which could include requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA or a comparable international regulatory authority grants marketing authorization for a candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the candidate will be subject to extensive and ongoing regulatory requirements. These requirements include, among others, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval, and prohibitions on the promotion of an authorized product for unauthorized indications or uses. The FDA and other or comparable international regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Similar considerations apply outside of the United States.

Later discovery of previously unknown problems with any authorized product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- untitled or warning letters from the FDA, or comparable notices of violation from comparable international regulatory authorities;
- imposition of clinical holds on ongoing clinical trials;
- refusal by the FDA or comparable international regulatory authorities to authorize pending applications or supplements to authorized applications we filed or suspension or revocation of marketing authorizations;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing authorization of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Future potential sales of our drug candidates may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

There is a risk that our drug candidates may not gain market acceptance among physicians, patients and the medical community, even if they are approved by the regulatory authorities. The degree of market acceptance of any of our approved drug candidates will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive products;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our drug candidates;
- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

As controlled substances, the products may generate public controversy. Physicians, patients, payers or the medical community may be unwilling to accept, use or recommend our drug candidates which would adversely affect our potential revenues and future profitability. Adverse publicity or public perception regarding cannabis and psilocybin to our investigational therapies using these substances may negatively influence the success of these therapies.

We face competition from entities that may develop drug candidates for our target disease indications and from entities currently providing treatment to our target disease indications.

The development and commercialization of drug candidates is highly competitive. We face or may face potential competition from many different sources, including major pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and medical research organizations. Many of our competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. There are a number of products that are currently under development and may become commercially available in the future, for the treatment of conditions for which we are developing, and may in the future try to develop, drug candidates. For instance, Zepbound (tirzepatide) was recently approved for the treatment of OSA in obese patients. . In addition, Apnimed's lead product candidate for OSA, AD109, has completed both Phase 2b and Phase 3 trials with topline results from its Phase 3 trial announced in July 2025. These and other potential competitors may succeed in obtaining FDA or other regulatory approval for alternative or superior products. Any drug candidates that we successfully develop will compete with the standard of care and new therapies that may become available in the future. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop and may make any products we develop obsolete or non-competitive before we recover the expense of developing and commercializing our drug candidates.

Our competitors also may compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs. These competitors could also recruit our employees, which could negatively affect our level of expertise and our ability to execute our business plan.

Our drug candidates for which we obtain approval may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a drug candidate ahead of a potential competitor, our future approved products may face direct competition from generic and other follow-on drug products. Any of our drug candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the U.S. prescription drug market. Our ability to compete may also be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

The Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to ANDAs, and also created the Section 505(b)(2) NDA pathway. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the reference listed drug. In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, a follow-on applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Such products, if approved and depending upon the scope of the changes made to the reference drug, may also compete with any drug candidates for which we receive approval.

The FDA is prohibited by statute from approving an ANDA or 505(b)(2) NDA when certain marketing or data exclusivity protections apply to the reference listed drug. However, if any competitor or third party is able to demonstrate bioequivalence without infringing our patents, then such competitor or third party may then be able to gain approval of an ANDA and introduce a competing generic product onto the market.

Furthermore, the CREATES Act established a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish necessary samples of an RLD on "commercially reasonable, market-based terms." If generic developers request samples of any drug candidates for which we receive marketing approval in order to conduct comparative testing to support one or more ANDAs for a generic version of our products, and we refuse any such request, we may be subject to litigation under the CREATES Act. Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have generally settled privately there continues to be uncertainty regarding the scope and application of the law.

Settlements and related licensing agreements resulting from Hatch-Waxman litigation can be challenged and have the potential to generate additional litigation which can be costly. The success of such litigation depends on the strength of the patents covering our branded products and our ability to prove that the follow-on applicant's product would infringe one or more such patents. The outcome of such litigation is inherently uncertain and may result in potential loss of any market exclusivity we may receive for our drug candidates, if approved, which may have a significant financial impact on our business. Furthermore, the FTC, has brought successful lawsuits challenging Hatch-Waxman litigation settlements as anti-competitive, and such decisions have been upheld by federal circuit courts. If we engage in Hatch-Waxman litigation, we may also face an FTC challenge with respect to any proposed settlement related to such litigation, which may result in additional expense or penalty. The FTC also has more recently been questioning pharmaceutical company patent listings in the Orange Book and raising concerns about "improper" listings that may be intended to discourage competition by follow-on drug developers, and certain members of Congress have been investigating similar issues. Accordingly, there could be future changes to federal laws, regulations, or guidelines related to Hatch-Waxman requirements or procedures that could have a material adverse impact on all pharmaceutical innovators, including us.

We cannot predict the interest of potential follow-on competitors or how quickly others may seek to come to market with competing products, whether approved as a direct ANDA competitor or as a Section 505(b)(2) NDA referencing one of our future drug candidates. If the FDA approves generic versions of any of our products in the future, should they be approved for commercial marketing, such competitive products may be able to immediately compete with us in each indication for which our product has received approval, which could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments.

In addition, while we are currently exploring potential patent protection strategies for our lead drug candidate, PSX-001, there can be no assurance that our efforts to provide intellectual property protection for PSX-001 will be successful. As such and if approved, we may experience significant competition in connection with our marketing efforts for PSX-001.

Even if we are able to commercialize any of our drug candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our or a partner's ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and reimbursement for these drug candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal healthcare programs or private health plans in the United States. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements.

Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of such products.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA, MHRA or other comparable regulatory agencies. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in other jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In August 2022, President Biden signed into the law the IRA, which among other things, contains multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States, including mandatory rebates to the federal government if a drug product's price increases faster than the rate of inflation and direct government negotiation of drug prices for certain Part D drugs (starting for payment year 2026) and Part B drugs (starting for payment year 2028). If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

In some other countries, particularly the Member States of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected.

We could become exposed to product liability claims that could adversely affect our business.

The testing, marketing and sale of therapeutic products entails an inherent risk of product liability. We rely on a number of third-party researchers and contractors to produce, collect, and analyze data regarding the safety and efficacy of our drug candidates.

Notwithstanding our control procedures, we may face product liability exposure related to the testing of our drug candidates in human clinical trials. If any of our drug candidates are approved for sale, we may face exposure to claims by an even greater number of people than were involved in the clinical trials once marketing, distribution and sales of our drug candidates begin. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize drug candidates.

With respect to product liability claims, we could face additional liability beyond insurance limits if testing mistakes were to endanger any human subjects. In addition, if a claim is made against us in conjunction with these research testing activities, the market price of our shares of common stock may be negatively affected.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of our drug candidates and the APIs used to manufacture them, along with the drugs used in our psychedelic-assisted psychotherapy services, will require import and export licenses. In the United States, the FDA, U.S. Customs and Border Protection, and the DEA; in Canada, the Canada Border Services Agency, Health Canada; in Europe, the EMA and the European Commission; in Australia and New Zealand, the Australian Customs and Board Protection Service, the TGA, the New Zealand Medicines and Medical Device Safety Authority and the New Zealand Customs Service; and in other countries, similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export processes require the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country.

We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of API and our drug candidates 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. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our drug candidates. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our drug candidates, could have a material adverse effect on our business, results of operations and financial condition.

Our drug candidates will be subject to controlled substance laws and regulations. Failure to receive necessary approvals may delay the launch of our drug candidates and failure to comply with these laws and regulations may adversely affect the results of our business operations.

Our drug candidates contain controlled substances as defined in the CSA. For a description of the CSA requirements, as enforced by the DEA, on facilities researching, manufacturing, distributing, dispensing, importing, or exporting controlled substances, see "Regulatory Authorities - United States - Regulation of Controlled Substances."

Our lead drug candidates are based on synthetic cannabinoids and psilocybin, which are both currently classified as Schedule I controlled substances by the DEA. However, products that obtain marketing approval for medical use in the United States that contain cannabis, cannabis extracts, or psilocybin should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when any of our future drug candidates receive FDA approval, the DEA will make a scheduling determination. The scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our drug candidates in the United States. If the FDA, the DEA or any international regulatory authority determines that our future drug candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent our drug candidate has an abuse potential, which could increase the development costs and/or delay the marketing approval and launch of that product. In addition, drug candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- *DEA registration and inspection of facilities*. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. We will need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the products to pharmacies and other healthcare providers, and these distributors would need to obtain Schedule II or III distribution registrations. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of our drug candidates. If we fail to obtain or maintain the necessary registrations, the DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

- *State-Controlled Substance Laws*. Individual states have also established controlled substance laws and regulations. We, our third-party manufacturers, our distributors or our other partners must obtain applicable DEA and state registrations, permits or licenses, as applicable, in order to be able to obtain, manufacture, process, handle, distribute, import or export controlled substances for clinical trials or commercial sale. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain FDA approval, and adverse scheduling could have a material adverse effect on the commercial sales of such product. Failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law, which could have a material adverse effect on our business, financial condition and results of operations.

- *Clinical trials*. To conduct clinical trials with any of our investigational drug candidates that fall into categories of substances that are "controlled substances," each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our drug candidates and to obtain the product from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We do not currently conduct any manufacturing or repackaging/relabeling of any of our drug candidates or their active ingredients in the United States.

- *Importation*. If our drug candidates are approved and classified as a Schedule II, III or IV substance, an importer can import them for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our drug candidates. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration. If our drug candidates are approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If our drug candidates are listed as a Schedule II substance, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if neither our drug candidates nor our drug substances could be imported, the drug candidates would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity. The failure to maintain the necessary registrations or comply with applicable laws could delay the commercialization of our drug candidates and could delay the completion of the clinical studies.

- *Distribution in the United States*. If our drug candidates are scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute our drug candidates and any future drug candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our drug candidates more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs. If our drug candidates are a Schedule II drug, participants in our supply chain may have to maintain enhanced security with alarms and monitoring systems and they may be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. In addition, our drug candidates will likely be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial updates. Furthermore, state and federal enforcement actions, regulatory requirements and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

In May 2024, the DEA published a notice of proposed rulemaking to reschedule marijuana (the cannabis plant and the various compounds, manufactures, salts, derivatives, mixtures, or preparations from it) from Schedule I to Schedule III. And in August 2025, the DEA forwarded to HHS a citizen petition proposing that the agencies reschedule psilocybin from Schedule I to Schedule II. HHS will conduct a scientific and medical review of the proposed rescheduling and supporting data and, once completed, will issue a recommendation to the DEA. Even if a final rule rescheduling is implemented in either case, we, our third-party manufacturers, and our other partners must still comply with all CSA requirements and DEA regulations applicable to the rescheduled controlled substances with respect to our product drug candidates.

We currently source APIs from Taiwan, India and the United States and our finished drug candidates are currently being manufactured in Colombia and the United States. In addition, we may decide to develop, manufacture or commercialize our drug candidates in additional countries. As a result, we will also be subject to controlled substance laws and regulations from the TGA in Australia and from other regulatory agencies in other countries where we develop, manufacture or commercialize our drug candidates in the future.

Other countries may have different laws and regulations with which we will be required to comply. For example, EU legislation does not establish different classes of narcotic or psychotropic substances. However, the United Nations ("UN"), Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971 (collectively, the "UN Conventions") codify internationally applicable control measures to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The individual EU member states are all signatories to these UN Conventions. All signatories have a dual obligation to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence. The UN Conventions regulate narcotic drugs and psychotropic substances as Schedule I, II, III, IV substances with Schedule III substances presenting the lowest relative risk of abuse among such substances and Schedule I and IV substances considered to present the highest risk of abuse. The UN Conventions require signatories to require all people manufacturing, trading (including exporting and importing) or distributing controlled substances to obtain a license from the relevant authority. Each individual export or import of a controlled substance must also be subject to authorization. The obligations provided in the UN Conventions and additional requirements are implemented at a national level, and requirements may vary from one member state to another. In order to develop and commercialize our products in the EU, we need to comply with the national requirements related to controlled substances which are costly and may affect our development plans in the EU.

Failure to comply with applicable legal requirements could lead to enforcement and sanctions by the responsible regulatory authorities, which could have a material adverse effect on our business, financial condition and results of operations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, substantial civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments in the United States as well as international governments in the jurisdictions in which we conduct our business. Physicians, other healthcare providers, and third-party payors will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations include the following:

The Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing any remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

The False Claims Act imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the Federal governments; and

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The Physician Payments Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family, which includes data collection and reporting obligations. Such information reported to CMS is made publicly available on a searchable website.

Analogous state and international laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and international laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of our drug candidates from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Changes in U.S. healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may harm our business and results of operations.

All aspects of our business, including R&D, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as international laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates or any potential future drug candidates of ours, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Congress also must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

The DSCSA, which became fully effective and applicable in November 2024 (except for certain trading partner-specific exemptions through specified dates in 2025 to accommodate additional time needed in order to fully implement DSCSA requirements for electronic drug tracing at the package level), imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Furthermore, in February 2022, FDA released proposed regulations to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. Then, in mid-2022, the FTC launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. In addition, in the last few years, several states have formed prescription drug affordability boards ("PDABs"), with the authority to implement upper payment limits ("UPLs"), on drugs sold in their respective jurisdictions. There are several pending federal lawsuits challenging the authority of states to impose UPLs, however.

Outside of the United States, particularly in the European Union, the coverage status and pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Furthermore, the requirements may differ across the EU Member States. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Also, at a national level, actions have been taken to enact transparency and anti-gift laws (similar to the U.S. Physician Payments Sunshine Act) regarding payments between pharmaceutical companies and healthcare professionals.

Our drug candidates contain cannabinoid and psychedelic substances, the use of which may generate public controversy. Adverse publicity or public perception regarding our current or future drug candidates may negatively influence the success of these therapies.

Our drug candidates contain cannabinoid and psychedelic substances that may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our current drug candidates and any future drug candidates we may develop. Opponents of these compounds may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products, if approved. Adverse publicity from misuse may adversely affect the commercial success or market penetration achievable by our drug candidates. Anti-cannabinoid and anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our drug candidates or any future drug candidates.

