

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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ANAVEX LIFE SCIENCES CORP.

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SIC: **2836** Biological products, (no diagnostic substances)

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**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: March 31, 2025

**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: 001-37606

ANAVEX LIFE SCIENCES CORP.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

98-0608404

(IRS Employer
Identification No.)

630 5th Avenue, 20th Floor, New York, NY USA 10111

(Address of principal executive offices) (Zip Code)

1-844-689-3939

(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock Par Value \$0.001	AVXL	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).

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

Large accelerated filer
Non-accelerated filer
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).

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date: 85,371,852 shares of Common Stock outstanding as of May 13, 2025.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ANAVEX LIFE SCIENCES CORP.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

March 31, 2025

(Unaudited)

Anavex Life Sciences Corp.
Condensed Consolidated Interim Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2025	September 30, 2024
	(Unaudited)	
Assets		
Current		
Cash and cash equivalents	\$ 115,771	\$ 132,187
Incentive and tax receivables	666	2,449
Prepaid expenses and other current assets	702	931
Total Assets	<u>\$ 117,139</u>	<u>\$ 135,567</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 6,997	\$ 9,627
Accrued liabilities - Note 3	9,555	4,835
Deferred grant income - Note 4	829	842
Total Liabilities	<u>\$ 17,381</u>	<u>\$ 15,304</u>
Commitments and Contingencies - Note 6		
Capital stock		
Authorized:		
10,000,000 preferred stock, par value \$0.001 per share		
200,000,000 common stock, par value \$0.001 per share		
Issued and outstanding:		
85,333,652 common shares (2024 - 84,795,517)	85	85
Additional paid-in capital	459,051	456,249
Accumulated deficit	(359,378)	(336,071)
Total Stockholders' Equity	<u>\$ 99,758</u>	<u>\$ 120,263</u>
Total Liabilities and Stockholders' Equity	<u>\$ 117,139</u>	<u>\$ 135,567</u>

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Condensed Consolidated Interim Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
Operating expenses				
General and administrative	\$ 2,621	\$ 2,895	\$ 5,767	\$ 5,590
Research and development	<u>9,892</u>	<u>9,729</u>	<u>20,338</u>	<u>18,413</u>
Total operating expenses	<u>12,513</u>	<u>12,624</u>	<u>26,105</u>	<u>24,003</u>
Operating loss	(12,513)	(12,624)	(26,105)	(24,003)
Other income (expense)				
Grant income	—	—	12	—
Research and development incentive income	96	472	508	1,064
Interest income, net	1,210	1,756	2,604	3,764
Foreign exchange gain (loss)	11	(150)	(326)	7
Total other income, net	<u>1,317</u>	<u>2,078</u>	<u>2,798</u>	<u>4,835</u>
Net loss and comprehensive loss	<u>\$ (11,196)</u>	<u>\$ (10,546)</u>	<u>\$ (23,307)</u>	<u>\$ (19,168)</u>
Net Loss per share				
Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>	<u>\$ (0.27)</u>	<u>\$ (0.23)</u>
Weighted average number of shares outstanding				
Basic and diluted	<u>85,073,769</u>	<u>82,464,226</u>	<u>84,938,400</u>	<u>82,269,965</u>

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Condensed Consolidated Interim Statements of Cash Flows
(in thousands, except share and per share amounts)
(Uaudited)

	Six months ended March 31,	
	2025	2024
Cash Flows used in Operating Activities		
Net loss	\$ (23,307)	\$ (19,168)
Adjustments to reconcile net loss to net cash used in operations:		
Share based compensation	3,504	4,938
Changes in working capital balances related to operations:		
Incentive and tax receivables	1,783	(1,076)
Prepaid expenses and deposits	229	(692)
Accounts payable	(4,893)	(596)
Accrued liabilities	4,720	(2,380)
Deferred grant income	(12)	—
Net cash used in operating activities	<u>(17,976)</u>	<u>(18,974)</u>
Cash Flows provided by Financing Activities		
Issuance of common shares	—	7,178
Proceeds from exercise of stock options	<u>1,560</u>	<u>158</u>
Net cash provided by (used in) financing activities	<u>1,560</u>	<u>7,336</u>
Decrease in cash and cash equivalents during the period	<u>(16,416)</u>	<u>(11,638)</u>

Cash and cash equivalents, beginning of period	132,187	151,024
Cash and cash equivalents, end of period	\$ 115,771	\$ 139,386
Supplemental Cash Flow Information		
Cash paid for state and local franchise taxes	\$ 36	\$ 220
Common stock issued upon cashless exercise of stock option	\$ 460	\$ —

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Condensed Consolidated Interim Statements of Changes in Stockholders' Equity
For the three months ended March 31, 2025 and 2024
(in thousands, except share and per share amounts)
(Uaudited)

	Common Stock		Additional		Share		Accumulated	
	Shares	Par Value	Paid-in Capital		Proceeds		Deficit	
	Shares	Par Value	Paid-in Capital		Receivable		Deficit	
Balance, January 1, 2025	84,985,449	\$ 85	\$ 459,012		\$ —		\$ (348,182)	\$ 110,915
Shares issued pursuant to exercise of stock options	130,700	—	852		—		—	852
Shares issued pursuant to cashless exercise of stock option	500,000	1	459		—		—	460
Shares withheld related to cashless exercise of stock option and taxes	(282,497)	(1)	(2,721)		—		—	(2,722)
Share based compensation	—	—	1,449		—		—	1,449
Net loss	—	—	—		—		(11,196)	(11,196)
Balance, March 31, 2025	85,333,652	\$ 85	\$ 459,051		\$ —		\$ (359,378)	\$ 99,758
Balance, January 1, 2024	82,086,511	\$ 82	\$ 437,184		\$ —		\$ (301,691)	\$ 135,575
Shares issued under 2023 purchase agreement	—	—	—		—		—	—
Purchase shares	1,500,000	2	7,410		(234)		—	7,178
Commitment shares	3,707	—	—		—		—	—
Shares issued pursuant to exercise of stock options	26,000	—	99		—		—	99
Share based compensation	—	—	2,652		—		—	2,652
Net loss	—	—	—		—		(10,546)	(10,546)
Balance, March 31, 2024	83,616,218	\$ 84	\$ 447,345		\$ (234)		\$ (312,237)	\$ 134,958

