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

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2024

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)	**(I.R.S. Employer Identification No.)**
Suite 105, 8 Century Circuit Norwest, NSW 2153 Australia	**Not applicable**
(Address of principal executive offices)	**(Zip Code)**

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

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 Stock Market LLC**

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

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

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

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

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

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

As of February 14, 2025, the registrant had 17,859,708 shares of Common Stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 Quarterly Report, including statements regarding our future results of operations or 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. These forward-looking statements include, but are not limited to, statements concerning the following:

- 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, and the extent to which the results of earlier clinical trials are not representative of later clinical trials, or that topline, initial, or interim data are not representative of final data;
- 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 expectations around feedback from and discussions with regulators, regulatory development paths and with respect to Controlled Substances Act designation;
- our ability to 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 ability to comply with applicable listing standards within the compliance period and to maintain the listing of shares of our Common Stock on the Nasdaq Global Market;
- 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 and our ability to continue as a going concern;
- our ability to comply with the provisions and requirements of our debt arrangements and to pay amounts owed, including any amounts that may be accelerated;

- 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.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section titled "Risk Factors" previously disclosed in Item IA in our Annual Report on Form 10-K for the fiscal year ended June 30, 2024, as filed with the Securities and Exchange Commission (the "SEC") on September 30, 2024 (the "2024 Annual Report"). Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

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 Quarterly Report and, 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.

The forward-looking statements made in this Quarterly Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report to reflect events or circumstances after the date of this Quarterly 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.

We may announce material business and financial information to our investors using our investor relations website (https://www.incannex.com/investors/). We therefore encourage investors and others interested in our company to review the information that we make available on our website. Our website and information included in or linked to our website are not part of this Quarterly Report.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	December 31, 2024	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 2,098	$ 5,858
Prepaid expenses and other assets	417	507
Assets pledged as security for short-term debt	1,383	-
Research and Development ("R&D") tax incentive receivable	6,606	9,837
Total current assets	**10,504**	**16,202**
Property, plant and equipment, net	273	472
Operating lease right-of-use assets	329	373
Total assets	**$ 11,106**	**$ 17,047**
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 845	$ 612
Accrued expenses and other current liabilities	3,435	4,845
Short-term debt	1,383	-
Operating lease liabilities, current	177	163
Total current liabilities	**5,840**	**5,620**
Operating lease liabilities, non-current	152	210
Long-term debt	2,385	-
Warrant liabilities	1,286	-
Convertible rights	478	-
Total liabilities	**10,141**	**5,830**
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common Stock, $0.0001 par value per share – 100,000,000 shares authorized; 17,785,235 and 17,642,832 shares issued and outstanding at December 31, 2024 and June 30, 2024 respectively	2	2
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2024 and June 30, 2024, respectively	-	-
Additional paid-in capital	126,354	125,218
Accumulated deficit	(121,984)	(110,671)
Foreign currency translation reserve	(3,407)	(3,332)
Total stockholders' equity	**965**	**11,217**
Total liabilities and stockholders' equity	**$ 11,106**	**$ 17,047**

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

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

	For the three months ended December 31,		For the six months ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenue from customers	12	-	86	-
Operating expenses:				
Research and development	(1,414)	(2,638)	(4,310)	(5,247)
General and administrative	(3,602)	(5,345)	(7,034)	(7,629)
Total operating expenses	**(5,016)**	**(7,983)**	**(11,344)**	**(12,876)**
Loss from operations	(5,004)	(7,983)	(11,258)	(12,876)
Other income, net:		-		-
R&D tax incentive	956	2,727	1,767	6,824
Foreign exchange losses	(326)	(5)	(331)	(6)
Interest income	28	20	57	90
Interest expense	(171)	-	(171)	-
Change in fair value of convertible rights	(179)	-	(179)	-
Change in fair value of warrant liabilities	(103)	-	(103)	-
ELOC commitment fee	(1,095)	-	(1,095)	-
Total other income, net	**(890)**	**2,742**	**(55)**	**6,908**
Loss before income tax expense	**(5,894)**	**(5,241)**	**(11,313)**	**(5,968)**
Income tax expense	-	-	-	-
Net loss	**$ (5,894)**	**$ (5,241)**	**$ (11,313)**	**$ (5,968)**
Other comprehensive income/(loss):				-
Currency translation adjustment, net of tax	(414)	927	(75)	418
Total comprehensive loss	**$ (6,308)**	**$ (4,314)**	**$ (11,388)**	**$ (5,550)**
Net loss per share: Basic and diluted	$ (0.33)	$ (0.33)	$ (0.65)	$ (0.38)
Weighted average number of shares outstanding, basic and diluted	17,624,422	15,873,113	17,563,200	15,873,113

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

INCANNEX HEALTHCARE INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(unaudited)
(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, 2024	17,642,832	2	125,218	(110,671)	(3,332)	11,217
Stock-based compensation	-	-	894	-	-	894
Share issuance	142,403	-	242	-	-	242
Net loss	-	-	-	(11,313)	-	(11,313)
Currency translation adjustment, net of tax	-	-	-	-	(75)	(75)
Balance at December 31, 2024	17,785,235	2	126,354	(121,984)	(3,407)	965

	Common Stock		Additional paid-in capital	Accumulated deficit	Foreign currency translation reserve	Total Stockholders' Equity (Deficit)
	Share	Amount	Amount	Amount	Amount	Amount
	#	$	$	$	$	$
Balance at September 30, 2024	17,642,832	2	125,677	(116,090)	(2,993)	6,596
Stock-based compensation	-	-	435	-	-	435
Share issuance	142,403	-	242	-	-	242
Net loss	-	-	-	(5,894)	-	(5,894)
Currency translation adjustment, net of tax	-	-	-	-	(414)	(414)
Balance at December 31, 2024	17,785,235	2	126,354	(121,984)	(3,407)	965

	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	-	-	3,597	-	-	3,597
Share issuance	-	-	-	-	-	-
Net loss	-	-	-	(5,968)	-	(5,968)
Currency translation adjustment, net of tax	-	-	-	-	418	418
Balance at December 31, 2023	15,873,113	2	119,887	(98,180)	(2,837)	18,872

	Common Stock		Additional paid-in capital	Accumulated deficit	Foreign currency translation reserve	Total Stockholders' Equity (Deficit)
	Share	Amount	Amount	Amount	Amount	Amount
	#	$	$	$	$	$
Balance at September 30, 2023	15,873,113	2	116,491	(92,939)	(3,764)	19,790
Stock-based compensation	-	-	3,396	-	-	3,396
Share issuance	-	-	-	-	-	-
Net loss	-	-	-	(5,241)	-	(5,241)
Currency translation adjustment, net of tax	-	-	-	-	927	927
Balance at December 31, 2023	15,873,113	2	119,887	(98,180)	(2,837)	18,872