If our drug candidates or any future drug candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of the safety and quality of our drug candidates. We may face limited adoption if third-party therapy sites, therapists or patients are unwilling to try such a novel treatment given that some of our drug candidates are from substances that might be controversial, overlooked or underused. There has been a history of negative media coverage regarding cannabinoid psychedelic substances, including compounds in many of our drug candidates, which may affect the public's perception of our drug candidates. In addition, compounds in most of our drug candidates may elicit intense psychological experiences, and this could deter patients from choosing this course of treatment, if our drug candidates were approved. Our business could be adversely affected if we were subject to negative publicity or if any of our drug candidates, if approved, or any similar drug candidates distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of any of our drug candidates, if approved or any similar products distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into depression and other mental health disorders, such as substance use disorder and anxiety, on which we focus our research efforts, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our drug candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our drug candidates or any future drug candidates.

The production and sale of our drug candidates may be considered illegal or may otherwise be restricted due to the use of controlled substances, which may have consequences for the legality of investments from international jurisdictions.

Our drug candidates contain controlled substances, including psychedelic substances, which are subject to strict legal requirements in certain jurisdictions where we will produce and intend to sell our products, if approved. Certain jurisdictions may not allow the use or production of the substances included in our drug candidates, nor provide any possibilities for an exemption or regulatory approval that could allow for the lawful use or production of such substances. In addition, these jurisdictions may prohibit any form of contributing to the production or use of these drug candidates and may also directly or indirectly prohibit the receipt of any benefits following from the production and sale of these substances. Under circumstances, this may have consequences for the legality of the purchase of our shares or receipt of dividends in or from international jurisdictions.

If certain international authorities consider it illegal to invest in our company, this will negatively affect the possibility to commercialize and generate revenue in the country of interest. Any investigations of authorities against international investors could generate negative publicity.

Risks Related to Our Business Operations

Our R&D efforts will be jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

Changes in our senior management could be disruptive to our business and may adversely affect our operations. For example, when we have changes in senior management positions, we may elect to adopt different business strategies or plans. Any new strategies or plans, if adopted, may not be successful and if any new strategies or plans do not produce the desired results, our business may suffer.

Moreover, competition among biotechnology and pharmaceutical companies for qualified employees is intense and as such, we may not be able to attract and retain personnel critical to our success. Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our product development and commercialization activities.

In addition, biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our drug candidates may be or become uncompetitive. To remain competitive, we must employ and retain suitably qualified staff that are continuously educated to keep pace with changing technology but may not be in a position to do so.

Inflation may adversely affect us by materially increasing our costs.

Recently, inflation has increased throughout the U.S. economy. While we do not believe we have been materially affected by inflation as of the date of this Annual Report, inflation can adversely affect us by materially increasing the costs of clinical trials and research, the development of our drug candidates, administration, and other costs of doing business. We may experience material increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may materially outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

Changes in interpretation or application of account principles generally accepted in the United States ("US GAAP") may adversely affect our operating results.

We prepare our consolidated financial statements to conform to US GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board, American Institute of Certified Public Accountants, the SEC and various other regulatory and accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences, including regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, and other loss of revenue or profits.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive information, including personal information (such as health-related information), data related to clinical trials, intellectual property, and trade secrets. We may rely upon third party service providers and technologies to operate critical business systems to process such information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place.

Despite our implementation of security measures, our internal information technology systems and those of our clinical sites, and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware, including as a result of advanced persistent threat intrusions, and other attacks by computer hackers, cracking, application security attacks, social engineering, including through phishing attacks, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats and occurrences. There can be no assurance that we will be successful in preventing cybersecurity incidents or successfully mitigating their effects. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are also becoming increasingly difficult to detect and come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, "hacktivists," and nation-state-supported actors now engage in attacks. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, significant extra expenses to restore our data or systems, reputational harm, and diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make payments to the threat actor(s), but we may be unwilling or unable to do so, including, for example, if applicable laws or regulations prohibit such payments.

Some threat actors also now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services. In addition to experiencing a cybersecurity incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Furthermore, future or past business transactions, such as acquisitions or integrations, could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security vulnerabilities or risks that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a cybersecurity incident has occurred, if at all. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Any of the previously identified or similar threats could cause a cybersecurity incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A cybersecurity incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services, develop our products, and conduct clinical trials.

The costs related to significant cybersecurity incidents or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our clinical sites, and other contractors and consultants become subject to disruptions or cybersecurity incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against cybersecurity incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of third parties upon which we rely (including sites performing our clinical trials), there can be no assurance that these measures will be effective. We also cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

If any cybersecurity incidents referenced above were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a drug candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or cybersecurity incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any drug candidates could be delayed. Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders of cybersecurity incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a cybersecurity incident or are perceived to have experienced a cybersecurity incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing information (including personal information); litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, financial loss, and other similar harms. Cybersecurity incidents and attendant consequences may also deter new clinical trial participants from participating in our services and negatively impact our ability to operate our business.

Our business is subject to complex and evolving U.S. federal and state, and international laws and regulations, imposing obligations on how we collect, use, disclose, store and process personal data. We are also subject to information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal data. The actual or perceived failure by us or vendors to comply with these laws and regulations, policies and contractual obligations could harm our business and/or reputation, and subject us to significant fines and liability.

We are or may become subject to domestic and international data protection laws and regulations that address privacy and data security and may affect our collection, use, storage, and transfer of personal information. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues with the potential to affect our business. In Australia, the collection, use, storage and disclosure of personal and sensitive information is governed by the Privacy Act 1988 (Cth) and the Australian Privacy Principles. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. For example, California has enacted the California Consumer Privacy Act ("CCPA"), which went into effect in January of 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain categories of health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally in 2020, California voters passed the California Privacy Rights Act ("CPRA"), which went into full effect on January 1, 2023. The CPRA significantly amended the CCPA, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA, including with respect to use of automated decision-making technology, annual cybersecurity audits, and risk assessments, and has expanded enforcement authority. In addition to California, numerous U.S. states have enacted or are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. The existence of differing comprehensive privacy laws in different states in the country may make our compliance obligations more complex and costly and may require us to modify our personal information processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington's "My Health My Data" Act, regulates "consumer health data," which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C.F.R. Part 46 and 21 C.F.R. Parts 50 and 56. Notably, the "My Health My Data" Act contains a private right of action. In addition, Nevada enacted a consumer health data privacy bill, SB 370, which also regulates "consumer health data" and shares many similarities with Washington's "My Health My Data" Act, and Connecticut recently amended its comprehensive privacy law to include heightened regulation of "consumer health data." Additional states may adopt health-specific privacy laws that could impact our business activities and our collection and handling of health-related data.

Globally, numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the General Data Protection Regulation ("GDPR") which took effect in May 2018 and governs the collection and use of personal data in the European Union, including by companies outside of the European Union. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification, and the use of third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR has been and will continue to be a rigorous and time-intensive process that has increased and will continue to increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with any European activities, which could adversely affect our business, prospects, financial condition and results of operations.

Additionally, following the United Kingdom's withdrawal from the European Union (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR - the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover.

Transfers of personal data to certain countries outside of the EU and the UK are also highly regulated under the GDPR and UK GDPR. For example, the GDPR only permits exports of personal data outside of the EU to "non-adequate" countries where there is a suitable data transfer mechanism in place to safeguard personal data (e.g., the EU Commission approved Standard Contractual Clauses or certification under the newly-adopted Data Privacy Framework). On July 16, 2020, the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) ("Schrems II"). This decision calls into question certain data transfer mechanisms as between the EU member states and the U.S. The CJEU is the highest court in Europe and the Schrems II decision heightened the burden to assess U.S. national security laws on their business, and future actions of EU data protection authorities are difficult to predict at this time. While the Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to flow down or help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the U.S. will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non-compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws of other countries in which we operate.

We intend to initiate studies in countries other than the United States. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their governments, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and U.S. Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products, if approved, in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

We incur, and will continue to incur, costs and expect significantly increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives.

As a public company listed on the Nasdaq Capital Market, and particularly if we cease to be a "smaller reporting company," we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company or as a public company without such specified statuses. We are subject to the reporting requirements of the Exchange Act, as well as various requirements imposed by the Sarbanes-Oxley Act, rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. The listing requirements of the Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct, each of which requires additional attention and effort of management and our board of directors and additional costs.

We expect the rules and regulations applicable to public companies to continue to result in substantial legal and financial compliance costs and to continue to make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We also expect that we will need to hire additional accounting, finance and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and committees thereof or as executive officers.

We are exposed to fluctuations in exchange rates which may adversely affect our operating results.

We maintain our consolidated financial statements in our functional currency, which is the Australian Dollar. For financial reporting purposes, we present our consolidated financial statements in the U.S. dollar, the reporting currency. Part of our monetary assets and liabilities are denominated in a currency other than our functional currency and are subject to risks associated with currency exchange fluctuation. We are exposed to changes in exchange rates arising from the mismatch of cash flows due to currency exchange fluctuations.

We are also subject to currency translation risk, which arises from the translation into our functional currency for reporting purposes of income from operations conducted in other currencies, which can cause volatility in reported earnings from our business conducted overseas and translation gains and losses. In preparing our financial statements, we translate as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, expenses and other income (expense), net are translated at the average exchange rates for the periods presented and stockholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to other comprehensive income, a component of stockholders' equity. We do not believe that a hypothetical 10% increase or decrease in the relative value of the U.S. dollar to other currencies would have had a material effect on our consolidated financial statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies.

We write business on a global basis, and our results of operations may be affected by fluctuations in the value of currencies other than the U.S. Dollar. The primary international currencies in which we currently operate are the Australian Dollar. However, in the future, we expect to derive a significant portion of our net revenue and incur a significant portion of our operating costs inside the United States, and changes in exchange rates may have a significant, and potentially adverse, effect on our results of operations. Changes in foreign currency exchange rates could reduce our revenues or increase our liabilities and costs. We could therefore suffer losses solely as a result of exchange rate fluctuations. We cannot assure you that we will be able to manage these risks effectively or that they will not have an adverse effect on our business, financial condition or results of operations.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, laboratory, sales, marketing, business, regulatory, and administrative personnel necessary to support our anticipated growth, develop our business, and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals.

We or the third parties upon whom we depend may be adversely affected by geopolitical events, accidents, conflicts, medical epidemics or pandemics, extreme weather or other natural disasters.

Our business, and any third parties with whom we do business, may be adversely affected by accidents, power shortages, telecommunications failures, war, conflicts (such as the current conflicts in the Middle East and the conflict between the Russian Federation and the Ukraine) acts of terrorism, protests or other geopolitical events. Any unplanned event that results in us, or our third-party partners, being unable to fully utilize facilities or technology may have a material and adverse effect on our ability to operate our business, conduct our research and development activities and to generally maintain operations. We may incur substantial expenses as a result of the limited nature of our, or our third-party's, disaster recovery and business continuity plans. While we may maintain insurance as we deem reasonably appropriate, many of these contingencies would likely not be covered by insurance, and we cannot assure you that the amounts of insurance coverage that we may acquire or have acquired will be sufficient to satisfy any damages and losses. If we or our third-party partners are unable to operate, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our existing and any future joint ventures may limit our flexibility with jointly owned investments and we may not realize the benefits we expect from these arrangements. We are currently party to a joint venture, and we may in the future sell or contribute additional assets or acquire, develop or recapitalize assets to or in this joint venture or other joint ventures that we may enter.

Our participation in our existing joint venture is, and our participation in future joint ventures may be, subject to risks, including the following:

- We share approval rights over certain major decisions affecting the ownership or operation of the joint venture and any assets owned by the joint venture;
- We may need to contribute additional capital in order to preserve, maintain or grow the joint venture and its investments;
- Our joint venture collaborators may have economic or other business interests or goals that are inconsistent with our business interests or goals and that could affect our ability to fully benefit from the assets owned by the joint venture;
- Our joint venture collaborators may be subject to different laws or regulations than us, which could create conflicts of interest;
- Disagreements with our joint venture investors could result in litigation or arbitration that could be expensive and distracting to management and could delay important decisions.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technology, and we may not be able to protect our intellectual property rights throughout the world.

Our success is to a certain degree also dependent on our ability to obtain and maintain protection of our intellectual property portfolio where applicable, to receive/maintain orphan drug designation/status and resulting marketing exclusivity for our drug candidates, and we may not be able to protect our intellectual property rights throughout the world.

We may be materially adversely affected by our failure or inability to protect our intellectual property rights. Without the granting of these rights, the ability to pursue damages for infringement would be limited. Similarly, any know-how that is proprietary or particular to our technologies may be subject to risk of disclosure by employees or consultants despite having confidentiality agreements in place.

Any future success will depend in part on whether we can obtain and maintain patents to protect our own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of third parties. As noted above, we are currently exploring potential patent protection strategies for our lead drug candidate, PSX-001. However, these efforts may be unsuccessful. Biotechnology patent matters can involve complex legal and scientific questions, and it is impossible to predict the outcome of biotechnology and pharmaceutical patent claims. Any of our future patent applications may not be approved, or we may not develop additional products or processes that are patentable. Filing, prosecuting and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some international countries do not protect intellectual property rights to the same extent as federal or state laws in the United States. For instance, some countries in which we may sell our drug candidate or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some countries in Europe and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are, or any of our licensors is, forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position or commercial advantage may be impaired, and our business and results of operations may be adversely affected.

Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in Australia, the United States, the United Kingdom, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Even if we are able to obtain patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner and export infringing products to territories where we do not have patent protection, or to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

Moreover, any of our pending applications may be subject to a third-party pre-issuance submission of prior art to the USPTO, the European Patent Office (“EPO”), the Intellectual Property Office, in the United Kingdom, the Australian Patent and Trademark Office and/or any patents issuing thereon may become involved in opposition, derivation, reexamination, post grant review, interference proceedings or other patent office proceedings, inter partes review or litigation, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop and commercialize drug candidates.