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Condensed Consolidated Interim Statements of Changes in Stockholders' Equity
For the six months ended March 31, 2025 and 2024
(in thousands, except share and per share amounts)
(Unaudited)

	Common Stock		Additional		Share		Accumulated	
	Shares	Par Value	Paid-in Capital		Proceeds		Deficit	
	<hr/>	<hr/>	<hr/>		<hr/>		<hr/>	
Balance, October 1, 2024	84,795,517	\$ 85	\$ 456,249		\$ —		\$ (336,071)	\$ 120,263
Shares issued pursuant to exercise of stock options	320,632	—	1,560		—		—	1,560
Shares issued pursuant to cashless exercise of stock option	500,000	1	459		—		—	460
Shares withheld related to cashless exercise of stock option and taxes	(282,497)	(1)	(2,721)		—		—	(2,722)
Share based compensation	—	—	3,504		—		—	3,504
Net loss	—	—	—		—		(23,307)	(23,307)
Balance, March 31, 2025	85,333,652	\$ 85	\$ 459,051		\$ —		\$ (359,378)	\$ 99,758
Balance, October 1, 2023	82,066,511	\$ 82	\$ 434,839		\$ —		\$ (293,069)	\$ 141,852
Shares issued under 2023 Purchase Agreement	1,500,000	2	7,410		(234)		—	7,178
Purchase shares	3,707	—	—		—		—	—
Commitment shares	—	—	—		—		—	—
Shares issued pursuant to exercise of stock options	46,000	—	158		—		—	158
Share based compensation	—	—	4,938		—		—	4,938
Net loss	—	—	—		—		(19,168)	(19,168)
Balance, March 31, 2024	83,616,218	\$ 84	\$ 447,345		\$ (234)		\$ (312,237)	\$ 134,958

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Notes to the Condensed Consolidated Interim Financial Statements
March 31, 2025 Page 1
(Unaudited)

Note 1 Business Description

Business

Anavex Life Sciences Corp. (“Anavex” or the “Company”) is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system (“CNS”) diseases with high unmet need. Anavex analyzes genomic data from clinical trials to identify biomarkers, which are used in the analysis of its clinical trials for the treatment of neurodegenerative and neurodevelopmental diseases.

The Company's focus is on developing innovative treatments for Alzheimer's disease, Parkinson's disease, schizophrenia, neurodevelopmental, neurodegenerative, and rare diseases, including Rett syndrome, and other central nervous system (CNS) disorders.

Note 2 Basis of Presentation

These accompanying unaudited condensed consolidated interim financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim reporting. Accordingly, certain information and note disclosures normally included in the annual financial statements in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the disclosures are adequate to make the information presented not misleading.

These accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, which in the opinion of management are necessary for fair presentation of the information contained herein. The consolidated balance sheet as of September 30, 2024 was derived from the audited annual financial statements but does not include all disclosures required by U.S. GAAP. The accompanying unaudited condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended September 30, 2024 filed with the SEC on December 23, 2024. The Company follows the same accounting policies in the preparation of interim reports.

Operating results for the six months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending September 30, 2025.

Certain immaterial amounts from prior periods have been reclassified to conform to the current year's presentation.

Liquidity

All of the Company's potential drug compounds are in the clinical development stage and the Company cannot be certain that its research and development efforts will be successful or, if successful, that its potential drug compounds will ever be approved for sales to pharmaceutical companies or generate commercial revenues. To date, we have not generated any revenue from our operations. The Company expects the business to continue to experience negative cash flows from operations for the foreseeable future and cannot predict when, if ever, our business might become profitable.

Management believes that the current working capital position will be sufficient to meet the Company's working capital requirements beyond the next 12 months after the date that these condensed consolidated interim financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trials are uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company's research and development programs and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials.

Anavex Life Sciences Corp.

Notes to the Condensed Consolidated Interim Financial Statements

March 31, 2025 Page 2

(Unaudited)

Other than our rights related to the 2023 Purchase Agreement (as defined below in Note 5), there can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. The Company will need to obtain effectiveness of a new registration statement in order to access the funds under the 2023 Purchase Agreement. If the Company is not able to obtain the additional financing on a timely basis, if and when it is needed, it will be forced to delay or scale down some or all of its research and development activities.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company regularly evaluates estimates and assumptions related to accounting for research and development costs, incentive and tax receivables, valuation and recoverability of deferred tax assets, share based compensation, and loss contingencies. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

Principles of Consolidation

These unaudited condensed consolidated interim financial statements include the accounts of Anavex Life Sciences Corp. and its wholly-owned subsidiaries, Anavex Australia Pty Limited ("Anavex Australia"), a company incorporated under the laws of Australia, Anavex Germany GmbH, a company incorporated under the laws of Germany, and Anavex Canada Ltd., a company incorporated under the laws of the Province of Ontario, Canada. All inter-company transactions and balances have been eliminated.

Fair Value Measurements

The fair value hierarchy under GAAP is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - observable inputs other than Level 1, quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; and

Level 3 - assets and liabilities whose significant value drivers are unobservable by little or no market activity and that are significant to the fair value of the assets or liabilities.