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

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

	For the six months ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (11,313)	$ (5,968)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	190	24
Unrealized loss on foreign currency remeasurement	273	-
Non-cash expense of ELOC commitment	1,095	-
Share-based compensation expense	894	3,471
Change in fair value of warrant liabilities	103	-
Change in fair value of convertible rights	179	-
Non-cash interest expense	176	-
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	146	(5,883)
R&D tax incentive	2,627	-
Assets pledged as securities for short-term debt	(1,383)	-
Trade and other payables	(859)	504
Net cash used in operating activities	(7,872)	(7,852)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(8)	(280)
Net cash used in investing activities	(8)	(280)
Cash flows from financing activities:		
Proceeds received from facility agreement	4,282	-
Repayment of facility agreement	(2,898)	-
Proceeds from issuance of convertible debt	2,779	-
Debt issuance costs	(113)	-
Net cash provided by financing activities	4,050	-
Effect of exchange rate changes on cash and cash equivalents	70	567
Net decrease in cash and cash equivalents	(3,830)	(8,132)
Cash and cash equivalents at beginning of period	5,858	22,120
Cash and cash equivalents at end of period	$ 2,098	$ 14,555
Non-cash investing and financing activities		
Issuance of ELOC warrants at initial fair value	1,284,108	-
Issuance of convertible note warrants at initial fair value	543,298	-
Issuance of conversion rights at initial fair value	449,334	-
Total	2,276,740	-

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

INCANNEX HEALTHCARE INC.
Notes To Unaudited Condensed Consolidated Financial Statements
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

Note 1 – Re-domiciliation and Business

Incannex Healthcare Inc. (the "Company") is a corporation formed under the laws of Delaware in July 2023. In November 2023, Incannex Healthcare Inc. acquired all the outstanding ordinary shares of Incannex Healthcare Limited, an Australian corporation ("Incannex Australia"), pursuant to a scheme of arrangement under Australian law (the "Re-domiciliation"). As a result of the Re-domiciliation, Incannex Australia became a wholly-owned subsidiary of Incannex Healthcare Inc., which is the new ultimate parent company.

Until the Re-domiciliation, Incannex Australia's ordinary shares were listed on the Australian Securities Exchange ("ASX") and American Depositary Shares ("ADSs"), each representing 25 ordinary shares of Incannex Australia, traded on Nasdaq. Following completion of the Re-domiciliation, Incannex Australia's ordinary shares were delisted from the ASX and Incannex Healthcare Inc. assumed Incannex Australia's listing on Nasdaq.

Pursuant to the Re-domiciliation, holders of Incannex Australia's ordinary shares received one share of Common Stock in Incannex Healthcare Inc. for every 100 ordinary shares held in Incannex Australia and holders of ADSs in Incannex Australia received one share of Common Stock of Incannex Healthcare Inc. for every 4 ADSs held in Incannex Australia.

The issued and outstanding shares of the Company's Common Stock as shown in this report have been adjusted in the consolidated financial statements to reflect the 100:1 exchange ratio as if it had occurred on July 1, 2022.

Incannex Healthcare Inc. 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 unaudited condensed consolidated financial statements of the Company are presented in United States dollars and consist of Incannex Healthcare Inc. and the following wholly-owned subsidiaries:

Subsidiary	Jurisdiction
Incannex Healthcare Limited	Victoria, Australia
Incannex Pty Ltd	Victoria, Australia
Psychennex Pty Ltd	Victoria, Australia
APIRx Pharmaceutical USA, LLC	Delaware, United States of America
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

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

Basis of Presentation

On November 28, 2023, the Company implemented the transaction to redomicile from Australia to United States and became the parent of Incannex Australia and the wholly owned subsidiaries listed in Note 1. The historical financial statements of Incannex Australia became the historical financial statements of the combined company upon consummation of the Re-domiciliation. As a result, the financial statements included in this report reflect (i) the historical operating results of Incannex Australia and subsidiaries prior to the Re-domiciliation; (ii) the combined results of the Company, Incannex Australia, and subsidiaries following the completion of the Re-domiciliation; and (iii) the Company's equity structure for all periods presented, including adjusting the issued and outstanding shares of Common Stock to reflect the 100:1 exchange ratio as if it had occurred on July 1, 2022.

Note 2 – Basis of Presentation and Summary of Significant Accounting Policies (continued)

The Company's unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and pursuant to the rules and regulations of the SEC. Prior to the Re-domiciliation, Incannex Australia reported its consolidated financial statements in accordance with International Financial Reporting Standards ("IFRS"). Following the Re-domiciliation, the Company transitioned to U.S. GAAP and applied U.S. GAAP retrospectively for all prior periods presented.

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

Unaudited Interim Financial Information

In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of December 31, 2024, and its results of operations for the three and six months ended December 31, 2024, and 2023, and cash flows for the three and six months ended December 31, 2024, and 2023. The Company has condensed or omitted certain information and note disclosures normally included in financial statements prepared in accordance with GAAP pursuant to the applicable required disclosures and regulations of the SEC. As such, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2024, filed with the Securities and Exchange Commission (the "SEC") on September 30, 2024 (the "2024 Annual Report").

Going Concern Basis

The Company believes there is substantial doubt about its ability to obtain additional capital when and as needed to continue as a going concern as previously disclosed in the 2024 Annual Report. The Company has not yet established an ongoing source of revenue sufficient to cover its operating and capital expenditure requirements and to cover any potential payments that may become due and payable pursuant to any debentures to provide sufficient certainty that the Company will continue as a going concern. 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 plan to address this condition through the sale of Common Stock in public offerings and/or private placements, debt financings, or through other capital sources, including collaborations with other companies or other strategic transactions, but there is no assurance these plans will be completed successfully or at all. Pursuant to the requirements of ASC 205-40, *Presentation of Financial Statements - Going Concern*, and as a result of the financial condition and other factors described herein, there is substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the date of this Quarterly Report.

The Company's independent auditor included a going concern opinion in its audit report, which is part of the 2024 Annual Report, raising substantial doubt about the Company's ability to continue as a going concern. This doubt may adversely impact the Company's ability to secure additional financing necessary for its business operations and could materially affect its ability to enter into contractual relationships with third parties. Uncertainty about the Company's ability to continue as a going concern could materially and adversely affect its liquidity, financial condition, and business prospects.

Note 2 – Basis of Presentation and Summary of Significant Accounting Policies (continued)

Principles of Consolidation

The accompanying unaudited condensed 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. All intercompany balances and transactions have been eliminated on consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 unaudited condensed consolidated financial statements and accompanying notes.

The most significant estimates and assumptions in the Company's unaudited condensed consolidated financial statements include the valuation of equity-based instruments (including the convertible rights and warrant liabilities) issued, accrued research and development expense, and the research and development 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, product 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 research and development 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.

Significant Accounting Policies

The following is provided to update the Company's significant accounting policies previously disclosed in Note 2 to the consolidated financial statements in the Company's 2024 Annual Report, reflecting those that have had a material impact on the Company's unaudited condensed consolidated financial statement and related notes.