The issuance of a patent is not conclusive as to the inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States, the European Union, Australia and elsewhere. Such challenges may result in loss of ownership or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to prevent such circumvention. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the European Union, Australia and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights because the legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to healthcare, medicine, or biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in international jurisdictions, whether or not successful, could result in substantial costs and divert our resources, efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights of third parties could adversely affect our ability to commercialize our drug candidates, such that we could be required to litigate with or obtain licenses from third parties in order to develop or market our drug candidates.

Our commercial success may depend upon our future ability and the ability of our potential collaborators to develop, manufacture, market and sell our drug candidates without infringing on valid intellectual property rights of third parties. If a third-party intellectual property right exists it may require the pursuit of litigation or administrative proceedings to nullify or invalidate the third-party intellectual property right concerned, or entry into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all.

Third-party intellectual property right holders, including our competitors, may bring infringement claims against us. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims or otherwise resolve such claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our drug candidate. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding international patent offices. Third parties own numerous U.S. and international issued patents and pending patent applications in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may be subject to claims of infringement of the patent rights of third parties. Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our drug candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expenses and may require a substantial diversion of resources from our business. In the event of a successful claim of patent infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third-party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us due to their substantially greater resources. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our drug candidates and our business could materially suffer.

If we fail to settle or otherwise resolve any such dispute, in addition to being forced to pay damages, we or our potential collaborators may be prohibited from commercializing any drug candidates we may develop that are held to be infringing, for the duration of the patent term. We might, if possible, also be forced to redesign our formulations so that we no longer infringe such third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could result in injury to our reputation or require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we collaborate with various organizations and academic institutions on the advancement of our technology and drug candidates, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our drug candidates.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us. In other cases, we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

We could be required to incur significant expenses to obtain our intellectual property rights, and we cannot ensure that we will obtain meaningful patent protection for our drug candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, it is also possible that we will fail to identify patentable aspects of further inventions made in the course of our research, development or commercialization activities before they are publicly disclosed, making it in many cases too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of a patent that covers an approved product where the permission for the commercial marketing or use of the product is the first permitted commercial marketing or use, and as long as the remaining term of the patent does not exceed 14 years from the product's approval date. However, the applicable authorities, including the FDA in the United States, and any comparable regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of international countries may not protect our rights to the same extent as the laws of the United States, and these international laws may also be subject to change. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our past, current or future collaboration partners or licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our past, current or future collaboration partners or licensors were the first to file for patent protection of such inventions.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and other governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various corresponding governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

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

Competitors may infringe our patents or other intellectual property, and we may inadvertently infringe the patent or intellectual property of others. To counter infringement or unauthorized use, we may be required to file claims, and any related litigation and/or prosecution of such claims can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid in whole or in part, unenforceable, or construe the patent's claims narrowly allowing the other party to commercialize competing products on the grounds that our patents do not cover such products.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. The effects of patent litigation or other proceedings could therefore have a material adverse effect on our ability to compete in the marketplace.

Issued patents covering our drug candidates, compositions or uses could be found invalid or unenforceable if challenged in a patent office or court.

Even if our patents or our past, current or future collaboration partners' or licensors' patents do successfully issue and even if such patents cover our technologies, drug candidates, compositions or methods of use, third parties may initiate interference, re-examination, post-grant review, inter partes review ("IPR") or derivation actions in the USPTO; may initiate third party oppositions in the EPO; or may initiate similar actions challenging the validity, enforceability, scope or term of such patents in other patent administrative or court proceedings worldwide, which may result in patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover competitive technologies, drug candidates, compositions or methods of use. Further, if we initiate legal proceedings against a third party to enforce a patent covering our technologies, drug candidates, compositions or uses, the defendant could counterclaim that our relevant patent is invalid or unenforceable. In patent litigation in the United States, certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims. Further, in the United States, a third party, including a licensee of one of our past, current, or future collaboration partners' patents, may initiate legal proceedings against us in which the third party challenges the validity, enforceability, or scope of our patent(s).

In administrative and court actions, grounds for a patent validity challenge may include alleged failures to meet any of several statutory requirements, including novelty, nonobviousness (or inventive step), clarity, adequate written description and enablement of the claimed invention. Grounds for unenforceability assertions include allegations that someone associated with the filing or prosecution of the patent withheld material information from the Examiner during prosecution in the USPTO or made a misleading statement during prosecution in the USPTO, the EPO or elsewhere. Third parties also may raise similar claims before administrative bodies in the USPTO or the EPO, even outside the context of litigation. The outcome following legal assertions of invalidity or unenforceability are unpredictable. With respect to patent claim validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner was unaware during prosecution. Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been brought to the attention of every patent office. If a defendant or other patent challenger were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our drug candidates, compositions and associated uses.

In addition, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which are subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

The patent protection and patent prosecution for some of our drug candidates may in the future be dependent on third parties.

While we normally seek to gain the right to fully prosecute the patent applications relating to our drug candidates, there may be times when certain patents or patent applications relating to our drug candidates, their compositions, uses or their manufacture may be controlled by our current or future collaboration partners or licensors. If any of our current or future collaboration partners fail to appropriately or broadly prosecute patent applications or maintain patent protection of claims covering any of our drug candidates, their compositions, uses or their manufacture, our ability to develop and commercialize those drug candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, offering to sell or selling competing products. In addition, even where we now have the right to control patent prosecution of patent applications or the maintenance of patents, we have licensed from third parties, presently or in the future, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

Confidentiality and invention assignment agreements with our employees, advisors and consultants may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, advisors and consultants to enter into confidentiality and invention assignment agreements with us. However, current or former employees, advisors and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality and invention assignment agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality and invention assignment agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how, our competitive position or commercial advantage may be impaired and our business and results of operations may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors wrongfully used or disclosed alleged confidential information of third parties or that our employees wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including potential competitors. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful at defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to ours but that are not covered by our intellectual property rights.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license or will own or will have obtained a license.
- It is possible that any pending patent applications that we have filed, or will file, will not lead to issued patents.
- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct R&D activities in countries where we do not have patent rights, or in countries where R&D safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- Ownership of our patents or patent applications may be challenged by third parties.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and any future drug candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in non-U.S. jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act ("Leahy-Smith Act"), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and a change allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions. The Leahy-Smith Act and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, financial condition and results of operations.

The Leahy-Smith Act also provides a process known as IPR, which has been used by many third parties to challenge and invalidate patents. The IPR process is not limited to patents filed after the Leahy-Smith Act was enacted and would therefore be available to a third party seeking to invalidate any of our U.S. patents, even those issued or filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures, e.g., an IPR, to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action.

We may not have sufficient patent term or regulatory exclusivity protections for our drug candidates to effectively protect our competitive position.

Patents have a limited term. In the United States and most jurisdictions worldwide, the statutory expiration of a non-provisional patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, drug candidates and associated uses are obtained, once the patent's life has expired, including for failure to pay maintenance fees or annuities, we may be open to competition from generic, biosimilar or biobetter medications.

Patent term extensions under the Hatch-Waxman Act in the United States, and regulatory extensions in Japan and certain other countries, and under Supplementary Protection Certificates in Europe, may be available to extend the patent or market or data exclusivity terms of our drug candidates depending on the timing and duration of the regulatory review process relative to patent term. In addition, upon issuance of a United States patent, any patent term may be adjusted based on specified delays during patent prosecution caused by the applicant(s) or the USPTO. Although we will likely seek patent term extensions in the U.S. and in one or more international jurisdictions where available, we cannot provide any assurances that any such patent term extensions will be granted and, if so, for how long. As a result, we may not be able to maintain exclusivity for our drug candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent term or regulatory exclusivity to protect our drug candidates, our business and results of operations will be adversely affected.

If we are unable to obtain and maintain patent protection for any drug candidates, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any drug candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary drug candidates and other technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our drug candidates and other technologies that are important to our business. Given that the development of our technology and drug candidates is at an early stage, our intellectual property portfolio directed to certain aspects of our technology and drug candidates is also at an early stage. We have filed or intend to file patent applications on core aspects of our technology and drug candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we only have filed provisional patent applications on certain aspects of our technology and drug candidates, and none of these provisional patent applications is eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our drug candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such drug candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our and drug candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Price controls may be imposed in non-U.S. markets, which may negatively affect our future profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our drug candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be harmed.

Risks Related to Investing in Our Securities

The price of our common stock has been and may continue to be highly volatile, which may make it difficult for stockholders to sell our common stock when desired or at attractive prices.

Following our redomiciliation, the trading price of our common stock has been volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. Factors such as announcements of variations in our quarterly financial results and fluctuations in revenue could also cause the market price of our common stock to fluctuate. In addition, the stock market in general and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to companies operating performance. The market price for our common stock may be influenced by many factors, including:

- our ability to obtain regulatory approvals for IHL-42X, PSX-001, and IHL-675A, or other drug candidates, and delays or failures to obtain such approvals;
- adverse results, clinical holds, or delays in the clinical trials of our drug candidates or any future clinical trials we may conduct, or changes in the development status of our drug candidates;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- negative publicity or public perception of the use of cannabinoid or psychedelic substances as a medical treatment;
- failure to maintain our existing third-party collaboration, license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our drug candidates;
- any inability to obtain adequate supply of our drug candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to maintain the listing of our Common Stock on the Nasdaq Capital Market and the effects of any reverse stock split that we may complete in order to maintain this listing;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- failure by securities or industry analysts to publish research or reports about our business, or issuance of any adverse or misleading opinions by such analysts regarding our business or stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions, such as inflation;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;

- sales or repurchases of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential drugs;
- changes in the structure of healthcare payment systems;
- the impact of political instability and military conflicts, such as the conflicts and recent events in Ukraine and the Middle East, which has resulted in instability in the global financial markets and export controls; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. If the price of our common stock declines, our ability to raise funds through the issuance of equity or otherwise use our common stock as consideration will be reduced. A low price for our equity may negatively impact our ability to access additional debt capital. These factors may limit our ability to implement our operating and growth plans.

U.S. investors may have difficulty enforcing civil liabilities against our directors or members of senior management.

Several of our officers and directors are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. As a result, it may be difficult to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the United States. Even if a claimant is successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions.

Certain provisions of our amended and restated certificate of incorporation may discourage, delay or prevent a change in control of our company and, therefore, depress the trading price of our securities.

Our amended and restated certificate of incorporation provides that our board of directors is classified into three classes of directors, each with staggered three-year terms. This provision may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for our securities.

In addition, as a Delaware corporation, we would also generally be subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders holding shares representing more than 15% of the voting power of our outstanding voting stock from engaging in certain business combinations with us. However, our amended and restated certificate of incorporation provides that we are not subject to Section 203 of Delaware General Corporation Law.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Our common stock could be further diluted as the result of the issuance of additional shares of common stock, warrants, options or other convertible securities. Future sales of shares of our common stock in the public market, or the perception that such sales could occur, have caused and could in the future cause our stock price to fall.

In the past, we have issued common stock and convertible securities in order to raise capital, including pursuant to our “at the market” offering program. We have also issued common stock, restricted stock units and options as compensation for services and incentive compensation for our employees, directors and certain vendors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options or warrants, including through our “at the market” offering program, could affect the rights of our stockholders, could reduce the market price of our common stock or could obligate us to issue additional shares of common stock to certain of our stockholders.

Further, sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act. We cannot predict the effect that future sales of common stock or other equity-related securities would have on the market price of our common stock.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our common stock.

We have never declared or paid cash dividends on shares of our common stock. As noted above, our board of directors authorized a share repurchase program pursuant to which we may repurchase up to $20 million of our common stock. The manner, timing and amount of any share repurchases may fluctuate and will be determined by us based on a variety of factors, including the market price of our common stock, our priorities for the use of cash to support our business operations and plans, general business and market conditions, tax laws, and alternative investment opportunities. The share repurchase program authorization does not obligate us to acquire any specific number or dollar value of shares. If we do not use the repurchase program or declare any dividends, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future.

In May 2025, our stockholders authorized us to complete a reverse stock split of our common stock which our board of directors may elect to do in an effort to regain compliance with the Nasdaq minimum bid price requirements (the "Minimum Bid Price Rule"). Following a reverse stock split, the resulting market price of our Common Stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors and may decline in greater proportion than the ratio of a reverse stock split. Consequently, the trading liquidity of our Common Stock may be adversely affected if we complete a reverse stock split.

Although we believe that a higher market price of our Common Stock may help generate greater or broader investor interest, and we may be required to complete a reverse stock split in an effort to comply with the Minimum Bid Price Rule, there can be no assurance that a reverse stock split, including any reverse stock split that we may complete in an effort to regain compliance with the Minimum Bid Price Rule, would actually result in a sustained or proportional share price increase sufficient to attract new investors, including institutional investors or to regain compliance with the Minimum Bid Price Rule. Any sustained proportionate increase in the market price of our Common Stock is dependent upon many factors, including the success of our research and development efforts, general market conditions, trading activity in our Common Stock and prospects for future success, which are unrelated to the number of shares of our common stock outstanding. It is not uncommon for the market price of a company's common stock to disproportionately decline in the period following a reverse stock split.

If securities or industry analysts do not publish, or cease publishing, research or reports, or publish unfavorable research or reports, about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced, in part, by the research and reports that industry or financial research analysts publish about us and our business. We do not have any control over these analysts. If only a few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively affected and there can be no assurance that analysts will provide favorable coverage. If securities or industry analysts who initiate coverage downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

Having availed ourselves of scaled disclosure available to smaller reporting companies, we cannot be certain if such reduced disclosure will make our common stock less attractive to investors.

Under Section 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is not an investment company, an asset backed issuer, or a majority-owned subsidiary of a parent company. Effective September 10, 2018, the definition of a "smaller reporting company" was amended to include companies with a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; they are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal controls over financial reporting; and they have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. As calculated as of December 31, 2024, we qualified as a smaller reporting company. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure may make it harder for investors to analyze our results of operations and financial prospects.

We may become involved in securities litigation that could materially divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

We may be exposed to securities litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources. We may become involved in such litigation, and our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of current or future collaboration partners or competitors, the addition or departure of our key personnel, the announcement of a strategic restructuring, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies.