At March 31, 2025 and September 30, 2024, the Company did not have any Level 2 or Level 3 assets or liabilities.

Basic and Diluted Loss per Share

Basic income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the sum of (1) the weighted-average number of common shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the diluted net loss per share calculation, options and warrants are potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

As of March 31, 2025 loss per share excludes 15,710,622 (March 31, 2024: 15,755,114) potentially dilutive common shares related to outstanding options and warrants, as their effect was anti-dilutive.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued ASU No. 2023-07, "Segment Reporting: Improvements to Reportable Segment Disclosures." This guidance requires disclosure of incremental segment information on an annual and interim

basis. This amendment is effective for our fiscal year ending September 30, 2025 and our interim periods within the fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes: Improvements to Income Tax Disclosures.” This guidance requires consistent categories and greater disaggregation of information in the rate reconciliation and disclosures of income taxes paid by jurisdiction. This amendment is effective for our fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

Note 3 Accrued Liabilities

The principal components of accrued liabilities consist of (in thousands):

	March 31, 2025	September 30, 2024
Accrued investigator payments	\$ 1,459	\$ 860
Accrued compensation and benefits	2,200	1,527
Milestone-based contract accruals	4,332	557
All other accrued liabilities	1,564	1,891
Total accrued liabilities	\$ 9,555	\$ 4,835

Note 4 Other Income

Grant income

As of March 31, 2025, the Company had received a \$1.0 million research grant awarded by the Michael J. Fox Foundation for Parkinson’s Research. The grant will be used to fund a clinical trial of the Company’s lead compound, ANAVEX®2-73 (blarcamesine) related to Parkinson’s disease. Of the total, \$0.5 million was received during the year ended September 30, 2023 and \$0.5 million was received during the year ended September 30, 2021.

The grant income was deferred when received and is being amortized to other income as the related research and development expenditures are incurred. During the three and six months ended March 31, 2025, the Company recognized \$0 and \$12,275, respectively (three and six months ended March 31, 2024: \$0) of this grant on its statements of operations within grant income. At March 31, 2025 an amount of \$0.8 million (September 30, 2024: \$0.8 million) of this grant is recorded as deferred grant income, representing the amount of this grant which has not yet been amortized to other income. The Company will recognize this income on its statements of operations as the related expenditures are incurred to offset the income.

Anavex Life Sciences Corp.

Notes to the Condensed Consolidated Interim Financial Statements

March 31, 2025 Page 4

(Unaudited)

Research and development incentive income

Research and development incentive income represents the income earned by Anavex Australia of the Australia R&D credit. This cash incentive is received by Anavex Australia, upon filing of a claim in connection with Anavex Australia’s annual income tax return.

During the three and six months ended March 31, 2025, the Company recorded research and development incentive income of \$0.1 million (AUD 0.2 million) and \$0.5 million (AUD 0.8 million), respectively (2024: \$0.5 million (AUD 0.7 million) and \$1.1 million (AUD 1.6 million), respectively) in respect of the Australia R&D credit for eligible research and development expenses incurred during the period. This amount is included within Other income (expense) on the condensed consolidated interim statements of operations and comprehensive loss.

At March 31, 2025, Incentive and tax receivables includes \$0.5 million (AUD 0.8 million) (September 30, 2024: \$2.3 million (AUD 3.3 million)) relating to Australia R&D credits earned during the period that are expected to be reimbursed upon filing of the Company's annual claim under this program.

The Australia R&D credit program is a self-assessment program whereby the Company must assess its eligibility each year to determine (i) if the entity is eligible (ii) if specific R&D activities are eligible and (iii) if the individual R&D expenditures have nexus to such R&D activities. The Company evaluates its eligibility under the tax incentive program as of each balance sheet date based on the most current and relevant data available. Anavex Australia is able to continue to claim the R&D tax incentive for as long as it remains eligible and continues to incur eligible research and development expenditures.

Although the Company believes that it has complied with all the relevant conditions of eligibility under the program for all periods claimed, the ATO has the right to review the Company's qualifying programs and related expenditures for a period of four years. If such a review were to occur, the ATO may have different interpretations of certain eligibility requirements. If the ATO disagreed with the Company's assessments and any related subsequent appeals, it could require adjustment to and repayment of current or previous years' claims already received. Additionally, if the Company was unable to demonstrate a reasonably arguable position taken on such claims, the ATO could also assess penalties and interest on any such adjustments.

Currently, the Company's tax incentive claims from 2020 to 2024 are open to potential review by the ATO. Additionally, the period open for review is indefinite if the ATO suspects fraud. The Company has not provided any allowance for any such potential adjustments, should they occur in the future.

Note 5 Equity Offerings

Common Stock

Common shares are voting and are entitled to dividends as declared at the discretion of the Board of Directors.

Preferred Stock

The Company's Board of Directors (the "Board") has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges, restrictions and the number of shares constituting any series or the designation of the series.

Anavex Life Sciences Corp.

Notes to the Condensed Consolidated Interim Financial Statements

March 31, 2025 Page 5

(Unaudited)

2023 Purchase Agreement

On February 3, 2023, the Company entered into a \$150.0 million purchase agreement (the "2023 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company has the right to sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$150.0 million in value of its shares of common stock from time to time over a three-year period until February 3, 2026.

In consideration for entering into the 2023 Purchase Agreement, the Company issued to Lincoln Park 75,000 shares of common stock as a commitment fee (the "initial commitment shares") and agreed to issue up to an additional 75,000 shares pro rata, when and if, Lincoln Park purchased, at the Company's discretion, the \$150.0 million aggregate commitment. The Company determined the fair value of the initial commitment shares was \$0.8 million with reference to the closing price of the Company's shares on the Purchase Agreement date. In addition, the Company incurred third party expenses of \$0.1 million in connection with entering into the Purchase Agreement. These amounts were expensed to other financing expense on the statements of operations during the year ended September 30, 2023.