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 has committed to purchase up to $50 million of the Company's Common Stock par value $0.0001 per share (the "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 is obtained by multiplying by 96% the daily volume weighted average price ("VWAP") on The Nasdaq Global Market ("Nasdaq") 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 will terminate 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 have 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 do not meet the definition of an asset and, therefore, are expensed as incurred.

As additional consideration for Arena Global's execution and delivery of the ELOC Purchase Agreement, the Company 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.

We determine whether to classify contracts, such as warrants, that may be settled in our 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 12 for the accounting of the ELOC Purchase Agreement.

Note 2 – Basis of Presentation and Summary of Significant Accounting Policies (continued)

Convertible Debenture Financing

On September 6, 2024, the Company entered into a Securities Purchase Agreement (the "September 2024 Purchase Agreement") with Arena Investors, LP ("Arena Investors"), which provides 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 September 2024 Purchase Agreement, the conversion price of each secured convertible debenture will equal 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 Nasdaq, as further detailed in the September 2024 Purchase Agreement. For each secured convertible debenture purchased under the September 2024 Purchase Agreement, the Company will also issue 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 is not obligated to issue warrants for any tranche that does not close. The exercise price of each warrant will be 115% of the closing price of the Common Stock on the issuance date, and the warrants will have a five-year term. Additionally, the Company has agreed to pay a financial advisor up to 7% of the gross proceeds raised under the September 2024 Purchase Agreement.

The Company completed the closing of the first tranche under the September 2024 Purchase Agreement for the issuance of a 10% original issue discount secured convertible debenture (the "First Tranche 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 First Tranche Debenture provides for a payment-in-kind interest rate at 5% and matures on April 14, 2026. In addition, the Company issued a warrant to Arena Investors exercisable for up to 453,749 shares of Common Stock (the "First Tranche Warrant"), at an exercise price of $1.89 per share.

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

The Company did not meet the closing conditions for the second and third tranche closings set forth in the September 2024 Purchase Agreement; however, the Company and Arena Investors may conduct additional closings under the September 2024 Purchase Agreement, subject to mutual agreement and the closing conditions described therein. There can be no assurance that the parties will reach such an agreement for additional tranche closings.

On November 6, 2024, and as required by our agreements in connection with the First Tranche 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 First Tranche Debenture and up to 453,749 shares of Common Stock issuable upon the exercise of the First Tranche 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

Refer to Note 12 and Note 13 for the accounting of the Convertible Debenture.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value in accordance with ASC 820, *Fair Value Measurement and Disclosures* ("ASC 820"). ASC 820 establishes a hierarchy of valuation techniques based on observability of the inputs used in those valuation techniques. Observable inputs are derived from market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two categories of inputs form 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 value drivers are observable in active markets; and

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

Note 3 – Prepaid expenses and other current assets

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Prepayments[1]	174	329
GST recoverable	243	178
Total prepaid expenses and other current assets	417	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 advertising subscription services.

Note 4 – Assets pledged as security for short-term debt

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Assets pledged as security for short-term debt	1,383	-

The amount consists of R&D tax incentive receivables, as detailed under Note 5, which have been pledged to FC Credit Pty Ltd ("FC Credit") as part of the facility agreement detailed under Note 12.

Note 5 – R&D tax incentive receivable

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
R&D tax incentive receivable	6,606	9,837

Based on multiple years of tax incentives granted and the successful lodgment of overseas findings related to the Company's lead assets, the Company revised its estimates for the R&D tax incentive receivable, primarily based on historical experience with similar claims. These amounts exclude the portion of R&D tax incentive receivable pledged as security for the facility agreement as detailed in Note 4.

Note 6 – Property, Plant and Equipment, net

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Furniture, fittings and equipment	560	597
Assets under construction	-	-
Total property, plant and equipment, gross	560	597
Accumulated depreciation and amortization	(287)	(125)
Total property, plant and equipment, net	$ 273	$ 472

Depreciation expense is recorded within general and administrative in the unaudited condensed consolidated statements of operations and comprehensive loss and amounted to $0.2 million and $25,000 for the three and six months ended December 31, 2024 and 2023, respectively.

Note 7 – Trade and other payables, accrued expenses and other current liabilities

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Current liabilities		
Trade payables	818	527
Contract liabilities	27	85
Total trade and other payables	845	612
Accrued expenses	3,066	4,512
Employee leave entitlements	369	333
Total accrued expenses and other current liabilities	3,435	4,845
Total Trade and other payables, accrued expenses and other current liabilities	4,280	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 8 – Leases

During fiscal year 2023, the Company entered into three new lease agreements for its corporate head office in Sydney, Melbourne office and Clarion Clinic site. The leases have four-, five-, and three-year terms respectively. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases provide renewal options at the Company's discretion, allowing the Company to renew or extend the lease for an additional three to five years. These optional renewal periods have not been included in the determination of the right-of-use assets or lease liabilities related to these leases, as the Company has not determined it reasonably certain it will exercise the renewal options.

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

	December 31, 2024	June 30, 2024
Lease term (years)	1.81	2.32
Discount rate	9.18%	9.18%

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

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Operating lease cost	96	172

Cash paid for amounts included in the measurement of operating lease liabilities during the three and six months ended December 31, 2024 and fiscal year June 30, 2024 was $96,000 and $0.2 million, 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 December 31, 2024, (in thousands):

Operating leases	Amount $ (in thousands)
June 30, 2025	98
June 30, 2026	189
June 30, 2027	45
June 30, 2028	30
Total minimum lease payments	363
Less amount representing interest	34
Total operating lease liabilities	329

As of December 31, 2024, the Company's operating lease has a weighted-average remaining lease term of 1.81 years and a discount rate of 9.18%.

Note 9 – 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 the Company 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 10 – Stockholder's equity/Issued capital

Common Stock

The Company has one class of Common Stock. In connection with the re-domiciliation, the Company's amended and restated certificate of incorporation became effective, which provides for the issuance of 100,000,000 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 Re-domiciliation. All references in these unaudited condensed consolidated financial statements to the Company's outstanding Common Stock, including per share information, have been retrospectively adjusted to reflect this Re-domiciliation.