This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, it could result in substantial costs for defending the lawsuit and diversion of the time, attention and resources of our board of directors and management, which could significantly harm our profitability and reputation.

We are and may continue to be subject to short selling strategies.

Short sellers of our stock may be manipulative and may attempt to drive down the market price of shares of our common stock. Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller's best interests for the price of the stock to decline, often short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum and generate profits for themselves after selling a stock short. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of technological advancements regarding document creation, videotaping and publication by blogging have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the United States, are not subject to certification requirements imposed by the SEC and, accordingly, the opinions they express may be based on distortions or omissions of actual facts or, in some cases, fabrications of facts. Short attacks have, in the past, led to selling of shares in the market, on occasion in large scale and broad base. Issuers who have limited trading volumes and are susceptible to higher volatility levels than large-cap stocks, can be particularly vulnerable to such short seller attacks. Significant short selling of a company's stock creates an incentive for market participants to reduce the value of that company's common stock. Short selling may lead to the placement of sell orders by short sellers without commensurate buy orders because the shares borrowed by short sellers do not have to be returned by any fixed period of time. If a significant market for short selling our common stock develops, the market price of our common stock could be significantly depressed.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and executive officers provide that:

- We will indemnify our directors and executive officers for serving us in those capacities or for serving other related business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive information, including personal information (such as health-related information), data related to clinical trials, intellectual property, and trade secrets. We depend on both our own systems, networks, and technology, as well as the systems, networks and technology of our collaborative partners, third-party service providers and other business partners, to safeguard our data. We recognize the critical importance of maintaining the trust and confidence of customers, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems.

Cybersecurity Program

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other cybersecurity incidents, including as perpetrated by hackers, and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential, personal, and other sensitive or proprietary information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program designed to ensure that our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We engage industry recognized third-party cybersecurity consultants and technology to assist us with monitoring and maintaining the performance and effectiveness of our systems, network, and data. We maintain a cybersecurity risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats. This program, in conjunction with our enterprise risk management assessment processes, addresses cybersecurity risks to our information technology environment including systems, hardware, software, data, people, and processes.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "*If our information technology systems or data, or those of third parties upon which we rely, are of were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, and other loss of revenue or profits,*" which disclosures are incorporated by reference herein.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

We engage third-party cybersecurity professionals and consultants, including those that provide cybersecurity risk advisory and information technology administration services, as a key component of our cybersecurity risk management strategy. Such third parties also generally assist us with oversight and administration of our cybersecurity risk management program and inform senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents.

We utilize third-party specialists to conduct annual assessments of our cybersecurity risk management program, which incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology Cybersecurity Framework. The annual risk assessment identifies, quantifies, and categorizes material cybersecurity risks. In addition, in conjunction with our third-party cybersecurity risk management specialists, we develop a risk mitigation plan to address identified risks, and where necessary, remediate potential vulnerabilities.

In addition, we maintain information security processes designed to safeguard and manage confidential, personal, and other sensitive or proprietary data, manage access and user accounts, and protect our information technology assets, data, and services from threats and vulnerabilities. We also maintain an information technology assets inventory, identity access management controls including restricted access to privileged accounts, and physical security measures at our facilities.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers who have access to our data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

During the last fiscal year, we have not experienced any material cybersecurity incidents.

Governance

Management Oversight

Our cybersecurity program is overseen by our management team principally our chief financial officer and chief executive officer, with assistance from our third-party information technology and cybersecurity consultants, with responsibility to lead our enterprise-wide cybersecurity strategy, policy, standards, architecture, and processes. This includes management of our controls and processes employed to assess, identify and manage material risks from cybersecurity threats. Our management team selects, deploys, and oversees cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners, and relies on threat intelligence as well as other information obtained from governmental, public, or private sources, including external consultants engaged for strategic cybersecurity risk management, advisory and decision making.

Board Oversight

Our board of directors oversees our cybersecurity risk exposures and the steps taken by our management team to monitor and mitigate cybersecurity risks. Our management team, in consultation with our third-party information technology and cybersecurity consultants, brief our board of directors on assessing and managing cybersecurity risks. In addition, cybersecurity risks are reviewed by our board of directors at least annually, as part of our corporate risk oversight processes. Our third-party information technology and cybersecurity consultants and management team provide periodic reports to our board of directors on cyber vulnerabilities identified through the risk management process, the effectiveness of our cybersecurity risk management program, the emerging threat landscape, and new cybersecurity risks on at least an annual basis. Such reports include updates on the processes to prevent, detect, and mitigate cybersecurity incidents.

Item 2. Properties

Our corporate headquarters are located in Norwest, New South Wales, where we lease commercial office space under a lease that expires in July 2026, with an option to extend the lease for two additional two-year periods.

We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet its current operational needs.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of our business. We are not currently a party to any material litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Our Common Shares

Our shares of common stock commenced trading on the Nasdaq Global Market in November 2023 under the symbol "IXHL" and were transferred to the Nasdaq Capital Market effective as of July 10, 2025.

Holders of Record

As September 28, 2025, there were 347,705,507 shares of our common stock outstanding and held of record by approximately 4,657 stockholders.

Dividend Policy

We have never declared or paid any dividends on our shares of common stock. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our shares of common stock. Dividends, if any, on our outstanding shares of common stock will be declared by and subject to the discretion of our board of directors, and subject to the terms of our debt arrangements, as described above, and Delaware law.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report. This discussion and analysis contains forward looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. For a discussion on forward-looking statements, see the information set forth in the introductory note to this Annual Report under the caption "Special Note Regarding Forward Looking Statements," which information is incorporated herein by reference.

Overview

We are a clinical-stage biopharmaceutical development company dedicated to developing innovative medicines for patients living with serious chronic diseases and significant unmet needs. Our lead drug candidates include IHL-42X for the treatment of OSA; PSX-001, our psilocybin treatment in combination with psychological therapy in development to treat patients with GAD; and IHL-675A for rheumatoid arthritis. Each of these programs target conditions that currently have limited, inadequate, or no approved pharmaceutical treatment options.

Recent Developments

ATM Program Increase

On July 24, 2025, we filed a prospectus supplement to increase the capacity of our existing "at-the-market" offering program (the "ATM") by up to an additional $100 million. While this filing increases the available capacity under the ATM, we are under no obligation to issue any shares of our commons stock pursuant to the program. The expanded facility is intended to enhance our financial flexibility, providing an efficient mechanism to access capital if, and when, deemed appropriate. Any utilization of the ATM will be at our discretion, taking into account prevailing market conditions and strategic priorities.

As previously disclosed, the ATM is conducted pursuant to the Amended and Restated Sales Agreement, dated May 28, 2025 (the "Amended and Restated Sales Agreement") by and among us, A.G.P./Alliance Global Partners ("A.G.P.") and Curvature Securities, LLC ("Curvature," and together with A.G.P, the "Sales Agents"). Accordingly, pursuant to the prospectus supplement, the amount of shares of our common stock that we may issue under the Amended and Restated Sales Agreement has been increased by up to an aggregate of $100 million of shares of our common stock. There can be no assurance that the Sales Agents will be able to complete future placements pursuant to the Amended and Restated Sales Agreement, even if instructed to do so. The number of shares of our common stock that we may ultimately sell under the Amended and Restated Sales Agreement will fluctuate based on a number of factors, including the market price of our common stock during the sales period, the limits it may set in any instruction to sell Shares, and the demand for our common stock during an applicable sales period.

Results of Operations

Comparison of Fiscal Years Ended June 30, 2025 to June 30, 2024

The following tables summarize our results of operations for the periods presented (in thousands):

	For the Years Ended June 30		$	%
	2025	2024	Change	Change
Revenue from customers	86	12	74	617
Operating expenses:				
Research and development	(10,747)	(12,879)	2,132	(17)
General and administrative	(13,128)	(17,174)	4,046	(24)
Total operating expenses	(23,875)	(30,053)	6,178	(21)
Loss from operations	(23,789)	(30,041)	6,252	(21)
Other income/(expense):				
R&D tax incentive	1,756	11,434	(9,678)	(85)
Foreign exchange gains (losses)	(289)	(28)	(261)	932
Interest expense	62	206	(144)	(70)
Interest income	(303)	-	(303)	100
Change in fair value of convertible rights	299	-	299	100
Change in fair value of warrant liabilities	(21,925)	-	(21,925)	100
Warrant issuance costs	(129)	-	(129)	100
Loss on extinguishment	(1,472)	-	(1,472)	100
ELOC commitment fee	(1,095)	-	(1,095)	100
Total other income/(expense), net	(23,096)	11,612	(34,708)	(299)
Loss before income tax expense	(46,885)	(18,429)	(28,456)	154
Income tax expense	-	(30)	30	(100)
Net loss	(46,885)	(18,459)	(28,426)	154
Other comprehensive income/(loss):				
Currency translation adjustment, net of tax	208	(77)	285	(370)
Comprehensive loss	$ (46,677)	$ (18,536)	$ (28,141)	152

Revenue from Customers

During the fiscal year ended June 30, 2025, we generated revenue from clinic patients for rehabilitation services. This figure reflects the consideration to which the Company expects to be entitled in exchange for those services. Revenue increased approximately 617% when compared to revenues generated during the fiscal year ended June 2024 primarily as a result of our expansion of these services. We have not generated any revenue from the sale of products. We do not expect to generate material revenues unless and until our drug candidates are approved.

Operating Expenses

Our operating expenses consist of (i) R&D expenses, (ii) acquisition of in-process research and development ("IPR&D") expense and (iii) general and administrative expenses.

R&D Expenses

R&D expenses consist primarily of external and internal costs incurred in performing clinical and preclinical development activities.

Our R&D expenses include:

- external costs incurred under agreements with CROs, contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies; and

- internal costs, including R&D personnel-related expenses such as salaries, and benefits, as well as allocated facilities costs and dues and subscriptions.

We expense R&D costs as incurred.

R&D expenses decreased by $2.1 million for the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024. The decrease was primarily due to a pause in our development activities that occurred during the fiscal year ended June 30, 2025 for resource conservation reasons. We have since resumed development activities for all of our lead drug candidates.

Although R&D activities are central to our business model, the successful development of our drug candidates is highly uncertain. There are numerous factors associated with the successful development of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. As a result, we expect our R&D expenses will increase substantially in connection with our ongoing and planned clinical and preclinical development activities in the near term and in the future to the extent our development activities are successful. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of our drug candidates. Our R&D expenses have varied, and our future R&D expenses may vary, significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our clinical trials and preclinical studies, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;

- per patient trial costs;

- the number of trials required for approval;

- the number of sites included in the trials;

- the countries in which the trials are conducted;

- the length of time required to enroll eligible patients;

- the number of patients that participate in the trials;

- the number of doses that patients receive;

- the drop-out or discontinuation rates of patients;

- the potential additional safety monitoring requested by regulatory agencies;

- the duration of patient participation in the trials and follow-up;

- the cost and timing of manufacturing of our drug candidates;

- the costs, if any, of obtaining third-party drugs for use in our combination trials;

- the extent of changes in government regulation and regulatory guidance;

- the efficacy and safety profile of our drug candidates;

- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and

- the extent to which we establish additional collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to the development of our drug candidates could significantly change the costs and timing associated with the development of that drug candidate. We may never succeed in obtaining regulatory approval for any drug candidate.

In addition, we are obligated under our contracts with CROs to reimburse these CROs for certain expenses incurred by them in the performance of the services they provide to us. The precise timing and amounts of these expenses and our corresponding reimbursement obligations are and may continue to be uncertain and outside of our control. We incur the costs for these reimbursement obligations when invoiced by the CRO. We often receive invoices long after the CRO has performed the services that are the subject of the invoice. As a result, our related operating expenses have and may continue to vary significantly period-to-period and are not necessarily indicative of the expenses associated with the activities of the CRO conducted during the period covered by the periodic report in which these expenses are disclosed.

Acquisition of IPR&D

Acquisition of IPR&D expense was recorded in the fiscal year ended June 30, 2024, in connection with the acquisition of APIRx Pharmaceutical USA, LLC ("APIRx") in August 2022. We concluded that the acquisition of APIRx did not meet the definition of business under Accounting Standards Codification ("ASC") 805, Business Combinations as APIRx did not have outputs present and a substantive process was not acquired and recorded the transaction as an asset acquisition as a result. We determined that drug candidates pertaining to APIRx had no alternative future use at the time of acquisition and charged $35.3 million, including transaction costs of $2.43 million, to the acquisition of IPR&D expense as of the date of acquisition.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses finance and accounting, human resources and other administrative functions, including salaries, stock-based compensation and benefits for employees, legal fees, expenses relating to patent and corporate matters and professional fees paid for accounting, auditing, consulting and tax services, as well as facilities-related costs not otherwise included in R&D expenses and other costs such as insurance costs and travel expenses.

General and administrative expenses decreased by $4.0 million for the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024. The decrease was mainly due to a decrease of $6.3 million (from $8.9 million to $2.6 million) in equity compensation and benefits for employees and directors, primarily driven by less amortization expense incurred as the equity compensation was issued in May 2025 (compared to the prior period the equity compensation was issued in December 2024). This decrease was partially offset by an increase of $1.4 million (from $2.8 million to $4.2 million) in salaries, and other employee benefits, which resulted from the appointment of Chief Medical Officer and additional middle management positions during the period. Additionally, compliance, legal and regulatory expenses increased by $0.8 million (from $3.1 million to $3.9 million) primarily due to enhanced reporting obligations.

We anticipate our general and administrative expenses will increase substantially in the future as we expand our operations, including increasing our headcount to support our continued R&D activities and preparing for potential commercialization of our drug candidates. We also anticipate we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a U.S. public company.

Other Income (Expense)

Benefit from R&D Tax Credit

We receive tax incentives from the Australian government for R&D activities. Subject to certain exclusions, the Australian Government tax incentives provide benefits for eligible R&D activities. Entities are entitled to either (i) a 48.5% refundable tax offset for eligible companies with an aggregated turnover of less than A$20 million per annum or (ii) a non-refundable 38.5% tax offset for all other eligible companies. As our aggregated turnover is less than A$20 million and we are not controlled by one or more income tax exempt entities, we anticipate being entitled to a claim of 48.5% refundable tax offset for costs relating to eligible R&D activities during the year.