During the six months ended March 31, 2025, the Company did not issue any shares of common stock under the 2023 Purchase Agreement (2024: an aggregate of 1,503,707 shares of common stock including 1,500,000 shares for an aggregate purchase price of \$7.4 million and 3,707 commitment shares).

At March 31, 2025, there was an unused amount of \$110.8 million under the 2023 Purchase Agreement. The Company will need to obtain effectiveness of a new registration statement in order to access funds under the 2023 Purchase Agreement.

2020 Sales Agreement

The Company entered into a Controlled Equity Offering Sales Agreement on July 6, 2018, which was amended and restated on May 1, 2020 (the “2020 Sales Agreement”) with Cantor Fitzgerald & Co. and SVB Leerink LLC (together the “Sales Agents”), pursuant to which the Company could offer and sell shares of common stock registered under an effective registration statement from time to time through the Sales Agents (the “Offering”).

During the six months ended March 31, 2024, no shares were sold pursuant to the Offering.

On July 24, 2024, the Company terminated the 2020 Sales Agreement.

Stock Options

During the three and six months ended March 31, 2025, the Company issued a net 217,503 shares of common stock to the Company’s Chief Executive Officer upon a net exercise of an option to purchase 500,000 shares of common stock at an exercise price of \$0.92 per share. In connection with the exercise, the Company withheld 47,745 shares of common stock as consideration of the exercise price of \$0.46 million and 234,752 shares of common stock as consideration for the payment of \$2.3 million in connection with tax withholding obligations associated with the exercise. The shares withheld were based upon a market price of \$9.63 per share as determined by reference to the average high and low sales price reported on the Nasdaq stock exchange on the date of exercise. At March 31, 2025, the amount of \$2.3 million in connection with the tax withholding obligations was included in accounts payable on the consolidated balance sheets.

Note 6 Commitments and Contingencies

Lease

The Company leases office space under an operating lease with an initial term of 12 months or less. Under the terms of the office lease, the Company is required to pay its proportionate share of operating costs.

Anavex Life Sciences Corp.

Notes to the Condensed Consolidated Interim Financial Statements

March 31, 2025 Page 6

(Unaudited)

The operating lease costs were as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2024	2025
Operating lease costs		\$33	\$31	\$66

Employee 401(k) Benefit Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers all United States based employees. United States based employees eligible to participate in the plan may contribute up to the current statutory limits under the Internal Revenue Service regulations. The 401(k) plan permits the Company to make additional matching contributions on behalf of contributing employees.

The Company made matching contributions under the 401(k) plan as follows (in thousands):

	Three Months Ended March 31,		Six Months ended March 31	
	2025	2024	2025	2024
Contributions to 401(k) plan	\$ 67	\$ 94	\$ 115	\$ 167

Litigation

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's consolidated financial statements. The Company does not believe that any of such pending claims and legal proceedings will have a material adverse effect on its consolidated financial statements.

On March 13, 2024, a shareholder class action complaint was filed in the United States District Court for the Southern District of New York and it named the Company and an officer of the Company as Defendants. The complaint was amended on July 12, 2024 (the "Initial Action"). The complaint alleged violations of the Securities and Exchange Act of 1934 associated with disclosures and statements made with respect to certain clinical trials for ANAVEX®2-73 related to Rett syndrome. The complaint seeks unspecified damages, as well as costs, including counsel and expert witness fees, on behalf of a class of investors. The Company believes the lawsuit is without merit and the Company denies any liability or wrongdoing and has filed a motion to dismiss the complaint, which is awaiting a decision by the Court. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

On May 8, 2024, a similar complaint was filed in the same court by Kenneth Downing, a purported shareholder of the Company, against the same defendants. The Company believed that this lawsuit was also without merit and filed a motion to dismiss the complaint. Plaintiff Downing voluntarily dismissed this complaint subsequent to the filing of the motion to dismiss.

On or about May 13, 2024, a derivative lawsuit was filed against the Company (as nominal defendant), an officer of the Company, and members of the Company's Board of Directors in the U.S. District Court for the District of Nevada by another purported shareholder. The complaint asserts various common law claims (including breach of fiduciary duty) and violation of Section 14(a) of the Securities Exchange Act regarding the same or similar allegations at issue in the purported class action lawsuit related to disclosures and statements made about certain clinical trials related to Rett Syndrome. On January 22, 2025, pursuant to a stipulation of the parties, the Court entered an order staying this purported derivative lawsuit until the motion to dismiss filed by defendants in the Initial Action is decided by the U.S. District Court for the Southern District of New York. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

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(Unaudited)

On February 14, 2025, another derivative lawsuit asserting state law breach of fiduciary duty and unjust enrichment claims based upon similar allegations was filed against the Company (as nominal defendant), an officer of the Company, and members of the Company's Board of Directors in the Supreme Court for the State of New York, County of New York, by another purported shareholder named Evan Levitan. The parties to that action also have stipulated to a stay of the proceeding until the Court rules on the motion to dismiss in the putative class action lawsuit pending in the U.S. District Court for the Southern District of New York. The New York state court has not yet entered an order pursuant to the stipulation of the parties. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

We know of no other material pending legal or governmental proceedings, other than ordinary routine litigation incidental to our business, to which our Company or our subsidiaries are a party or of which any of their property is subject. There are no other proceedings in which

any of our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, or any associate of such persons, is an adverse party or has a material interest adverse to our or our subsidiaries' interest.