Note 11 – Stock-based payments

	For the six months ended December 31,	
	2024 $	2023 $
	(in thousands)	
Research and development	-	-
General and administrative	894	3,597
Total stock-based compensation expense	894	3,597

	For the three months ended December 31,	
	2024 $	2023 $
	(in thousands)	
Research and development	-	-
General and administrative	435	3,396
Total stock-based compensation expense	435	3,396

Restricted stock units

A summary of the changes in the Company's restricted stock activity for the period ended December 31, 2024, are as follows:

	Numbers of Shares	Weighted Average Grant Date Fair Value $
	(in thousands, expect per share data)	
Unvested and Outstanding as of June 30, 2024	651,939	3.91
Granted	27,795	1.84
Vested	9,265	1.84
Forfeited	-	-
Unvested and Outstanding as of September 30, 2024	670,469	3.86

	Numbers of Shares	Weighted Average Grant Date Fair Value $
	(in thousands, expect per share data)	
Unvested and Outstanding as of September 30, 2024	670,469	3.86
Granted	-	-
Vested	-	-
Forfeited	-	-
Unvested and Outstanding as of December 31, 2024	670,469	3.86

Note 11 – Stock-based payments (continued)

Stock options

A summary of the changes in the Company's stock options activity for the period ended December 31, 2024, are as follows:

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands) ($)
Outstanding as of June 30, 2024	235,008	26.76	1.93	-
Granted	-	-	-	-
Exercised	-	-	-	-
Cancelled or forfeited	-	-	-	-
Outstanding as of September 30, 2024	235,008	28.00	1.93	-
Unvested as of September 30, 2024	14,001	24.26	4.01	-

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands) ($)
Outstanding as of September 30, 2024	235,008	28.00	1.93	-
Granted	-	-	-	-
Exercised	-	-	-	-
Cancelled or forfeited	-	-	-	-
Outstanding as of December 31, 2024	235,008	28.00	1.43	-
Unvested as of December 31, 2024	14,001	24.26	3.5	-

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's Common Stock for those options with exercise prices lower than the fair value of the Company's Common Stock.

As of December 31, 2024, there was $56,727 of unrecognized compensation cost related to unvested share options, which is expected to be recognized over a weighted-average period of 0.5 years.

Note 12 – Fair value of Financial Instruments

Cash and cash equivalents, accounts receivable (including assets pledged as security for short-term debt and 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.

The fair value of the Company's debt approximates its carrying value and is classified as Level 3 within the fair value hierarchy, as it is derived from discounted cash flows using a current borrowing rate.

ELOC Purchase Agreement

The Company evaluated the ELOC Purchase Agreement to determine whether it should be accounted for under 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. Therefore, it requires fair value accounting as a derivative. The Company has analyzed the terms of the ELOC Purchase Agreement as a freestanding purchased put right and has concluded that it had insignificant value as of December 31, 2024.

ELOC Warrants

Classification of the ELOC 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 entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies."

Note 12 – Fair value of Financial Instruments (continued)

Management considered whether the ELOC Warrant displayed the three characteristics of a derivative under ASC 815 and concluded that the ELOC Warrant meets 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 conclusion is based on the fact that the ELOC Warrant includes certain cash-settlement features in the event of a tender offer, which is outside the control of the Company, and that the exercise price is denominated in a currency other than the reporting entity's functional currency. As a result, the instrument is not considered to be indexed to the reporting entity's own stock. The Company measured 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 was valued using the Black-Scholes option pricing model ("BSOPM"). The following table presents the fair value of the ELOC Warrant and the valuation assumptions under the BSOPM as of December 31, 2024 and at inception.

	December 31, 2024	At inception
Fair value	$ 739	820
Exercise price	$ 1.66	1.66
Common stock price	$ 2.12	2.27
Expected option term (years)	4.8	5
Expected volatility	60.0%	60.0%
Risk free rate of return	4.27%	4.06%
Expected annual dividend yield	Nil	Nil

The changes in the fair value of the ELOC Warrant liability resulted in a decrease of $80,328 for the six months ended December 31, 2024.

Convertible Debentures

The Company has accounted for the First Tranche Debenture as a financing transaction, with the net proceeds allocated to the financial instruments issued. Prior to making this allocation, the Company evaluated the First Tranche Debenture under ASC 815, *Derivatives and Hedging* ("ASC 815"). ASC 815 generally requires an analysis of embedded terms and features that may exhibit characteristics of derivatives, to determine if bifurcation and separate accounting are necessary when their economic risks and characteristics are not clearly and closely related to the risks of the host contract.

The Company evaluated that the conversion right of the First Tranche Debenture meets the definition of a derivative under ASC 815-10-15-83. Furthermore, the Company determined that the conversion right of the First Tranche Debenture requires bifurcation from the debt host, as it fails to meet the equity scope exception in ASC 815-10-15-74(a) and thus is classified as a liability, measured at fair value, and subject to remeasurement at each reporting period.

The Company evaluated that the First Tranche Warrant is a detachable freestanding instrument. The First Tranche Warrant includes certain cash settlement features in the event of a tender offer, which are outside the Company's control, and the exercise price is denominated in a currency (USD) other than the reporting entity's functional currency (AUD). As a result, it fails to meet the equity scope exception in ASC 815-10-15-74(a), and is not considered indexed to the reporting entity's own stock. As such, the First Tranche Warrant is classified as a liability and measured at fair value, with changes in fair value each period reported in earnings.

The proceeds from issuing the First Tranche Debenture were allocated first to the First Tranche Warrant based on its fair value. The remaining proceeds allocated to the debt instrument were 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
Conversion rights (liability) at fair value	302
First Tranche Warrants (liability) at fair value	365
Debt issuance costs	122
Debt liability host	2,211
Face value	3,333

Note 12 – Fair value of Financial Instruments (continued)

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 First Tranche Warrant was classified as a Level 3 financial instrument in the fair value hierarchy and were valued using the BSOPM. The following table presents the fair value of the First Tranche Warrant and the valuation assumptions under the BSOPM as of December 31, 2024, and at inception.

	December 31, 2024	At inception
Fair value	$ 547	$ 365
Exercise price	$ 1.89	$ 1.89
Common stock price	$ 2.12	$ 1.60
Expected option term (years)	4.7	4.9
Expected volatility	60.0%	60.0%
Risk free rate of return	4.28%	3.81%
Expected annual dividend yield	Nil	Nil

The conversion right of the First Tranche Debenture classified as a Level 3 financial instrument within the fair value hierarchy and were valued using the Monte Carlo option pricing model ("MCSOPM"). The following table presents the fair value of the conversion right of the First Tranche Debenture and the valuation assumptions under the MCSOPM as of December 31, 2024 and at inception.

	December 31, 2024	At inception
Fair value	$ 477	$ 300
Exercise price	$ 1.84	$ 1.84
Common stock price	$ 2.12	$ 1.64
Expected option term (years)	1.3	1.5
Expected volatility	60.0%	60.0%
Risk free rate of return	4.10%	3.98%
Expected annual dividend yield	Nil	Nil

For subsequent measurement of the debt host, refer to Note 13.

Note 13 – Debt

The table below presents details of the Company's debt as of the following periods:

	December 31, 2024 $	June 30, 2024 $
	(in thousands)	
Short-term debt		
FC Credit – 14.5% Facility agreement due 2025	1,383	-
Long-term debt		
Arena LP – 10% Original discount secured convertible debenture due April 14, 2026	2,385	-

FC Credit – 14.5% Facility agreement due 2025

On October 9, 2024, the Company entered into a Facility Agreement with FC Credit, under which, the Company received approximately A$6.9 million (USD$4.3 million) on October 10, 2024, as the initial drawdown amount.