Benefit from R&D tax credit decreased by $9.7 million (from $11.4 million to $1.8 million) for the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024. The decrease primarily due to the multiple years of tax incentives being granted and successful lodgement of overseas findings on the Company's lead assets, which we revised the estimates for the R&D tax incentive receivable, primarily based on historical experience of claims in the fiscal year ended June 30, 2024.

Foreign Exchange Losses

Foreign exchange losses increased by $0.3 million for the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024, primarily due to unfavorable currency exchange rates during the period.

Change in fair value of convertible rights

On October 17, 2024, we issued a convertible debenture as part of a financing arrangement. The convertible debenture was repaid in full on March 13, 2025, and the convertible rights associated with the convertible debenture were derecognized along with the debt repayment. The changes in the fair value of the convertible rights amounted to $0.3 million for the fiscal year ended June 30, 2025.

Change in fair value of warrant liabilities

In 2024 and 2025 we issued warrants in connection with our equity line of credit financing, convertible debenture financing and private investment in public equity financing. These warrants were subsequently exercised or cancelled later during the year. The changes in the fair value of warrant liabilities amounted to $21.9 million for the fiscal year ended June 30, 2025.

Loss on extinguishment

As mentioned above, the convertible debenture was repaid in full on March 13, 2025, and the associated convertible rights were derecognized along with the debt repayment. This resulted in a total loss on extinguishment of $1.5 million, comprising a $1.0 million loss on the debt host contract and $0.5 million related to the associated convertible rights.

ELOC commitment fee

We entered into an equity line of credit purchase agreement in September 2024 and as part of that arrangement, we issued shares as commitment fee to secure the equity line of credit facility. The commitment fee expense incurred for the fiscal year ended June 30, 2025 as a result of these share issuances was $1.1 million.

Currency Translation Adjustment Losses

Currency translation adjustment, net of tax increased by $0.3 million for the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024. The increase resulted primarily from the translation of financial statements from the functional currency to U.S. dollars. For certain of our international subsidiaries, the local currency is the functional currency, and their financial statements are then translated into U.S. dollars for reporting purposes. See Note 2 to our financial statements included in this Annual Report for further information, under the heading “Foreign Currency Translation.”

Liquidity and Capital Resources

We have incurred net losses since inception and expect to incur substantial and increasing losses in the future as we expand our R&D activities in an effort to move our drug candidates into later stages of development. Historically, we have funded our operations primarily through the sale of equity securities, proceeds from the exercise of options, tax grants from R&D activities and interest income.

We incurred total comprehensive losses of $46.7 million and $18.5 million for the fiscal years ended June 30, 2025 and 2024, respectively. The increase in net loss is attributable to a $24.3 million increase driven by financing activities, including changes in the fair value of warrants and convertible debt, as well as loss on extinguishment of debt during the fiscal year ended June 30, 2025. As of June 30, 2025, we had accumulated comprehensive losses of $157.6 million.

As of June 30, 2025, we had cash and cash equivalents of $15.0 million. Although we expect our negative cash flows from operating activities to continue, we believe our current cash balances, together with anticipated cash flows and available financing arrangements, provide sufficient resources to meet our obligations and sustain operations for at least one year from the issuance date of the financial statements in this Annual Report.

For the fiscal year ended June 30, 2025, we experienced net cash outflows from operating activities of $12.5 million, a decrease of $3.3 million compared to the fiscal year ended June 30, 2024. As of June 30, 2025, we had cash and cash equivalents of $15.0 million, an increase of $9.2 million compared to our cash and cash equivalents as of June 30, 2024 of $5.9 million. As of June 30, 2025, our current assets exceed our current liabilities by $13.0 million, a $2.4 million increase compared to the difference between our current assets and current liabilities as of June 30, 2024 of $10.6 million.

Going Concern

As of the date of this Annual Report, we believe there is no longer substantial doubt about our ability to continue as a going concern. Although we have not yet established an ongoing source of revenue sufficient to cover all operating and capital expenditure requirements, including any potential payments pursuant to debentures, recent improvements in our financial position provide reasonable assurance that we will continue as a going concern for at least twelve months from the date of the financial statements.

Historically, we have financed our operations to date primarily through partnerships, funds received from public offerings of common stock, a debt financing facility, as well as funding from governmental bodies. We continue to plan for additional capital through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including pursuant to the ATM, collaborations with other companies or other strategic transactions. While there can be no assurance that these plans will be completed successfully or at all, our current financial position and resources mitigate prior concerns related to going concern uncertainties.

During the three months ended June 30, 2025, we sold 163,283,465 shares of common stock for aggregate gross proceeds of $40.2 million and net proceeds of approximately $38.7 million after deducting $1.5 million in commissions payable to the sales agent. As of September 29, 2025, our unrestricted cash and cash equivalents were $73.4 million. Based on our unrestricted cash and cash equivalents as of September 29, 2025, we anticipate that we will be able to fund our planned operating expenses and capital expenditure requirements for at least twelve months from the date of the financial statements included in this Annual Report. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Off-Balance Sheet Arrangements

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

Cash Flows

Comparison of Cash Flows for the Fiscal Year ended June 30, 2025, with June 30, 2024

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

	Year Ended June 30,	
	2025	**2024**
Net cash used in operating activities	$ (12,513)	$ (15,845)
Net cash provided by/(used in) investing activities	(8)	(277)
Net cash provided by financing activities	21,396	-
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ 8,875	$ (16,122)

Net cash flows from operating activities

Net cash used in operating activities decreased by $3.3 million in the fiscal year ended June 30, 2025 compared to the fiscal year ended June 30, 2024. The decrease was primarily driven by a $6.3 million reduction in share-based compensation expense (from $8.9 million to $2.6 million) and a decrease in cash paid related to trade and other payables of $1.6 million (from $3.0 million to $1.4 million), partially offset by an increase in R&D tax incentive received of $15.4 million (from outflow of $9.8 million to inflow of $5.6 million).

Net cash flows from investing activities

Net cash used in investing activities decreased by $0.3 million in the fiscal year ended June 30, 2025 compared to fiscal year ended June 30, 2024. The decrease was due to less spending on property, plant and equipment.

Cash flows from financing activities

Cash provided by financing activities increased by $21.4 million in the fiscal year ended June 30, 2025, compared to the fiscal year ended June 30, 2024. This increase was primarily driven by share issuance proceeds of $48.3 million, partially offset by cash outflows related to financing arrangements entered into during the year, including the cancellation of warrants amounting to $24.8 million and the repayment of convertible debt totaling $3.8 million.

Critical Accounting Estimates

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

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report, we believe the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Acquisitions

We evaluate acquisitions under the accounting framework in ASC 805, Business Combinations, to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, we first perform a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, we further evaluate whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, we conclude that the acquired set is a business.

We measure and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes pre-acquisition direct costs recorded in accrued professional and consulting fees. Goodwill is not recognized in asset acquisitions.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including share options. The fair value method requires us to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use either the trinomial pricing or Black-Scholes option-pricing model ("BSOPM") to estimate the fair value of options granted. Stock-based compensation awards are expensed using the graded vesting method over the requisite service period, which is generally the vesting period, for each separately vesting tranche. We have elected a policy of estimating forfeitures at grant date. Option valuation models, including the trinomial pricing and BSOPM, require the input of several assumptions. These inputs are subjective and generally require significant analysis and judgment to develop.

R&D Costs

R&D costs are expensed as incurred. R&D costs consist of salaries, benefits and other personnel related costs including equity-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain R&D activities on our behalf and allocated facility and other related costs.

Nonrefundable advance payments for goods or services that will be used or rendered for future R&D activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

We record accrued liabilities for estimated costs of R&D activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of R&D activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in trade and other payables on the consolidated balance sheets and within R&D expenses on the consolidated statements of operations and comprehensive loss.

We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. We make significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred.

Benefit from R&D Tax Incentive

Benefit from R&D tax credit consists of the R&D tax credit received in Australia, which is recorded within other income (expense), net. The Company recognizes grants once both of the following conditions are met: (i) the Company is able to comply with the relevant conditions of the grant and (ii) the grant is received.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to opt out of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We will continue to remain an emerging growth company until the earliest of the following:

- the last day of the fiscal year following the fifth anniversary of the date of the completion of the first sale of common equity securities pursuant to an effective registration statement under the Securities Act;
- the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion;
- the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or
- the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Incannex Healthcare Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Incannex Healthcare Inc. (a Delaware corporation) and subsidiaries (the "Company") as of June 30, 2025, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity (deficit), and cash flows for each of the two years in the period ended June 30, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON AUDIT PTY LTD

We have served as the Company's auditor since 2023.

Perth, Australia

September 29, 2025

INCANNEX HEALTHCARE INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	June 30, 2025	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 15,039	$ 5,858
Prepaid expenses and other assets	791	507
R&D tax incentive receivable	4,132	9,837
Total current assets	**19,962**	**16,202**
Property, plant and equipment, net	227	472
Operating lease right-of-use assets, net	258	373
Total assets	**$ 20,447**	**$ 17,047**
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 6,104	$ 612
Accrued expenses and other current liabilities	696	4,845
Operating lease liabilities, current	184	163
Total current liabilities	**6,984**	**5,620**
Operating lease liabilities, non-current	74	210
Total liabilities	**7,058**	**5,830**
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.0001 par value – 800,000,000 shares authorized; 194,379,996 and 17,642,832 shares issued and outstanding at June 30, 2025 and 2024, respectively	20	2
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2025 and 2024, respectively	-	-
Additional paid-in capital	174,049	125,218
Accumulated deficit	(157,556)	(110,671)
Foreign currency translation reserve	(3,124)	(3,332)
Total stockholders' equity	**13,389**	**11,217**
Total liabilities and stockholders' equity	**$ 20,447**	**$ 17,047**

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

INCANNEX HEALTHCARE INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	For the fiscal year ended June 30,	
	2025	**2024**
Revenue from customers	86	12
Operating expenses:		
Research and development	(10,747)	(12,879)
General and administrative	(13,128)	(17,174)
Total operating expenses	(23,875)	(30,053)
Loss from operations	(23,789)	(30,041)
Other income, net:		
R&D tax incentive	1,756	11,434
Foreign exchange expense	(289)	(28)
Interest expense	(303)	-
Interest income	62	206
Change in fair value of convertible rights	299	-
Change in fair value of warrant liabilities	(21,925)	-
Warrant issuance costs	(129)	-
Loss on extinguishment	(1,472)	-
ELOC commitment fee	(1,095)	-
Total other income, net	(23,096)	11,612
Loss before income tax expense	(46,885)	(18,429)
Income tax expense	-	(30)
Net loss	$ (46,885)	$ (18,459)
Other comprehensive income/ (loss):		
Currency translation adjustment, net of tax	208	(77)
Total comprehensive loss	$ (46,677)	$ (18,536)
Net loss per share: Basic and diluted	$ (1.35)	(1.15)
Weighted average number of shares outstanding, basic and diluted	34,454,269	16,164,338

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

INCANNEX HEALTHCARE INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	Common Stock		Additional Paid-in capital	Accumulated deficit	Foreign currency translation reserve	Total stockholders' equity (deficit)
	Share	Amount	Amount	Amount	Amount	Amount
	#	$	$	$	$	$
Balance at June 30, 2023	15,873,113	2	116,290	(92,212)	(3,255)	20,825
Stock-based compensation	-	-	8,928	-	-	8,928
Convertible note conversion	-	-	-	-	-	-
Share issuance	1,769,719	-	-	-	-	-
Share issuance costs	-	-	-	-	-	-
Net loss	-	-	-	(18,459)	-	(18,459)
Currency translation adjustment, net of tax	-	-	-	-	(77)	(77)
Balance at June 30, 2024	17,642,832	2	125,218	(110,671)	(3,332)	11,217
Stock-based compensation	-	-	2,609	-	-	2,609
Convertible note conversion	64,127	-	100	-	-	100
Share issuance	176,673,037	18	48,401	-	-	48,419
Share issuance costs	-	-	(2,279)	-	-	(2,279)
Net loss	-	-	-	(46,885)	-	(46,885)
Currency translation adjustment, net of tax	-	-	-	-	208	208
Balance at June 30, 2025	194,379,996	20	174,049	(157,556)	(3,124)	13,389

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

INCANNEX HEALTHCARE INC.
Consolidated Statements of Cash Flows
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	For the fiscal year ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	(46,885)	(18,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	246	103
Stock-based compensation expense	2,609	8,928
Unrealized losses/(gains) on foreign currency remeasurement	294	28
Non-cash expense of ELOC commitment	1,048	-
Change in fair value of warrant liabilities	21,925	-
Change in fair value of convertible rights	(299)	-
Non-cash interest expense	302	-
Loss on extinguishment	1,472	-
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(189)	369
R&D tax incentive receivable	5,579	(9,837)
Trade and other payables	1,385	3,023
Net cash used in operating activities	**(12,513)**	**(15,845)**
Cash flows from investing activities:		
Purchase of property, plant and equipment	(8)	(277)
Net cash used in investing activities	**(8)**	**(277)**
Cash flows from financing activities:		
Proceeds received from facility agreement	4,282	-
Repayment of facility agreement	(4,459)	-
Proceeds share issuance	48,343	-
Share issuance costs	(747)	-
Warrant issuance costs	(125)	-
Proceeds from issuance of convertible debt	2,779	-
Cancellation of warrants	(24,769)	-
Repayment of convertible debt	(3,795)	-
Debt issuance costs	(113)	-
Net cash provided by financing activities	**21,396**	**-**
Effect of exchange rate changes on cash and cash equivalents	306	(140)
Net (decrease)/increase in cash and cash equivalents	8,875	(16,122)
Cash and cash equivalents at beginning of period	5,858	22,120
Cash and cash equivalents at end of period	15,039	5,858
Non-cash investing and financing activities		
Issuance of ELOC warrants at initial fair value	806	-
Issuance of convertible note warrants at initial fair value	341	-
Issuance of convertible rights at initial fair value	282	-
Issuance of Series A warrants at initial fair value	2,843	-
Partial conversion of convertible note	100	-
Total	4,372	-

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

Note 1 – Company Overview

Incannex Healthcare Inc. ("Incannex") is a corporation formed under the laws of the State of Delaware in July 2023. Incannex and its subsidiaries are referred to as "the Company" unless the text otherwise requires.