Share Purchase Warrants

At March 31, 2025 and September 30, 2024, the Company had 10,000 share purchase warrants outstanding exercisable at \$12.00 per share until April 21, 2026.

Share-based Compensation Plan

2015 Stock Option Plan

On September 18, 2015, the Company's Board approved a 2015 Omnibus Incentive Plan (the "2015 Plan"), which provided for the grant of stock options and restricted stock awards to directors, officers, employees and consultants of the Company.

The maximum number of our common shares reserved for issue under the 2015 Plan was 6,050,553 shares, subject to adjustment in the event of a change of the Company's capitalization.

2019 Stock Option Plan

On January 15, 2019, the Board approved the 2019 Omnibus Incentive Plan (the "2019 Plan"), which provides for the grant of stock options and restricted stock awards to directors, officers, employees, consultants and advisors of the Company.

The maximum number of our common shares reserved for issue under the 2019 Plan was 6,000,000 shares, subject to adjustment in the event of a change of the Company's capitalization.

During the year ended September 30, 2022, 406,453 options previously available under the 2019 Plan and the 2015 Plan became available under the 2022 Plan (as defined below).

2022 Stock Option Plan

On March 25, 2022, the Board approved the 2022 Omnibus Incentive Plan (the "2022 Plan"). The 2022 Plan was approved by stockholders on May 24, 2022. Under the terms of the 2022 Plan, 10,000,000 additional shares of Common Stock will be available for issuance under the 2022 Plan, in addition to the shares available under the 2019 Plan and the 2015 Plan. Any awards outstanding under a previous stock option plan will remain subject to and be paid under such plan, and any shares subject to outstanding awards under a previous plan that subsequently cease to be subject to such awards (other than by reason of settlement of the awards in shares) will automatically become available for issuance under the 2022 Plan.

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(Unaudited)

The 2022 Plan provides that it may be administered by the Board, or the Board may delegate such responsibility to a committee. The exercise price will be determined by the Board at the time of grant shall be at least equal to the fair market value on such date. If the grantee is a 10% stockholder on the grant date, then the exercise price shall not be less than 110% of fair market value of the Company's shares of common stock on the grant date. Stock options may be granted under the 2022 Plan for an exercise period of up to ten years from the date of grant of the option or such lesser periods as may be determined by the Board, subject to earlier termination in accordance with the terms of the 2022 Plan. As at March 31, 2025, 6,751,000 options had been issued under the 2022 Plan and 3,978,702 options were available for issue under the 2022 Plan.

The following summarizes information about stock option activity during the six months ended March 31, 2025:

	Number of Options	Weighted Average Exercise Price (\$)	Weighted Average Grant Date Fair Value (\$)	Aggregate intrinsic value (\$)
Outstanding, September 30, 2024	15,037,754	6.80	5.12	15,825,791
Granted	1,483,500	8.58	6.22	—
Exercised	(820,632)	2.46	1.89	6,785,518
Outstanding, March 31, 2025	15,700,622	7.19	5.39	38,630,198
Exercisable, March 31, 2025	10,346,086	6.03	4.68	34,276,704

The following summarizes information about stock options at March 31, 2025 by a range of exercise prices:

Range of exercises prices		Number of outstanding	Weighted average remaining contractual life (in years)	Weighted average exercise	Number of vested	Weighted average exercise
From	To					
\$ 0.92	\$ 3.00	2,400,150	3.92	\$ 2.69	2,400,150	\$ 2.69
\$ 3.01	\$ 5.00	2,197,500	3.44	\$ 3.41	2,027,916	\$ 3.31
\$ 5.01	\$ 9.00	8,028,972	6.36	\$ 6.95	4,297,519	\$ 6.39
\$ 9.01	\$ 13.00	1,609,000	6.81	\$ 10.29	998,834	\$ 10.42
\$ 13.01	\$ 25.00	1,465,000	5.97	\$ 18.18	621,667	\$ 18.34
		<u>15,700,622</u>	<u>5.59</u>	<u>\$ 7.19</u>	<u>10,346,086</u>	<u>\$ 6.03</u>

The weighted average per share fair value of options vested at March 31, 2025 was \$4.68 (September 30, 2024: \$4.34). At March 31, 2024, the weighted average contractual life of options outstanding was 5.59 years (September 30, 2024: 5.48 years) and for options exercisable was 4.16 years (September 30, 2024: 4.03 years).

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(Unaudited)

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted market price of the Company's stock for the options that were in-the-money at March 31, 2025.

The Company recognized share-based compensation expense of \$1.4 million and \$3.5 million during the three and six months ended March 31, 2025, respectively (three and six months ended March 31, 2024: \$2.7 million and \$4.9 million, respectively) in connection with the issuance and vesting of stock options in exchange for services. These amounts have been included in general and administrative expenses and research and development expenses on the Company's condensed consolidated interim statements of operations as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
General and administrative	\$ 605	\$ 979	\$ 1,407	\$ 1,905
Research and development	844	1,673	2,097	3,033
Total share-based compensation	<u>\$ 1,449</u>	<u>\$ 2,652</u>	<u>\$ 3,504</u>	<u>\$ 4,938</u>

An amount of approximately \$14.5 million in share-based compensation is expected to be recorded over the remaining term of such options and warrants through fiscal 2029.

The fair value of each stock option award is estimated on the date of grant using the Black Scholes option pricing model. The fair value of share-based compensation charges recognized during the three and six months ended March 31, 2025 was determined with reference to the quoted market price of the Company's shares on the grant date and based on the following weighted average assumptions:

	2025	2024
Risk-free interest rate	3.98%	4.28%
Expected life of options (years)	5.56	5.74
Annualized volatility	86.49%	84.84%
Dividend rate	0.00%	0.00%

Note 7 Subsequent Events

The Company evaluates subsequent events occurring between the most recent balance sheet date and the date the financial statements are available to be issued in order to determine whether the subsequent events are to be recorded and/or disclosed in the Company's financial statements and footnotes. The financial statements are considered to be available to be issued at the time they are filed with the Securities and Exchange Commission (SEC).