This facility provides the Company with immediate access to funds based on R&D expenses incurred during the 2023 and 2024 financial years, aligning with the end of the Australian financial year. The Research and Development Tax Incentive ("RDTI") program is a key program under the Australian government's innovation framework, designed to encourage companies to undertake R&D activities that benefit Australia. It offers a tax rebate, currently at 48.5%, for eligible R&D expenses, enabling companies to recover nearly half of their R&D spending.

Arena LP – 10% Original discount secured convertible debenture due April 14, 2026

For initial recognition of the long-term debt, refer to Note 12. For more information on the September 2024 Debenture, refer to Note 2. The value allocated to the debt at initial recognition is classified as a liability and accreted or amortized to par value.

Note 14 – Income Tax

For the three and six months ended December 31, 2024, and December 31, 2023, respectively, the Company did not recognize a provision or benefit for income taxes due to incurring net losses. In addition, the net deferred tax assets arising from net operating losses were fully offset by a valuation allowance as the Company believes it is not more likely than not that the benefit will be realized.

Note 15 – Loss per share

All share and earnings per share amounts presented below reflect the impact of the Re-domiciliation as if it had taken effect on July 1, 2022.

Basic and diluted net loss per share attributable to stockholders was calculated as follows (in thousands, except share and per share amounts):

	For the six months ended December 31,	
	2024 $	2023 $
Basic and diluted loss per share – (dollars per share)	(0.65)	(0.38)
The loss and weighted average number of Common Stock used in the calculation of basic loss per share is as follows:		
Total comprehensive loss for the year (in thousands)	(11,388)	(5,550)
- Weighted average number of Common Stock (number)	17,563,200	15,873,113

	For the three months ended December 31,	
	2024 $	2023 $
Basic and diluted loss per share – (dollars per share)	(0.33)	(0.33)
The loss and weighted average number of Common Stock used in the calculation of basic loss per share is as follows:		
Total comprehensive loss for the year (in thousands)	(6,308)	(4,314)
- Weighted average number of Common Stock (number)	17,624,422	15,873,113

The Company notes that the diluted loss per share is the same as basic loss per share.

Note 16 – Related Party Transactions

Transactions between related parties are conducted on commercial terms and conditions, no more favorable than those available to other parties, unless otherwise stated.

There were no amounts payable to any related parties as of December 31, 2024 and June 30, 2024.

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

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report"). This Quarterly Report contains forward-looking statements. This discussion and analysis contain forward looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" section in our Annual Report on Form 10-K for the fiscal year ended June 30, 2024, as filed with the Securities and Exchange Commission (the "SEC") on September 30, 2024 (the "2024 Annual Report") and this Quarterly Report. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Quarterly Report. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Quarterly Report.

Our accounting policies under U.S. GAAP are referred to in Note 1 of the unaudited condensed consolidated financial statements in this Quarterly Report. All amounts are in United States dollars, unless otherwise indicated.

Overview

We are a clinical-stage biopharmaceutical development company dedicated to developing combination medicines that target the underlying biological pathways associated with chronic conditions, including obstructive sleep apnea ("OSA"), rheumatoid arthritis and generalized anxiety disorder. We are advancing novel oral fix-dosed treatments and therapeutic regimens based on evidence-based innovation. Our lead Phase 2/3 and Phase 2 clinical programs include IHL-42X for the treatment of OSA; IHL-675A for the treatment of inflammatory conditions, including rheumatoid arthritis, and PSX-001, our oral synthetic psilocybin treatment, in combination with psychotherapy, for the treatment of generalized anxiety disorder. Our programs target disorders that have limited, inadequate, or no approved pharmaceutical treatment options.

Recent Developments

Topline Results from Pharmacokinetics ("PK") Study of IHL-42X

In January 2024, we released positive topline results from a completed PK and safety study of IHL-42X, a novel, oral fixed-dose combination of acetazolamide and dronabinol for the treatment of OSA. The study confirmed bioavailability of IHL-42X, demonstrating delivery of both dronabinol and acetazolamide. The PK profile of IHL-42X was observed to be similar to those established for the respective reference listed drugs ("RLDs"), including equivalent total exposure levels 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 RLD, an increase in overall exposure to delta-9-tetrahydrocannabinol was observed when IHL-42X was administered with food, compared to fasted state. No serious adverse events were reported during the study. All but one Treatment-Emergent Adverse Event ("TEAE") was reported to be mild or 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 believe this data establishes a scientific bridge to the RLD, potentially enabling us to leverage existing safety and toxicology data in an FDA 505(b)(2) new drug application for IHL-42X, and assist in the analysis of the global Phase 2/3 RePOSA trial.

Update on Australian IHL-675A clinical trial in patients with rheumatoid arthritis

In November 2024, we decided to pause the Australian Phase 2 clinical trial investigating IHL-675A in rheumatoid arthritis patients with pain and reduced function regardless of current treatment due to slower than anticipated patient recruitment. The Company intends to re-allocate use of resources to a larger U.S. Phase 2 IHL-675A clinical study. Adaptations to the study design will be implemented in the U.S. Phase 2 study, investigating safety and efficacy of IHL-675A in patients with rheumatoid arthritis.

Equity-Line of Credit Purchase Agreement

On September 6, 2024, we 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 has committed to purchase up to $50 million of Common Stock at our direction from time to time, subject to the satisfaction of the conditions in the ELOC Purchase Agreement. The purchase price per share of the Common Stock is obtained by multiplying by 96% the daily volume weighted average price ("VWAP") on The Nasdaq Global Market ("Nasdaq") 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 will terminate automatically upon the earliest to occur of (i) the first day of the month 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). In connection with the ELOC Purchase Agreement we agreed, among other things to issue to Arena Global, as a commitment fee, that number of shares of our Common Stock equal to 250,000 divided by the simple average of the daily VWAP of our Common Stock during the five trading days immediately preceding the effectiveness of a "shelf" registration statement on Form S-1 on which the estimated number of shares of our Common Stock are registered. As additional consideration for Arena Global's execution and delivery of the ELOC Purchase Agreement, we issued on October 31, 2024, a five-year warrant (the "ELOC Warrant") exercisable for 585,000 shares of our Common Stock with an exercise price equal to $1.66 per share. However, we may not sell Common Stock to Arena Global under the ELOC Purchase Agreement if (i) a shelf registration statement on Form S-1 that registers the Common Stock issuable under the ELOC Purchase Agreement has not been declared effective by the SEC; (ii) the number of shares of our Common Stock issuable to Arena Global pursuant to a sale notice causes the aggregate number of shares of our Common Stock beneficially owned by Arena Global and its affiliates would exceed 9.99% of the number of shares of our Common Stock then outstanding; (iii) the Shareholder Approval (as defined in the ELOC Purchase Agreement) to issue Common Stock in excess of the Exchange Cap (a cap limiting the issuance of shares pursuant to the ELOC Purchase Agreement and ELOC Warrant to 19.99% of the Company's issued and outstanding shares on the date of the ELOC Purchase Agreement (3,526,802 shares of Common Stock) to the extent such prior stockholder approval would be required for compliance with the rules and regulations of Nasdaq); or (iv) such sale of shares of our Common Stock would exceed, during any 12-month period, one-third of the Company's public float under the SEC's "baby shelf" rule for SEC-registered transactions by an issuer with a public float under $75 million when using a "shelf" registration statement on Form S-1. On November 6, 2024, we filed a registration statement on Form S-1/A (File No. 333-283025) registering for resale up to 61,389,758 shares of our Common Stock (the "Resale Registration Statement"), including the issuances to be made under the ELOC Purchase Agreement which was declared effective on December 6, 2024. On December 11, 2024, our stockholders approved, for purposes of complying with Nasdaq Listing Rule 5635(d), the issuances of shares pursuant to the ELOC in excess of the Exchange Cap. Our ability to make advances under the ELOC Purchase Agreement will also depend on the trading volume of our Common Stock. If trading of our Common Stock fails to achieve or maintain the requisite volume levels, we will be limited in our ability to use the ELOC Purchase Agreement and/or advances we make pursuant to the ELOC Purchase Agreement may adversely affect the trading price of our Common Stock.