The Company's fiscal year end is June 30. References to a particular "fiscal year" are to the Company's fiscal year ended June 30 of that calendar year.

The consolidated financial statements of the Company are presented in U.S. dollars and consist of Incannex and the following wholly-owned subsidiaries:

Subsidiary	Jurisdiction
Incannex Healthcare Pty Ltd	Victoria, Australia
Incannex Pty Ltd	Victoria, Australia
Psychennex Pty Ltd	Victoria, Australia
APIRx Pharmaceutical USA, LLC	Delaware
APIRx Pharmaceuticals Holding BV	IJsselstein, Netherlands
Clarion Clinics Group Pty Ltd	Victoria, Australia
Clarion Model Clinic Pty Ltd	Victoria, Australia
Psychennex Licensing and Franchising Pty Ltd	Victoria, Australia

Description of Business

The Company is a clinical-stage biopharmaceutical development company dedicated to developing innovative medicines for patients living with serious chronic diseases and significant unmet needs. The Company's lead drug candidates include IHL-42X for the treatment of obstructive sleep apnea ("OSA"); PSX-001, the Company's psilocybin treatment in combination with psychological therapy in development to treat patients with generalized anxiety disorder ("GAD"); and IHL-675A for rheumatoid arthritis. Each of these programs target conditions that currently have limited, inadequate, or no approved pharmaceutical treatment options.

Note 2 - Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements included in this report have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Reference is frequently made herein to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC"). This is the source of authoritative US GAAP recognized by the FASB to be applied to non-governmental entities.

Going concern basis

The financial report has been prepared on the going concern basis, which assumes continuity of normal business activities and the realization of assets and the settlement of liabilities in the ordinary course of business.

The Company has incurred total comprehensive losses of $46.7 million and $18.5 million for the fiscal years ended June 30, 2025 and 2024, respectively, and experienced net cash outflows from operating activities of $12.5 million and $15.8 million for the fiscal years ended June 30, 2025 and 2024, respectively.

As of June 30, 2025 and 2024, the Company had cash and cash equivalents of $15.0 million and $5.9 million, respectively, and current assets exceeded its current liabilities by $13.0 million and $10.6 million, respectively.

Historically, the Company has financed its operations to date primarily through partnerships, funds received from public offerings of common stock, a debt financing facility, as well as funding from governmental bodies. The Company continues to plan for additional capital through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including pursuant to the ATM, collaborations with other companies or other strategic transactions.

Based on the Company's unrestricted cash and cash equivalents as of June 30, 2025, the Company anticipates that it will be able to fund its planned operating expenses and capital expenditure requirements into for at least twelve months from the date of these financial statements.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Details of all controlled entities are set out in Note 1 - "Company Overview." All intercompany balances and transactions have been eliminated on consolidation.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes.

The most significant estimates and assumptions in the Company's consolidated financial statements include the valuation of equity-based instruments issued for other than cash, accrued research and development ("R&D") expense, R&D tax credit. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry. The Company believes that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, drug candidates; performance of third-party clinical research organizations and manufacturers upon which the Company relies; protection of the Company's intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; the Company's ability to attract and retain employees.

There can be no assurance that the Company's R&D will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. As of June 30, 2025 and 2024, all deposits are held in banks outside of the United States.

Cash and Cash Equivalents

Cash and cash equivalents, which includes cash and deposits held at call with financial institutions with original maturities of three months or less that are readily convertible to known amounts of cash, are carried at cost, which approximates fair value.

Property, Plant and Equipment, Net

Recognition and Measurement

All property, plant and equipment is recognized at historical cost less depreciation.

Depreciation

Depreciation is calculated using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives or, in the case of leasehold improvements and certain leased plant and equipment, the shorter lease term as follows:

- Machinery 10-15 years
- Vehicles 3-5 years
- Furniture, fittings and equipment 3-8 years

Furniture, fittings and equipment include assets in the form of office fit outs. These assets and other leasehold improvements are recognized at their fair value and depreciated over the shorter of their useful life or the lease term, unless the entity expects to use the assets beyond the lease term.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property, plant and equipment, net, and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated by the asset group to the carrying amount of the asset group. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

During the fiscal years ended June 30, 2025 and 2024, the Company did not record any impairment charges on its long-lived assets.

Leases

The Company determines if an arrangement is, or contains, a lease at inception and then classifies the lease as operating or financing based on the underlying terms and conditions of the contract. Leases with terms greater than one year are initially recognized on the consolidated balance sheets as right-of-use assets and lease liabilities based on the present value of lease payments over the expected lease term. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less and does not include any options to purchase the underlying asset that the Company is reasonably certain to exercise.

Lease expense for minimum lease payments on operating leases is recognized on a straight-line basis over the lease term. Variable lease payments are excluded from the right-of-use assets and operating lease liabilities and are recognized in the period in which the obligation for those payments is incurred. Operating lease expenses are categorized within R&D and general and administrative expenses in the consolidated statements of operations and comprehensive loss. Operating lease cash flows are categorized under net cash used in operating activities in the consolidated statements of cash flows.

As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments.

Trade and other payables

These amounts represent liabilities for goods and services provided to the Company prior to the end of the period and which are unpaid. Due to their short-term nature, they are measured at amortized cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

Segment information

The Company operates and manages its business as one reportable and operating segment, which is the R&D of the use of psychedelic medicine and therapies. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for the purposes of allocating resources and evaluating financial performance. The Company's long-lived assets are primarily in Australia.

Revenue Recognition

The Company recognizes revenue to depict the transfer of goods and services to clients in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services by applying the following steps:

- Identify the contract with a client;
- Identify the performance obligations in the contract;
- Determine the transaction price;
- Allocate the transaction price to the performance obligations; and
- Recognize revenue when, or as, the Company satisfies a performance obligation.

Revenue may be earned over time as the performance obligations are satisfied or at a point in time which is when the entity has earned a right to payment, the customer has possession of the asset and the related significant risks and rewards of ownership, and the customer has accepted the asset.

The Company's arrangements with clients can include multiple performance obligations. When contracts involve various performance obligations, the Company evaluates whether each performance obligation is distinct and should be accounted for as a separate unit of accounting under ASC 606-Revenue from Contracts with Customers ("ASC 606"), Revenue from Contracts with Customers.

The Company determines the standalone selling price by considering its overall pricing objectives and market conditions. Significant pricing practices taken into consideration include discounting practices, the size and volume of our transactions, our marketing strategy, historical sales, and contract prices. The determination of standalone selling prices is made through consultation with and approval by management, taking into consideration our go-to-market strategy. As the Company's go-to-market strategies evolve, the Company may modify its pricing practices in the future, which could result in changes in relative standalone selling prices.

The Company disaggregates revenue from contracts with customers based on the categories that most closely depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors.

The Company receives payment from its clients after invoicing within the normal 28-day commercial terms. If a client is specifically identified as a credit risk, recognition of revenue is stopped except to the extent of fees that have already been collected.

R&D Costs

R&D costs are expensed as incurred. Research and development consist of salaries, benefits and other personnel related costs including equity-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain R&D activities on the Company's behalf and allocated facility and other related costs.

Nonrefundable advance payments for goods or services that will be used or rendered for future R&D activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

The Company records accrued liabilities for estimated costs of R&D activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of R&D activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in trade and other payables on the consolidated balance sheets and within R&D expenses on the consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred.

Acquisitions

The Company evaluates acquisitions under the accounting framework in ASC 805, Business Combinations, to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, the Company first performs a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, the Company further evaluates whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquired set is a business.

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes pre-acquisition direct costs recorded in accrued professional and consulting fees. Goodwill is not recognized in asset acquisitions.

Stock-based compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company uses either the trinomial pricing or Black-Scholes option-pricing model ("BSOPM") to estimate the fair value of options granted. Stock-based compensation awards are expensed using the graded vesting method over the requisite service period, which is generally the vesting period, for each separately vesting tranche. The Company has elected a policy of estimating forfeitures at grant date. Option valuation models, including the trinomial pricing and the BSOPM, require the input of several assumptions. These inputs are subjective and generally require significant analysis and judgment to develop. Refer to Note 12 - "Stock-based payments" for a discussion of the relevant assumptions.

Equity-Line of Credit Purchase Agreement

On September 6, 2024, the Company entered into an equity line of credit Purchase Agreement (the "ELOC Purchase Agreement") with Arena Business Solutions Global SPC II, Ltd ("Arena Global"). Under the ELOC Purchase Agreement, Arena Global was committed to purchase up to $50 million of the Company's common stock, at the Company's direction from time to time, subject to the satisfaction of the conditions in the ELOC Purchase Agreement.

The purchase price per share of Common Stock was obtained by multiplying by 96% the daily volume weighted average price ("VWAP") on The Nasdaq Global Market for the trading day specified in the sale notice (same trading day or one trading day following such notice) delivered to Arena Global. The ELOC Purchase Agreement would have terminated automatically upon the earliest to occur of (i) the first day of the month next following the 36-month anniversary of the date of the ELOC Purchase Agreement; or (ii) the date on which Arena Global shall have purchased shares of Common Stock under the ELOC Purchase Agreement for an aggregate gross purchase price equal to the Commitment Amount (as defined in the ELOC Purchase Agreement). We had also agreed to pay a financial advisor up to 7% of the gross proceeds raised under the ELOC Agreement.

On December 9, 2024, in connection with the ELOC Purchase Agreement, the Company issued 142,403 shares of common stock as a commitment fee to Arena Global. On January 16, 2025 the Company issued 10,346 true-up shares of common stock to Arena Global. The Company evaluated that the costs incurred in connection with the commitment fee and the true-up shares did not meet the definition of an asset and, therefore, were expensed as incurred.

As additional consideration for Arena Global's execution and delivery of the ELOC Purchase Agreement, the Company had issued a five-year warrant (the "ELOC Warrant") on October 31, 2024, exercisable for 585,000 shares of common stock with an exercise price equal to $1.66 per share.

The Company determines whether to classify contracts, such as warrants, that may be settled in the Company's own stock as equity of the entity or as a liability. An equity-linked financial instrument must be considered indexed to the Company's own stock to qualify for equity classification. The Company classifies warrants as liabilities for any contracts that may require a transfer of assets. Warrants classified as liabilities are accounted for at fair value and remeasured at each reporting date until exercise, expiration or modification that results in equity classification. Any change in the fair value of the warrants is recognized in the Consolidated Statements of Operations and Comprehensive Loss.

Refer to Note 13 – “Fair Value of Financial Instruments” for the accounting of the ELOC Purchase Agreement.

Convertible Debenture Financing

On September 6, 2024, the Company entered into a Securities Purchase Agreement (the “Debenture Purchase Agreement”) with Arena Investors, LP (“Arena Investors”), which had provided for the issuance of secured convertible debentures in an aggregate principal amount of up to $10 million at an aggregate purchase price of up to $9 million (a 10% original issue discount), divided into three separate tranches, each subject to closing conditions. Under the Debenture Purchase Agreement, the conversion price of each secured convertible debenture would have equalled 115% of the closing price of the common stock on the trading day preceding the date of the issuance of the respective secured convertible debenture, subject to subsequent adjustments and alternative conversion prices based on the then-current trading price of the common stock on the Nasdaq Global Market, as further detailed in the Debenture Purchase Agreement. For each secured convertible debenture purchased under the Debenture Purchase Agreement, the Company would have issued a warrant to the purchaser, exercisable to purchase up to the number of shares of Common Stock equal to 25% of the total principal amount of the related secured convertible debenture, divided by 115% of the closing price of the Company’s common stock on the trading day immediately preceding the applicable closing date. The Company would not have been obligated to issue warrants for any tranche that did not close. The exercise price of each warrant would have been 115% of the closing price of the common stock on the issuance date, and the warrants would have had a five-year term. Additionally, the Company had agreed to pay a financial advisor up to 7% of the gross proceeds raised under the Debenture Purchase Agreement.

The Company completed the closing of the first tranche under the Debenture Purchase Agreement for the issuance of a 10% original issue discount secured convertible debenture (the “Debenture”) in the principal amount of $3,333,333 at an aggregate purchase price of $3 million (a 10% original issue discount) to Arena Special Opportunities (Offshore) Master II LP (“Arena Opportunities”). The Debenture had provided for a payment-in-kind interest rate at 5% and would have matured on April 14, 2026. In addition, the Company issued a warrant to Arena Offshore exercisable for up to 453,749 shares of the Company’s common stock (the “Debenture Warrant”), at an exercise price of $1.89 per share.

The net proceeds received from the issuance of the Debenture, after deduction of expenses reimbursable to the Arena Investors, was $2,877,588.

The Company had not met the closing conditions for the second and third tranche closings set forth in the Debenture Purchase Agreement; however, the Company and Arena Investors could have conducted additional closings under the Debenture Purchase Agreement, subject to mutual agreement and the closing conditions described therein. There were assurances that the parties could have reached such an agreement for additional tranche closings.

On November 6, 2024, and as required by our agreements in connection with the Debenture, the Company filed a resale Registration Statement on Form S-1/A with the SEC, registering for resale up to 61,389,758 shares of common stock, including up to 10,101,009 shares of common stock issuable upon conversion of the Debenture and up to 453,749 shares of common stock issuable upon the exercise of the Debenture Warrant. This registration statement was declared effective on December 6, 2024.

The Company evaluates its convertible instruments and warrants to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for under ASC 815, Derivatives and Hedging. The classification of derivative instruments, including whether such instruments should be recorded as assets, liabilities, or equity, is reassessed at the end of each reporting period. For equity-linked financial instruments, the Company must determine whether the underlying instrument is indexed to its own Common Stock in order to classify the derivative instrument as equity. Otherwise, the derivative asset or liability, including embedded derivatives, is recognized at fair value with subsequent changes in fair value recognized in the consolidated statements of operations and comprehensive income (loss).