On April 17, 2025, the Board approved, subject to stockholder approval, an amendment to the 2022 Plan (the "Amendment"). The Amendment, if approved by stockholders, will increase the number of shares of common stock reserved for issuance under the 2022 Plan by 4,000,000 shares. In addition, the Amendment will establish a minimum vesting period of one year for all awards granted under the Plan and limit the discretion to accelerate the vesting of awards upon a separation from service, with limited exceptions permitted. Finally, the Amendment would prohibit liberal share recycling provisions.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our anticipated future clinical and regulatory milestone events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" "should," "forecast," "potential," "predict", "could," "would," "will," "suggest," "plan" and similar expressions, as they relate to us, are intended to identify forward-looking statements. Such forward-looking statements include, without limitation, statements regarding:

- volatility in our stock price and in the markets in general;
- our ability to successfully conduct preclinical studies and clinical trials for our product candidates;
- our ability to raise additional capital on favorable terms and the impact of such activities on our stockholders and stock price;
- our ability to generate any revenue or to continue as a going concern;
- our ability to execute our research and development plan on time and on budget;
- our product candidates' ability to demonstrate efficacy or an acceptable safety profile;
- our ability to obtain the support of qualified scientific collaborators;
- our ability, whether alone or with commercial partners, to successfully commercialize any of our product candidates that may be approved for sale;
- our ability to identify and obtain additional product candidates;
- our reliance on third parties in non-clinical studies and clinical trials;
- our ability to defend against product liability claims;
- our ability to safeguard against security breaches;
- our ability to obtain and maintain sufficient intellectual property protection for our product candidates;
- our ability to comply with our intellectual property licensing agreements;
- our ability to defend against claims of intellectual property infringement;
- our ability to comply with the maintenance requirements of the government patent agencies;

- our ability to protect our intellectual property rights throughout the world;
- competition;
- the anticipated start dates, durations and completion dates of our ongoing and future clinical trials;
- the anticipated designs of our future clinical trials;
- our ability to attract and retain qualified employees;
- the impact of Fast Track designation on receipt of actual U.S. Food and Drug Administration (“FDA”) approval;
- our anticipated future regulatory submissions and our ability to receive regulatory approvals to develop and market our product candidates, including any orphan drug or Fast Track designations;
- the timing and likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product
- development objectives, including the timing of a decision by the European Medicines Agency, or EMA, regarding whether to approve the Marketing Authorization Application, or MAA, for blarcamesine for the treatment of Alzheimer’s disease; and
- our anticipated future cash position and ability to obtain funding for our operations.

We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the FDA and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, preclinical studies and clinical trials, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions including without limitation the risks described in “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K filed with the Securities and Exchange

Commission on December 23, 2024. These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable laws including the securities laws of the United States, we assume no obligation to update or supplement forward-looking statements.

As used in this Quarterly Report on Form 10-Q, the terms “we,” “us,” “our,” “Company”, and “Anavex” mean Anavex Life Sciences Corp., unless the context clearly indicates otherwise.

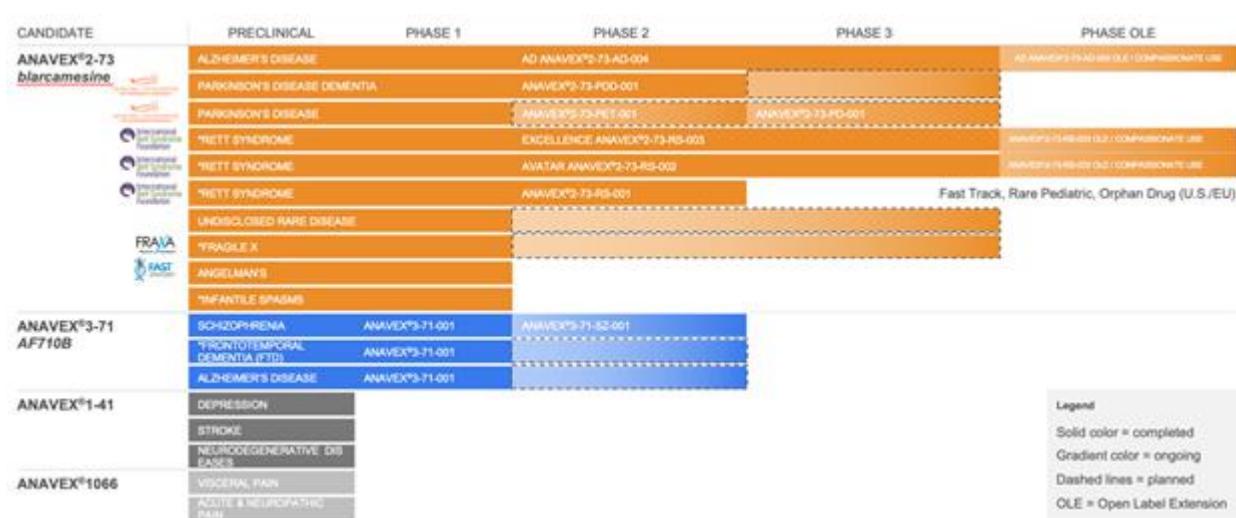
Overview and Strategy

Anavex Life Sciences Corp. is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system (“CNS”) diseases with high unmet need. We analyze genomic data from clinical trials to identify biomarkers, which we use in the analysis of our clinical trials.