Convertible Debenture Financing

On September 6, 2024, we entered into a Securities Purchase Agreement (the "September 2024 Purchase Agreement") with Arena Investors, LP ("Arena Investors"), which provides for the issuance of 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 subject to closing conditions for each tranche. Pursuant to the September 2024 Purchase Agreement, the conversion price of each secured convertible debenture is to equal to 115% of the closing price of our 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 related to the then-current trading price of our Common Stock on Nasdaq as further described in the September 2024 Purchase Agreement. For each secured convertible debenture purchased under the September 2024 Purchase Agreement, the Company will also issue to the purchaser a warrant exercisable to purchase up to that number of shares of Common Stock equal to 25% of the total principal amount of the related secured convertible debenture purchased by the purchaser on the applicable closing date divided by 115% of the closing price of the Company's Common Stock on the trading day immediately preceding such closing date. The Company is not obligated to issue warrants with respect to any tranche that does not close. The exercise price of each warrant issued pursuant to the September 2024 Purchase Agreement will be 115% of the closing price of the Common Stock on its issuance date and the warrants will have a five-year term.

As described in Note 16 of the Financial Statements included in this Quarterly Report, on October 17, 2024, we completed the closing of the first tranche under the September 2024 Purchase Agreement for the issuance of a 10% original issue discount secured convertible debenture (the "First Tranche 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 First Tranche Debenture provides for a payment-in-kind interest rate at 5% and matures on April 14, 2026. In addition, we issued a warrant to Arena Investors exercisable for up to 453,749 shares of Common Stock (the "First Tranche Warrant"). The exercise price of the First Tranche Warrant is $1.89 per share. The net proceeds received from the issuance of the First Tranche Debenture, after deduction of expenses reimbursable to the Arena Investors, were $2,877,588. The Company did not meet the closing conditions for the second and third tranche closings set forth in the September 2024 Purchase Agreement, but the Company and Arena Investors may conduct additional closings under the September 2024 Purchase Agreement as they may agree and subject to the closing conditions set forth therein. There can be no assurance that the parties will reach such an agreement for additional tranche closings.

Pursuant to the September 2024 Purchase Agreement, we, certain of our subsidiaries (the "Subsidiaries"), and Arena Opportunities entered into a security agreement, effective as of October 14, 2024 (the "Security Agreement"), under which we (i) pledged the equity interests in the Subsidiaries and (ii) granted to Arena Opportunities a security interest in, among other items, all of our owned assets, whether currently owned or later acquired, and all proceeds therefrom (the "Assets"), as described in the Security Agreement. In addition, our Subsidiary, Incannex Healthcare Pty Ltd ("IHPL"), entered into a patent security agreement (the "Patent Security Agreement") and a trademark security agreement (the "Trademark Security Agreement"), each effective as of October 14, 2024, under which IHPL granted the investors a security interest in its patents, patent applications, and all proceeds therefrom, and a security interest in its trademarks, trademark applications, and all proceeds therefrom, respectively. In addition, pursuant to the Security Agreement, the Subsidiaries granted to Arena Opportunities a security interest in its Assets and, under a Subsidiary Guarantee, effective as of October 14, 2024 (the "Subsidiary Guarantee"), jointly and severally agreed to guarantee and act as surety for our obligation to repay the September 2024 Debentures and other obligations under the related transaction documents.

We are required to register the shares of our Common Stock issuable upon conversion of the September 2024 Debentures and upon exercise of the September 2024 Debenture Warrants. However, the issuance of the common stock underlying the September 2024 Debentures and the September 2024 Debenture Warrants are subject to stockholder approval to the extent the issuance would exceed 19.99% of the number of shares of our common stock outstanding as of the date of the September 2024 Purchase Agreement. On December 11, 2024, our stockholders approved, for purposes of complying with Nasdaq Listing Rule 5635(d), the issuance of 20% or more of our issued and outstanding Common Stock pursuant to the September 2024 Purchase Agreement, including upon the conversion of September 2024 Debentures and September 2024 Warrants.

On November 6, 2024, pursuant to our agreements in connection with the First Tranche 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 First Tranche Debenture and up to 453,749 shares of Common Stock issuable upon the exercise of the First Tranche Warrant. This registration statement was declared effective on December 6, 2024.

Facility Agreement

On October 9, 2024, we entered into a Facility Agreement (the "Facility Agreement") with FC Credit Pty Ltd ("FC Credit"), under which FC Credit will provide a term loan facility for up to $4.7 million (the "Loan Facility"). On October 10, 2024, we received approximately $4.6 million in an initial drawdown, after deducting certain fees payable by us under the Facility Agreement. The Facility Agreement has a term of 12 months from the date of the initial drawdown (the "Final Repayment Date"). Interest will accrue at the rate of 14.5% per annum, and is payable on the last date of each calendar month and on the Final Repayment Date.

Subject to its terms, this facility provides us with immediate access to funds based on research and development expenses incurred during the 2023 and 2024 financial years, aligning with the end of the Australian financial year, when the Research and Development Tax Incentive program ("RDIT") rebates are paid. The RDIT is a key initiative under the Australian government's innovation framework, designed to encourage companies to undertake research and development activities that benefit Australia. It offers a tax rebate, currently at 48.5%, for eligible research and development expenses, allowing companies to recoup almost half of their research and development spending.