For hybrid instruments, ASC 815-15 requires bifurcation of embedded features if (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The nature of the host instrument is therefore evaluated to determine if it is more akin to a debt-like or equity-like host. In this assessment, the Company considers the stated and implied substantive features of the contract as well as the economic characteristics and risks of the hybrid instrument. Each term and feature are then weighed based on the relevant facts and circumstances to determine the nature of the host contract. Terms and features of the hybrid.

On February 5, 2025, Arena Investors converted a total of $100,000 debt into shares of the Company's common stock.

On March 13, 2025 the Company repaid in full the Debenture by making a cash payment of $3,851,111.00, representing the outstanding principal, interest, amounts and redemption premiums due as of February 28, 2025. In connection with the repayment of the Debenture, the Debenture Purchase Agreement, the Security Documents (as defined in the Debenture Purchase Agreement) and the ELOC Purchase Agreement were terminated, except with respect to the indemnification and registration rights set forth therein. The (i) Debenture Warrant, (ii) Registration Rights Agreement, dated as of October 14, 2025, by and between the Company and Arena Investors and (iii) the ELOC Warrant remain in effect.

Refer to Note 13 – "Fair Value of Financial Instruments" for the accounting of the Convertible Debenture.

Private placement arrangement

On March 7, 2025, the Company entered into a private placement (the "Private Placement") pursuant to a securities purchase agreement (the "March 2025 Securities Purchase Agreement") with certain institutional investors for the purchase and sale of approximately $12.5 million in gross proceeds of 9,687,045 shares of the Company's common stock for a purchase price of $1.08 per share of common stock (and, in lieu thereof, pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,887,045 shares of common stock (the "Pre-Funded Warrant Shares") at a price of $1.0799 per Pre-Funded Warrant) and Series A common stock warrants (the "Series A Warrants") to purchase up to 11,574,090 shares of Common Stock at an initial exercise price of $2.16 per share.

The Pre-Funded Warrants were exercisable for shares of common stock for a nominal exercise price of $0.0001 per Pre-Funded Warrant Share, were immediately exercisable upon issuance and expired when exercised in full. On March 10, 2025, the Company received substantially all the Pre-Funded Warrants proceeds upfront as part of the Pre-Funded Warrants' purchase price and in return the Company is obligated to issue up to a fixed number of 1,887,045 shares of common stock to the investors. Thus, Pre-Funded Warrants were accounted for and were classified as additional paid-in capital as part of the Company's equity. Total incremental and direct issuance costs were deducted from additional paid-in-capital as they were allocated to shares of common stock and Pre-Funded Warrants.

The Series A Warrants were classified as liabilities and accounted for at fair value and re-measured at each reporting date until exercise, expiration or modification that resulted in equity classification. Any change in the fair value of the Series A Warrants was recognized in the Consolidated Statements of Operations and Comprehensive Loss.

The issuance of common stock is recognized on its settlement date. Upon issuance, the common stock is recorded at its fair value.

In May 2025, the Company entered into letter agreements with the holders of the Series A Warrants pursuant to which the Company paid to the holders of Series A Warrants an aggregate of $24.8 million in exchange for the cancellation of all of the outstanding Series A Warrants.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value. ASC 820, Fair Value Measurement and Disclosures ("ASC 820"), specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs have created the following fair-value hierarchy:

Level 1: Quoted prices for identical instruments in active markets;

Level 2: Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and

Level 3: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Benefit from R&D Tax Incentive

Benefit from R&D tax credit consists of the R&D tax credit received in Australia, which is recorded within other income (expense), net. The Company recognizes grants once both of the following conditions are met: (1) the Company is able to comply with the relevant conditions of the grant and (2) the grant is received.

Interest income

Interest income is recognized as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

Foreign Currency Translation

For certain of the Company's international subsidiaries, the local currency is the functional currency. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

For financial reporting purposes, the consolidated financial statements of the Company have been presented in the U.S. dollar, the reporting currency. The financial statements of entities are translated from their functional currency into the reporting currency as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, expenses and other income (expense), net are translated at the average exchange rates for the periods presented and stockholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to other comprehensive income, a component of stockholders' equity.

The following table presents data regarding the dollar exchange rate of relevant currencies:

	June 30, 2025	**June 30, 2024**
Exchange rate on balance sheet dates		
USD: AUD Exchange Rate	0.6550	0.6624
Average exchange rate for the period		
USD: AUD Exchange Rate	0.6482	0.6556

Income tax

The Company is governed by Australia and U.S income tax laws. The Company follows ASC 740, Accounting for Income Taxes, when accounting for income taxes, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for temporary differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount more likely than not to be realized.

For uncertain tax positions that meet a "more likely than not" threshold, the Company recognizes the benefit of uncertain tax positions in the consolidated financial statements. The Company's practice is to recognize interest and penalties, if any, related to uncertain tax positions in income tax expense in the consolidated statements of operations.

Net loss per share attributable to holders of common stock

The Company has reported losses since inception and has computed basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per share after giving consideration to all potentially dilutive share issuances, including unvested restricted shares and outstanding options. Because the Company has reported net losses since inception, these potential issuances of common stock have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the fiscal years ended June 30, 2025 and 2024, the only component of accumulated other comprehensive loss is foreign currency translation adjustment.

Note 3 - Prepaid expenses and other current assets

	June 30, 2025	June 30, 2024
	(in thousands)	
Prepayments[1]	297	329
GST recoverable	494	178
Total other assets	791	507

[1] Prepayments consist of prepaid clinical trial insurances, prepaid R&D expenditure relating to PSX-001 and IHL-675A clinical trials and scientific, marketing, and adverting subscription services.

Note 4 - R&D tax incentive receivable

	June 30, 2025	June 30, 2024
	(in thousands)	
R&D tax incentive receivable	4,132	9,837

R&D tax incentive is recorded within the Consolidated Statements of Operations and Comprehensive Loss and amounted to $1.8 million and $11.4 million for the fiscal years ended June 30, 2025 and 2024, respectively. In the fiscal year ended June 30, 2024, due to multiple years of tax incentives being granted and successful lodgement of overseas findings on the Company's lead assets, the Company changed its estimates for the R&D tax incentive receivable, primarily based on historical experience of claims, which resulted in an increase in R&D tax incentive receivable in the fiscal year ended June 30, 2024.

Note 5 - Property, Plant and Equipment, net

	June 30, 2025	June 30, 2024
	(in thousands)	
Furniture, fittings and equipment	495	598
Assets under construction	-	-
Total property, plant and equipment, gross	495	598
Accumulated depreciation and amortization	(269)	(126)
Total property, plant and equipment, net	$ 227	$ 472

Depreciation expense is recorded within general and administrative expense in the Consolidated Statements of Operations and Comprehensive Loss and amounted to $143,000 and $103,000 million for the fiscal years ended June 30, 2025 and 2024, respectively.

Note 6 - Trade and other payables, accrued expenses and other current liabilities

	June 30, 2025	June 30, 2024
	(in thousands)	
Current liabilities		
Trade payables	6,074	527
Contract liabilities	30	85
Total trade and other payables	6,104	612
Accrued expenses	661	4,512
Employee leave entitlements	35	333
Total accrued expenses and other current liabilities	696	4,845
Total trade and other payables, accrued expenses and other current liabilities	6,800	5,457

Trade and other payables are unsecured, non-interest bearing and are normally settled within 30 days. The carrying amounts are a reasonable approximation of fair value.

Note 7 - Leases

As of June 30, 2025, the Company has three lease agreements for its corporate head office in Sydney and two sites in Melbourne (an office and the Clarion Clinic). The leases have original terms of approximately four, five and three years, respectively, require monthly payments that may be subject to annual increases, and include certain renewal options. The Company did not include the renewal periods in measuring the related right-of-use assets and lease liabilities because it was not reasonably certain that the options would be exercised.

The following table summarizes the weighted-average remaining lease term and discount rates for the Company's operating leases:

	June 30, 2025	June 30, 2024
Lease term (years)	1.32	2.32
Discount rate	9.18%	9.18%

The following table summarizes the lease costs pertaining to the Company's operating leases:

	June 30, 2025	June 30, 2024
Operating lease cost	203	172

Cash paid for amounts included in the measurement of operating lease liabilities during the fiscal years ended June 30, 2025 and 2024 was $203,000 and $172,000, respectively, and was included within net cash used in operating activities in the cash flows.

The following table summarizes the future minimum lease payments due under operating leases as of June 30, 2025, (in thousands):

Operating leases	Amount $ (in thousands)
June 30, 2026	199
June 30, 2027	48
June 30, 2028	32
Total minimum lease payments	279
Less amount representing interest	21
Total operating lease liabilities	258

Note 8 - Commitments and contingencies

The Company records a loss contingency when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company also discloses material contingencies when it believes a loss is not probable but reasonably possible. Accounting for contingencies requires us to use judgment related to both the likelihood of a loss and the estimate of the amount or range of loss. Although the Company cannot predict with assurance the outcome of any litigation or tax matters, it does not believe there are currently any such actions that, if resolved unfavorably, would have a material impact on the Company's operating results, financial position or cash flows.

Note 9 - Stockholder's equity/Issued capital

Common stock

The Company has one class of common stock. In connection with the redomiciliation, the Company's amended and restated certificate of incorporation became effective, which originally provided for the issuance of 100 million authorized shares of common stock with a par value of $0.0001 per share, with one vote per share. Holders of common stock are entitled to receive any dividends as may be declared from time to time by the Company's board of directors.

On November 28, 2023, the Company effected the redomiciliation. All references in these consolidated financial statements to the Company's outstanding common stock, including per share information, have been retrospectively adjusted to reflect this redomiciliation.

	For the fiscal year ended June 30, 2024	
	$	No. of Shares
	(in thousands, except per share data)	
Opening balance	2	15,873,113
Issues of new shares - employees and directors	-	1,769,719
Closing balance	2	17,642,832

	For the fiscal year ended June 30, 2025	
	$	No. of Shares
	(in thousands, except per share data)	
Opening balance	2	17,642,832
Issue of new shares	18	176,049,053
Issues of new shares – convertible note conversion	-	64,127
Issues of new shares - employees and directors	-	623,984
Closing balance	20	194,379,996

On May 27, 2025, the Company filed a certificate amendment to its restated certificate of incorporation to increase its authorized shares of common stock to 800 million shares.

Note 10 - Additional paid-in capital

Additional paid-in capital:

	June 30, 2025	June 30, 2024
	(in thousands except per share data)	
Opening balance	125,218	116,290
Equity instruments issued to management and directors[1]	2,609	8,928
Convertible note conversion	100	-
Share issuance	48,401	-
Share issuance costs	(2,279)	-
Ending balance	174,049	125,218

[1] The equity-based premium reserve is used to record the value of equity issued to raise capital, and for stock-based payments.

Note 11 - General and Administration expenses

	June 30, 2025	June 30, 2024
	(in thousands)	
Salaries, and other employee benefits	(4,217)	(2,809)
Stock-based payments expense	(2,609)	(8,928)
Depreciation expense	(246)	(103)
Compliance, legal and regulatory	(3,939)	(3,108)
Occupancy expenses	(390)	(348)
Advertising and investor relations	(795)	(1,055)
Other administration expenses	(932)	(823)
Total general and administration expenses	(13,128)	(17,174)

Note 12 - Stock-based payments

	June 30, 2025	June 30, 2024
	(in thousands)	
Research and development	-	-
General and administrative	(2,609)	(8,928)
Total stock-based compensation expense	(2,609)	(8,928)

Restricted stocks

A summary of the changes in the Company's restricted stock activity for the fiscal year ended June 30, 2025, are as follows:

	Numbers of Shares	Weighted Average Grant Date Fair Value $
Unvested and Outstanding as of June 30, 2024	651,939	3.91
Granted	40,739,093	0.23
Vested	(623,984)	3.97
Forfeited	-	-
Unvested and Outstanding as of June 30, 2025	40,767,047	0.23

Stock Options

A summary of the changes in the Company's stock options activity for the fiscal year ended June 30, 2025, are as follows:

	Numbers of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands) ($)
Unvested and Outstanding as of June 30, 2024	235,008	26.76	1.93	-
Granted	-	-	-	-
Vested	-	-	-	-
Forfeited	(7,500)	3.28	-	-
Outstanding as of June 30, 2025	227,508	27.22	1.46	-
Unvested as of June 30, 2025	-	-	-	-

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's shares of common stock for those stock options that had exercise prices lower than the fair value of the Company's shares of common stock.

Note 13 – Fair value of Financial Instruments

Cash and cash equivalents, accounts receivable (including R&D tax incentive receivable), prepaid expenses and other current assets, accounts payable, accrued expenses and current liabilities are reflected on the consolidated balance sheets at amounts that approximate fair value because of the short-term nature of these financial assets and liabilities.

ELOC Purchase Agreement

The Company evaluated the ELOC Purchase Agreement to determine whether it should be accounted for considering the guidance in ASC 815-40, "Derivatives and Hedging - Contracts on an Entity's Own Equity" ("ASC 815-40") and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting as a derivative.

The ELOC Purchase Agreement was terminated on March 13, 2025.

ELOC Warrant

Classification of the ELOC Warrant as a liability instrument was based on management's analysis of the guidance in ASC 815 and in a statement issued by the staff of the SEC regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies."

Management considered whether the ELOC Warrant displayed the three characteristics of a derivative under ASC 815, and concluded that the ELOC Warrant mets the definition of a derivative. However, the ELOC Warrant failed to meet the equity scope exception in ASC 815-10-15-74(a) and thus is classified as a liability measured at fair value, subject to remeasurement at each reporting period. This is on the basis that the ELOC Warrant included certain cash-settlement features in the event of a tender offer, which is outside the control of the Company, and that the exercise price was denominated in a currency other than the reporting entity's functional currency, and therefore the instrument is not considered indexed to the reporting entity's own stock. The Company measures the ELOC Warrant as a liability at fair value as at each reporting period with changes in fair value recognized as other (income) expense, net in the consolidated statements of operations and comprehensive income (loss).