The Company’s focus is on developing innovative treatments for Alzheimer’s disease, Parkinson’s disease, schizophrenia, neurodevelopmental, neurodegenerative, and rare diseases, including Rett syndrome, and other central nervous system (CNS) disorders.

Our research and development pipeline includes ANAVEX®2-73 currently in three different clinical trial indications, and ANAVEX®3-71 currently in one clinical trial and several other compounds in different stages of clinical and pre-clinical development.

The following table summarizes key information about our programs:

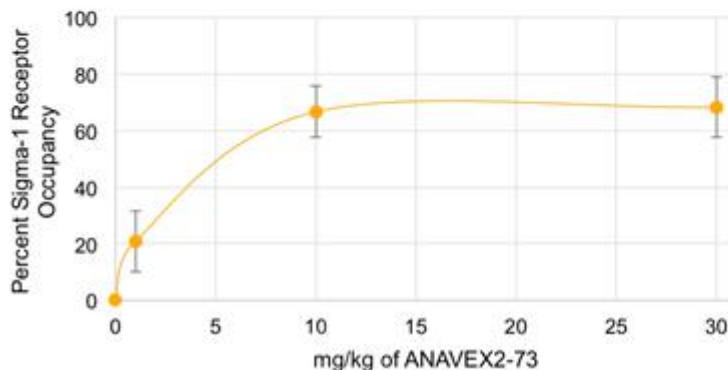
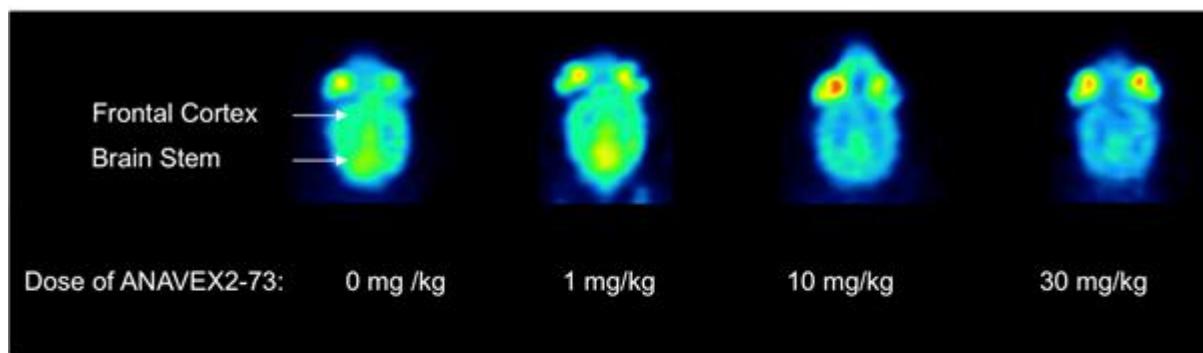


* = Orphan Drug Designation by the FDA

Anavex has a portfolio of compounds varying in sigma-1 receptor (SIGMAR1) binding activities. Sigma receptors may be targets for therapeutics to combat many human diseases, both of neurodegenerative nature, including Alzheimer's disease, as well as of neurodevelopmental nature, like Rett syndrome. When bound by the appropriate ligands, sigma receptors influence the functioning of multiple biochemical signals that are involved in the pathogenesis (origin or development) of disease. Multiple viruses including SARS-CoV-2 (COVID-19) induce cellular stress by intrinsic mitochondrial apoptosis and other related cellular processes, in order to ensure survival and replication. Hence, it is possible that SIGMAR1 could also play a role in modulating the cellular response to viral infection and ameliorate pathogenesis.

The SIGMAR1 gene encodes the SIGMAR1 protein, which is an intracellular chaperone protein with important roles in cellular communication. SIGMAR1 is also involved in transcriptional regulation at the nuclear envelope and restores homeostasis and stimulates recovery of cell function when activated. In order to validate the ability of our compounds to activate quantitatively the SIGMAR1, we performed, in collaboration with Stanford University, a quantitative Positron Emission Tomography (PET) imaging scan in mice, which demonstrated a dose-dependent ANAVEX®2-73 (blarcamesine) target engagement or receptor occupancy with SIGMAR1 in the brain.

2D [¹⁸F]FTC-146-PET imaging of ANAVEX®2-73



Sigma-1 receptor target occupancy study with quantitative PET scan of ANAVEX®2-73

Source: Reyes Setal., Sci Rep. 2021 Aug 25; 11(1):17150

Cellular Homeostasis

Many diseases are possibly directly caused by chronic homeostatic imbalances or cellular stress of brain cells. In pediatric diseases, such as Rett syndrome or infantile spasms, chronic cellular stress is possibly caused by the presence of a constant genetic mutation. In neurodegenerative diseases, such as Alzheimer's and Parkinson's diseases, chronic cellular stress is possibly caused by age-correlated buildup of cellular insult and hence chronic cellular stress. Specifically, defects in homeostasis of protein or ribonucleic acid ("RNA") lead to the death of neurons and dysfunction of the nervous system. The spreading of protein aggregates resulting in a proteinopathy, a characteristic found in Alzheimer's and Parkinson's diseases that results from disorders of protein synthesis, trafficking, folding, processing or degradation in cells. The clearance of macromolecules in the brain is particularly susceptible to imbalances that result in aggregation and degeneration in nerve cells. For example, Alzheimer's disease pathology is characterized by the presence of amyloid plaques, and neurofibrillary tangles, which are aggregates of hyperphosphorylated Tau protein that are a marker of other diseases known as tauopathies as well as inflammation of microglia. With the SIGMAR1 activation through SIGMAR1 agonists like ANAVEX®2-73 (blarcamesine), our approach is to restore cellular balance (i.e. homeostasis). Therapies that correct defects in cellular homeostasis might have the potential to halt or delay neurodevelopmental and neurodegenerative disease progression.