Results of Operations

Comparison of the Three and Six Months Ended December 31, 2024 and 2023

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

	For the Three Months Ended December 31		$	%	For the Six Months Ended December 31		$	%
	2024	2023	Change	Change	2024	2023	Change	Change
Revenue from customers	$ 12	$ -	$ 12	100%	$ 86	$ -	$ 86	100%
Operating expenses:								
Research and development	(1,414)	(2,638)	1,224	(46)%	(4,310)	(5,427)	1,117	(21)%
General and administrative	(3,602)	(5,345)	1,743	(33)%	(7,034)	(7,360)	326	(4)%
Total operating expenses	(5,016)	(7,983)	2,967	(37)%	(11,344)	(12,877)	1,533	(12)%
Loss from operations	(5,004)	(7,983)	2,979	(37)%	(11,258)	(12,877)	1,619	(13)%
Other income / (expense):								
R&D tax incentive	956	2,727	(2,033)	(65)%	1,767	6,824	(5,057)	(74)%
Foreign exchange gains (losses)	(326)	(5)	(321)	6,240%	(331)	(6)	(325)	5,147%
Interest income	28	20	8	40%	57	90	(33)	(37)%
Interest expense	(171)	-	(171)	(100)%	(171)	-	(171)	(100)%
Change in fair value of convertible rights	(179)	-	(179)	(100)%	(179)	-	(179)	(100)%
Change in fair value of warrant liabilities	(103)	-	(103)	(100)%	(103)	-	(103)	(100)%
Other expenses	(1,095)	-	(1,095)	(100)%	(1,095)	-	(1,095)	(100)%
Total other income / (expenses), net	(890)	2,742	(3,632)	(132)%	(55)	6,908	(6,963)	(101)%
Currency translation adjustment, net of tax	(414)	927	(1,341)	(145)%	(75)	418	(493)	(118)%
Comprehensive loss	$ (6,308)	$ (4,314)	$ (1,994)	(46)%	$ (11,388)	$ (5,550)	$ (5,838)	105%

Revenue from Customers

We have generated revenue from Clarion Clinics for patient services for the three and six months ended December 31, 2024. However, we do not expect to generate material revenues unless and until our drug candidates are approved.

Operating Expenses

Research and development

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

Our R&D expenses include:

- external costs associated with services provided by contract research organizations, 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 research and development costs as incurred.

Research and development expenses decreased by $1.2 million for the three months ended December 31, 2024 compared to the three months ended December 31, 2023. The decrease was primarily due to the completion of the IHL-42X safety and pharmacokinetics clinical trial and the pausing of patient recruitment in the Australian Phase 2 clinical trial for IHL-675A in rheumatoid arthritis. This decision was made to reallocate resources for the IHL-675A program and focus on expanding research efforts in the United States, where an expedited regulatory pathway may be available. The primary R&D expense for the period was the Phase 2/3 RePOSA clinical trial investigating IHL-42X in patients with OSA.

Research and development expenses decreased by $1.1 million for the six months ended December 31, 2024 compared to the six months ended December 31, 2023. The decrease was primarily due to the completion of the IHL-42X safety and pharmacokinetics clinical trial and the pausing of patient recruitment in the Australian Phase 2 clinical trial for IHL-675A in rheumatoid arthritis. This decision was made to reallocate resources for the IHL-675A program and focus on expanding research efforts in the United States, where an expedited regulatory pathway may be available. The primary R&D expense for the period was the Phase 2/3 RePOSA clinical trial investigating IHL-42X in patients with OSA.

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.

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 research and development expenses and other costs such as insurance costs and travel expenses.

General and administrative expenses decreased by $1.7 million for the three months ended December 31, 2024, compared to the three months ended December 31, 2023. The decrease was primarily attributable to a decrease in employee benefits, resulting from a reduction in the amount of restricted stock issued to our directors and officers.

General and administrative expenses decreased by $0.3 million for the six months ended December 31, 2024, compared to the six months ended December 31, 2023. The decrease was primarily attributable to a decrease in employee benefits, resulting from a reduction in the amount of restricted stock issued to our directors and officers.

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 research and development 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. If our aggregated turnover is less than A$20 million and is 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 incentive decreased by $2.0 million for the three months ended December 31, 2024 compared to the three months ended December 31, 2023. The decrease was due to a lower estimate of our R&D tax incentive receivable for the three months ended December 31, 2024.

Benefit from R&D tax incentive decreased by $5.1 million for the six months ended December 31, 2024 compared to the six months ended December 31, 2023. The decrease was due to a lower estimate of our R&D tax incentive receivable for the six months ended December 31, 2024.

Foreign exchange losses and Interest Income

Foreign exchange losses increased by $0.3 million for the three months ended December 31, 2024, compared to the three months ended December 31, 2023, due to unfavorable currency exchange rates. Interest income increased over the same period, reflecting higher interest received from cash deposits.

Foreign exchange losses also increased by $0.3 million for the six months ended December 31, 2024 compared to the six months ended December 31, 2023, due to unfavorable currency exchange rates. Interest income increased over the same period, reflecting higher interest received from cash deposits.

Currency translation adjustment, net of tax

Currency translation adjustment, net of tax, decreased by $1.3 million for the three months ended December 31, 2024, compared to the three months ended December 31, 2023. The decrease was due to the depreciation of the Australian dollar against the U.S. dollar. We maintain our consolidated financial statements in Australian dollars, our functional currency, while our financial statements are translated into U.S. dollars for reporting purposes.

Currency translation adjustment, net of tax decreased by $0.5 million for the six months ended December 31, 2024, compared to the six months ended December 31, 2023. The decrease was due to the depreciation of the Australian dollar against the U.S. dollar.

Liquidity and Capital Resources

Sources of Liquidity

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 advance 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 $11.4 million and $5.6 million for the six months ended December 31, 2024 and six months ended December 31, 2023, respectively. We incurred net losses of $5.9 million and $11.3 million for the six months ended December 31, 2024 and six months ended December 31, 2023, respectively. As of December 31, 2024, we had accumulated deficit of $122.0 million.

As of December 31, 2024, we had cash and cash equivalents of $2.1 million. We expect our negative cash flows from operating activities to continue and thus have determined that the losses and negative cash flows from operations and uncertainty in generating sufficient cash to meet our obligations and sustain our operations raise substantial doubt about our ability to continue as a going concern for at least one year from the issuance date of the financial statements included in this Quarterly Report. We do not currently have an update to our previously disclosed cash runway estimate. We have based our cash runway estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

For the six months ended December 31, 2024, we experienced net cash used in operating activities of $7.9 million, an increase of $0.1 million compared to the six months ended December 31, 2023. As of December 31, 2024, we had cash and cash equivalents of $2.1 million, a decrease of $3.8 million compared to our cash and cash equivalents as of June 30, 2024 of $5.9 million. As of December 31, 2024, our current assets exceed our current liabilities by $4.7 million, a $5.9 million decrease compared to the difference between our current assets and current liabilities as of June 30, 2024 of $10.6 million.

Going Concern

Refer to Note 2 – Basis of Presentation and Summary of Significant Accounting Policies – Going Concern Basis

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 for the six months ended December 31, 2024 and six months ended December 31, 2023

The following table summarizes our cash flows for the periods presented (in thousands):

	For the Six Months Ended December 31, 2024	For the Six Months Ended December 31, 2023
Net cash used in operating activities	$ (7,872)	$ (7,852)
Net cash used in investing activities	(8)	(280)
Net cash provided by financing activities	4,050	-
Net (decrease)/increase in cash	$ (3,830)	$ (8,132)

Net cash flows from operating activities

Net cash used in operating activities increased an insignificant amount for the six months ended December 31, 2024, compared to the six months ended December 31, 2023. The increase was due to a decrease in in R&D tax incentive received.