The ELOC Warrant was classified as a level 3 financial instrument in the fair value hierarchy and were valued using the BSOPM.

The changes in the fair value of the ELOC Warrant liability were a decrease of $0.6 million for the fiscal year ended June 30, 2025.

Convertible Debentures

The Company has accounted for the Debenture as a financing transaction, wherein the net proceeds that were received were allocated to the financial instruments issued. Prior to making the accounting allocation, the Company evaluated the Convertible Debentures under ASC 815 Derivatives and Hedging ("ASC 815"). ASC 815 generally requires the analysis of embedded terms and features that have characteristics of derivatives to be evaluated for bifurcation and separate accounting in instances where their economic risks and characteristics are not clearly and closely related to the risks of the host contract.

The Company evaluated that the convertible right met the definition of a derivative under ASC 815-10-15-83. Further the Company evaluated that the convertible right requires bifurcation from the debt host on the basis that it fails to meet the equity scope exception in ASC 815-10-15-74(a) and thus are classified as a liability measured at fair value, subject to remeasurement at each reporting period.

The Company evaluated that the Debenture Warrant was a detachable freestanding instrument. The Debenture Warrant included certain cash-settlement features in the event of a tender offer, which is outside the control of the Company, and that the exercise price was denominated in a currency (USD) other than the reporting entity's functional currency (AUD), and thus failed to meet the equity scope exception in ASC 815-10-15-74(a). Therefore, the instrument was not considered indexed to the reporting entity's own stock. As such the Debenture Warrant were classified as a liability and measured at fair value, with changes in fair value each period reported in earnings.

The proceeds from issuing the Debenture were allocated first to the Debenture Warrant based on its fair value. The proceeds allocated to the debt instrument was then further allocated between the debt host contract and the bifurcated derivative based on the fair value of that derivative as prescribed by ASC 815-15-30-2.

The proceeds of the transaction were initially allocated as follows:

	Amount (in thousands)
10% Original issue discount	333
Convertible rights (liability) at fair value	302
Debenture Warrant (liability) at fair value	365
Debt issuance costs	122
Debt liability host	2,211
Face value	3,333

Debt discount and the debt issuance costs were capitalized to the carrying amount of the debt. Such costs are presented on the balance sheet as a direct deduction from that debt liability host.

The convertible debt was repaid in full on March 13, 2025, including the outstanding principal, interest, amounts and redemption premiums that was due as of February 28, 2025. The convertible rights are derecognized along with the debt repayment. The Company recognized a $1.0 million loss on extinguishment of the debt host contract and the bifurcated derivative.

The changes in the fair value of the Debenture Warrants liability were a decrease of $0.2 million for the fiscal year ended June 30, 2025.

Series A Warrants

Classification of the Series A Warrants as liability instruments was based on management's analysis of the guidance in ASC 815 and in a statement issued by the staff of the SEC regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies."

Management considered whether the Series A Warrants displayed the three characteristics of a derivative under ASC 815 and concluded that the Series A Warrants met the definition of a derivative. However, the Series A Warrants failed to meet the equity scope exception in ASC 815-10-15-74(a) and thus were classified as a liability measured at fair value, subject to remeasurement at each reporting period. This is on the basis that the exercise price of the Series A Warrants was denominated in a currency other than the reporting entity's functional currency, and therefore the instrument was not considered indexed to the reporting entity's own stock. The Company measured the Series A Warrants as a liability at fair value as at each reporting period with changes in fair value recognized as other (income) expense, net in the Consolidated Statements of Operations and Comprehensive Income (Loss).

The Series A Warrants were classified as a level 3 financial instrument in the fair value hierarchy and were valued using the BSOPM.

The changes in the fair value of the Series A Warrant liability were an increase of $22.7 million for the fiscal year ended June 30, 2025.

In May 2025, the Company entered into letter agreements with the holders of the Series A Warrants pursuant to which the Company paid to the holders of Series A Warrants an aggregate of $24.8 million in exchange for the cancellation of all of the outstanding Series A Warrants.

Note 14 - Income Tax

The prima facie income tax benefit on pre-tax accounting loss from operations reconciles to the income tax benefit in the financial statements as follows:

	June 30, 2025	June 30, 2024
	(in thousands)	
Accounting loss before tax	(46,885)	(18,415)
Income tax benefit at the applicable tax rate of 30%	(14,066)	(5,525)
Non-deductible expenses	4,511	6,545
Non-assessable income	(1,527)	(3,431)
Deferred tax assets not recognized	1,143	927
Income tax benefit	-	(30)
Unrecognized Deferred Tax Asset		
Deferred tax asset not recognized in the financial statements:		
Unused tax losses	10,648	6,887
Net unrecognized tax benefit at 25%	11,790	7,813

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carry forwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carry forward period. Because of the Company’s recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. As of June 30, 2025 and 2024, the Company established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

Note 15 - Loss per share

All stock and earnings per share amounts presented below reflect the impact of the redomiciliation as if it had taken effect on July 1, 2022.

Basic and diluted net loss per share attributable to stockholders was calculated as follows:

	June 30, 2025	June 30, 2024
Basic and diluted loss per share (dollars per share)	1.35	1.15
The loss and weighted average number of shares of common stock used in the calculation of basic loss per share is as follows:		
Total comprehensive loss for the year (in thousands)	(46,677)	(18,536)
- Weighted average number of shares of common stock (number)	34,454,269	16,164,338

The Company notes that the diluted loss per share is the same as basic loss per share.

Note 16 -Related Party Transactions

There were no amounts payable to any related parties as of June 30, 2025 and 2024.

Note 17 - Subsequent Events

ATM Program Increase

On July 24, 2025, the Company filed a prospectus supplement to increase the capacity of its ATM by up to an additional $100 million. While this filing increases the available capacity under the ATM, the Company is under no obligation to issue any share of its common stock pursuant to the program. The expanded facility is intended to enhance the Company's financial flexibility, providing an efficient mechanism to access capital if, and when, deemed appropriate. Any utilisation of the ATM will be at the discretion of the Company, taking into account prevailing market conditions and strategic priorities.

As previously disclosed, the ATM is conducted pursuant to the Amended and Restated Sales Agreement, by and among the Company and the Sales Agents. Accordingly, pursuant to the prospectus supplement, the amount of shares of the Company's common stock that the Company may issue under the Amended and Restated Sales Agreement has been increased by up to an aggregate of $100 million of shares of the Company's common stock. There can be no assurance that the Sales Agents will be able to complete future placements pursuant to the Amended and Restated Sales Agreement, even if instructed to do so. The number of shares of the Company's common stock that the Company may ultimately sell under the Amended and Restated Sales Agreement will fluctuate based on a number of factors, including the market price of its common stock during the sales period, the limits it may set in any instruction to sell shares of its common stock, and the demand for its common stock during an applicable sales period.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated, as of the end of the period covered by this Annual Report, the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2025, our disclosure controls and procedures were not effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with US GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with US GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management, with the participation of our principal executive and principal financial officers, assessed the effectiveness of our internal control over financial reporting on June 30, 2025. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control - Integrated Framework (2013). Based on its assessment, management has concluded that our internal control over financial reporting was not effective as of June 30, 2025.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Management has concluded that we did not maintain effective disclosure controls and procedures due to the material weakness in internal control over financial reporting which existed as of June 30, 2025, relating to the documentation of accounting policies and procedures, particularly relating to the correct application of complex accounting measures.

Remediation Efforts

The measures that we are undertaking to remediate the material weakness in internal control over financial reporting have and will include: (a) hiring qualified internal control personnel or consultants to manage the implementation of internal control policies, procedures and improvement of the internal audit function, as applicable; (b) developing and implementing written policies and procedures for accounting and financial reporting that meet the standards applied to public companies listed in the United States; and (c) conducting internal control training to management, key operations personnel and the accounting department, so that management and relevant personnel understand the requirements and elements of internal control over financial reporting mandated by the US securities laws.

We believe we have made progress in accordance with our remediation plan even though the material weaknesses will not be considered remediated until we have completed implementing the necessary additional applicable controls and operate with them for a sufficient period of time to allow management and our auditors to conclude that these controls are operating effectively.

We cannot determine when our remediation plan will be fully completed, and we cannot provide any assurance that these remediation efforts will be successful or that our internal control over financial reporting will be effective as a result of these efforts.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

Other than the remediation of the material weakness discussed above, there were no changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) that occurred during three months ended June 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the three months ended June 30, 2025, none of our directors or officers adopted or terminated "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report ("2025 Proxy Statement").

Item 11. Executive and Director Compensation

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our 2025 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1)

The information required by this item is incorporated herein by reference to the financial statements and notes thereto listed in Item 8 of Part II and included in this Annual Report.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed, furnished or incorporated by reference as part of this Annual Report. Exhibits which are incorporated herein by reference can be obtained on the SEC website at www.sec.gov.

Exhibit No.	Description
2.1	Deed of Amendment and Restatement to Scheme Implementation Deed, dated September 13, 2023, between Incannex Healthcare Limited and Incannex Healthcare Inc. (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
3.1	Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on July 31, 2023 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
3.1.1	Certificate Amendment to Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of Delaware on May 27, 2025 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 28, 2025).
3.2	Amended and Restated Bylaws, dated November 20, 2023 (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
4.1*	Description of Securities.
4.2	Form of Warrant Agency Agreement, by and among the Company, Computershare Inc., and its affiliate Computershare Trust Company, N.A., dated December 29, 2023 (incorporated by reference to Exhibit 4.2 of the Company's Annual Report on Form 10-K filed with the SEC on September 30, 2024).
4.3	First Tranche Warrant (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
4.4	ELOC Warrant (incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
4.5	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2025).
10.1#	Employment Agreement between Incannex Healthcare Limited and Joel Latham, dated July 1, 2020 (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 20-F, File No. 001-41106, filed with the SEC on January 25, 2022).
10.2	Share Sale and Purchase Agreement between Incannex Healthcare Limited and the sellers of APIRx Pharmaceutical USA, LLC, dated May 12, 2022. (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 20-F, File No. 001-41106, filed with the SEC on October 28, 2022).
10.3#	Service Agreement between Incannex Healthcare Limited and Lekhram Changoer, dated August 5, 2022 (incorporated by reference to Exhibit 4.12 to the Company's Annual Report on Form 20-F, File No. 001-41106, filed with the SEC on October 31, 2023).

Exhibit No.	Description
10.4	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
10.5#	Incannex Healthcare Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
10.6#	Employment Agreement between Incannex Healthcare Limited and Joseph Swan, dated February 27, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on March 5, 2024).
10.7^	Purchase Agreement between Incannex Healthcare Inc. and Arena Business Solutions Global SPC II, Ltd, dated as of September 6, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 10, 2024).
10.8^	Securities Purchase Agreement between Incannex Healthcare Inc. and Arena Investors, LP, dated as of September 6, 2024 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on September 10, 2024).
10.9	2023 Australian Incentive Sub-Plan (incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K filed with the SEC on September 30, 2024).
10.10	Form of Facility Agreement between Incannex Healthcare Pty Ltd, Incannex Pty Ltd, Psychennex Pty Ltd, and FC Credit Pty Ltd, dated October 9, 2024. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 15, 2024).
10.11^	First Registration Rights Agreement (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
10.12#^	Employment Agreement, effective October 21, 2024, by and between the Company and Luigi M. Barbato, M.D. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 24, 2024).
10.13^	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2025).
10.14^	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2025).
10.15	Form of Placement Agency Agreement (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on March 10, 2025).
10.16	Form of Letter Agreement (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed with the SEC on May 15, 2025).
10.17^	Amended and Restated Sales Agreement, dated May 27, 2025, by and among Incannex Healthcare Inc., A.G.P./Alliance Global Partners and Curvature Securities, LLC (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed with the SEC on May 28, 2025).
10.18	Form of Second Letter Agreement (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 28, 2025).
10.19#	Amendment No. 1 to Incannex Healthcare Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on May 28, 2025).

Exhibit No.	Description
16.1	Letter to Securities and Exchange Commission from PKF Brisbane Audit, dated December 14, 2023 (incorporated by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2023).
19.1	Securities Trading Policy, adopted on October 5, 2023 (incorporated by reference to Exhibit 19.1 of the Company's Annual Report on Form 10-K filed with the SEC on September 30, 2024).
21.1	List of subsidiaries (incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K filed with the SEC on September 30, 2024).
23.1*	Consent of Grant Thornton, independent registered public accounting firm
24.1	Power of Attorney (included on the signature page hereto)
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.
32.2**	Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.
97.1	Policy for Recovery of Erroneously Awarded Compensation, adopted on October 5, 2023 (incorporated by reference to Exhibit 97.1 of the Company's Annual Report on Form 10-K filed with the SEC on September 30, 2024).
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith

** Furnished herewith

# Indicates management contract or compensatory plan.

^ Certain schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Copies of the omitted schedules will be furnished to the SEC upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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, thereunto duly authorized.

Date: September 29, 2025

Incannex Healthcare Inc.

By: /s/ Joel Latham
Name: Joel Latham
Title: Chief Executive Officer and President

POWER OF ATTORNEY

IN WITNESS WHEREOF, each person whose signature appears below constitutes and appoints Joel Latham and Joseph Swan as his true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (i) act on and sign any amendments to this report, with exhibits thereto and other documents in connection therewith, (ii) act on and sign such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, and in each case file the same with the SEC, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Joel Latham Joel Latham	Chief Executive Officer, President and Director (principal executive officer)	September 29, 2025
/s/ Joseph Swan Joseph Swan	Chief Financial Officer (principal financial and accounting officer)	September 29, 2025
/s/ Troy Valentine Troy Valentine	Director	September 29, 2025
/s/ Peter Widdows Peter Widdows	Director	September 29, 2025
/s/ George Anastassov George Anastassov	Director	September 29, 2025
/s/ Robert Clark Robert Clark	Director	September 29, 2025