Net cash flows from investing activities

Net cash used in investing activities decreased by $0.3 million for the six months ended December 31, 2024 compared to the six months ended December 31, 2023. The decrease was due to reduced spending on property, plant and equipment.

Net cash flows from financing activities

Net cash provided by financing activities increased by $4.1 million for the six months ended December 31, 2024, compared to the three months ended December 31, 2023. The increase was due to the issuance of the FC Credit Facility Agreement and the issuance of the First Tranche Debenture.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited interim condensed consolidated financial statements as of December 31, 2024, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these unaudited interim condensed consolidated financial statements requires our management to make judgments and estimates that affect the reported amounts of assets, liabilities, costs, and expenses, and the disclosure of contingent assets and liabilities during the reporting periods. 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 these 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 consolidated financial statements described in the 2024 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.

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 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 Black-Scholes option-pricing model, require the input of several assumptions. These inputs are subjective and generally require significant analysis and judgment to develop.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development 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 research and development 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 based on estimated services to be conducted by third-party service providers, which include preclinical studies and clinical trials, and contract manufacturing activities. We record these estimated costs based upon the estimated amount of services provided, but not yet invoiced, and include 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 these costs based on factors such as estimates of the work completed and in accordance with agreements established with our third-party service providers. We make significant judgments and estimates when determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, we adjust our accrued liabilities accordingly. To date, we have not experienced any material differences between the accrued costs and actual costs incurred.

Benefit from R&D Tax Incentive

Benefit from the 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.

Warrants

We determine whether to classify contracts, such as warrants, that may be settled in our 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.

Derivative Financial Instruments

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 instrument (i.e. embedded derivatives) are then assessed to determine if they must be bifurcated and separately accounted for as freestanding derivatives.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a "smaller reporting company" (as defined by Item 10 of Regulation S-K), we are permitted to omit information required by this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, designed to ensure that information required to be disclosed in our reports is recorded, processed, summarized, and reported within the time periods specified by the SEC's rules and forms. These controls are intended to accumulate and communicate to our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), or persons performing similar functions, as appropriate to enable 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 CEO and CFO, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on this evaluation, our CEO and CFO concluded that, as of December 31, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level due to a material weakness in internal control over financial reporting, which existed as of December 31, 2024, relating to the documentation of accounting policies and procedures, particularly relating to the correct application of complex accounting measures, as previously reported in our 2024 Annual Report.

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 December 31, 2024, 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 include, but are not limited to: (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) providing 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.

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 concluded 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.

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 defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act, that occurred during the three and six months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we 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 1A. Risk Factors

Except as set forth below, there have been no material changes to the risk factors set forth in Part I, Item 1A, "Risk Factors," of the 2024 Annual Report.

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

Our Common Stock is currently listed on the Nasdaq Global Market. Continued listing of a security on the Nasdaq Stock Market is conditioned upon compliance with various continued listing standards for the applicable market tier. On January 3, 2025, we received a letter (the "Notice") from Nasdaq notifying us that, we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) (the "Listing Rule"), which requires us to maintain a minimum Market Value of Listed Securities ("MLVS") of at least $50.0 million. The Notice stated that we have 180 calendar days, or until July 2, 2025, to regain compliance with the Listing Rule. There is no immediate effect on the trading of our Common Stock. To regain compliance, our MVLS must meet or exceed $50.0 million for a minimum of ten consecutive business days during the 180-day compliance period ending on July 2, 2025.

We are actively monitoring our stock price and our MLVS and will consider any and all options available to us to maintain or, if necessary, regain compliance, including, to the extent we may then be eligible, listing on the Nasdaq Capital Market. There can be no assurance, however, that we will be able to maintain or, if necessary, regain compliance and meet Nasdaq's continued listing requirements for any market tier when or as needed. To the extent that we are unable to maintain or, if necessary, regain compliance with the Listing Rule or the other requirements of Nasdaq for continued listing, there is a risk that our Common Stock may be delisted from Nasdaq. Delisting from Nasdaq may limit the range and attractiveness of strategic alternatives that we are able to consider, adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities, or negatively affect the value and liquidity of our Common Stock.

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

As described in Note 2 of the Condensed Consolidated Financial Statements included in this Quarterly Report on 10-Q, we issued 142,403 shares of Common Stock to Arena Global on December 9, 2024 and issued a warrant to Arena Global to purchase up to 585,000 shares of Common Stock on October 31, 2024. These issuances were made pursuant to the requirements of Section 4(a)(2) of the Securities Act and applicable blue sky exemptions, as additional consideration for Arena Global's entry into the ELOC Agreement. The information in Note 2 of the Condensed Consolidated Financial Statements is hereby incorporated by reference to this item.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 trading arrangements

During the three and six months ended December 31, 2024, 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 6. Exhibits

The information required by this Item 6 is set forth on the Exhibit Index that immediately precedes the signature page to this report and is incorporated herein by reference.

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).
3.2	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 Capital Stock (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed with the SEC on November 29, 2023).
4.2	Debenture, dated October 14, 2024 (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 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).
10.1	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).
10.2^	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).
10.3	Security Agreement (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
10.4^	Patent Security Agreement (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
10.5^	Trademark Security Agreement (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
10.6	Subsidiary Guarantee (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-3 filed with the SEC on November 6, 2024).
10.7#^	Employment Agreement, effective October 21, 2024, by and between the Company and Luigi M. Barbato, M.D. (incorporated by referenced to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 24, 2024).
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 and 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.
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.
101.INS	Inline XBRL Instance Document.
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 (embedded within the Inline XBRL document).

* 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.

SIGNATURES

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

Incannex Healthcare Inc.

Date: February 14, 2025

By: /s/ Joel Latham
Joel Latham
Chief Executive Officer,
Director and President

Date: February 14, 2025

By: /s/ Joseph Swan
Joseph Swan
Chief Financial Officer,
Treasurer and Secretary

Exhibit 31.1

I, Joel Latham, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 of Incannex Healthcare Inc. (the "Company");

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 14, 2025

By: /s/ Joel Latham
Name: Joel Latham
Title: President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

I, Joseph Swan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 of Incannex Healthcare Inc. (the "Company");

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 14, 2025

By: /s/ Joseph Swan
Name: Joseph Swan
Title: Chief Financial Officer, Treasurer and Secretary
(principal financial and accounting officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Incannex Healthcare Inc. (the "Company") on Form 10-Q for the quarter ended December 31, 2024 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, I, Joel Latham, Chief Executive Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2025

By: /s/ Joel Latham
Name: Joel Latham
Title: President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Incannex Healthcare Inc. (the "Company") on Form 10-Q for the quarter ended December 31, 2024 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, I, Joseph Swan, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2025

By: /s/ Joseph Swan
Name: Joseph Swan
Title: Chief Financial Officer, Treasurer
and Secretary
(principal financial and accounting officer)