Clinical Program Overview

ANAVEX®2-73 (blarcamesine)

We believe ANAVEX®2-73 may offer a disease-modifying approach in neurodegenerative and neurodevelopmental diseases by activation of SIGMAR1. ANAVEX®2-73 is being developed as well as an oral once-daily capsule formulation for diseases such as Alzheimer's disease and Parkinson's disease, and in an oral liquid once-daily formulation for rare diseases such as Rett syndrome and Fragile X.

In November 2016, we completed a Phase 2a clinical trial, consisting of Part A and Part B, which lasted a total of 57 weeks, for ANAVEX®2-73 in mild-to-moderate Alzheimer's patients. This open-label randomized trial in Australia met both primary and secondary endpoints and was designed to assess the safety and exploratory efficacy of ANAVEX®2-73 in 32 patients. ANAVEX®2-73 targets sigma-1 and muscarinic receptors, which have been shown in preclinical studies to reduce stress levels in the brain believed to restore cellular homeostasis and to reverse the pathological hallmarks observed in Alzheimer's disease. In October 2017, we presented positive pharmacokinetic ("PK") and pharmacodynamic ("PD") data from the Phase 2a clinical trial, which established a concentration-effect relationship between ANAVEX®2-73 and trial measurements. These measures obtained from all patients who participated in the entire 57 weeks include exploratory cognitive and functional scores as well as biomarker signals of brain activity. Additionally, the clinical trial appeared to show that ANAVEX®2-73 activity was enhanced by its active metabolite (ANAVEX19-144), which also targets the SIGMAR1 receptor and has a half-life approximately twice as long as the parent molecule.

Two consecutive trial extensions for the Phase 2a trial have allowed participants who completed the 52-week Part B of the trial to continue taking ANAVEX®2-73, providing an opportunity to gather extended safety data for a cumulative time period of five years. In August 2020, patients completing these Phase 2a trial extensions were granted continued access to treatment with ANAVEX®2-73 through the Australian Government Department of Health – Therapeutic Goods Administration's compassionate use Special Access Scheme.

In July 2018, we presented the results of a genomic DNA and RNA evaluation of the participants in the Phase 2a clinical trial. More than 33,000 genes were analyzed using unbiased, data driven, machine learning, artificial intelligence (AI) system for analyzing DNA and RNA data in patients treated with ANAVEX®2-73. The analysis identified genetic variants that impacted response to ANAVEX®2-73, among them variants related to the SIGMAR1, the target for ANAVEX®2-73. Results showed that trial participants with the common SIGMAR1 wild type gene variant, which is estimated to be about 80% of the population worldwide, demonstrated improved cognitive (MMSE) and functional (ADCS-ADL) scores. The results from this evaluation supported the continued evaluation of genomic information in subsequent clinical trials, since these signatures can now be applied to neurological indications tested in future clinical trials with ANAVEX®2-73 including Alzheimer's disease, Parkinson's disease dementia and Rett syndrome.

ANAVEX®2-73 data met prerequisite information in order to progress into a Phase 2b/3 placebo-controlled trial. This larger Phase 2b/3 double-blind, placebo-controlled trial of ANAVEX®2-73 in early Alzheimer's disease commenced in August 2018. The trial enrolled 508 patients, which were treated with a convenient once-daily oral formulation of ANAVEX®2-73 for 48 weeks, randomized 1:1:1 to two different ANAVEX®2-73 doses or placebo. The trial took place at 52 sites across North America, Europe and Australia. Primary and secondary endpoints to assess safety and both cognitive and functional efficacy, were measured through the Alzheimer's Disease Assessment Scale – Cognitive Subscale test ("ADAS-Cog"), Alzheimer's Disease Cooperative Study – Activities of Daily Living ("ADCS-ADL") and Clinical Dementia Rating – Sum of Boxes for cognition and function ("CDR-SB"). In addition to these endpoints, the ANAVEX®2-73 Phase 2b/3 trial design incorporated pre-specified statistical analyses related to potential genomic precision medicine biomarkers previously identified in the ANAVEX®2-73 Phase 2a clinical trial. The trial was completed in mid-2022 and, in December 2022, the Company presented topline results from the Phase 2b/3 clinical trial. All statistical analyses were performed by outside consultancy companies.

Furthermore, all pre-specified clinical endpoints were analyzed using a mixed model for repeated measures (MMRM). Under the multiplicity control rule, a trial is successful in meeting the co-primary endpoints if the significance of each endpoint is $P < 0.05$, or if the significance of only one co-primary endpoint is $P < 0.025$. If only one primary endpoint is significant at an α level of 0.025, then the secondary endpoint will be evaluated at the same level of 0.025. The trial was successful, the differences in the least-squares mean (LSM) change from baseline to 48 weeks between the ANAVEX®2-73 and placebo groups for ADAS-Cog13 was significant at a level of $P < 0.025$ and for CDR-SB was significant at a level of $P < 0.025$, in the patients with early Alzheimer's disease.

The comparison of individual dose groups vs placebo also supports blarcamesine's efficacy. For the primary endpoint ADAS-Cog13, blarcamesine is significantly better than placebo (-2.027 ; $P = 0.0079$) as well as for both the 50 mg (-2.149 ; $P = 0.021$) and the 30 mg (-1.934 ; $P = 0.026$) blarcamesine dosage groups at Week 48, representing that blarcamesine slowed clinical progression at 48 weeks by 36.3% and by 38.5% and 34.6% in 50 mg and 30 mg groups vs. placebo, respectively. The functional co-primary endpoint, ADCS-ADL,

was trending in a positive direction but did not reach significance at Week 48. The key secondary endpoint CDR-SB was significantly improved vs. placebo (-0.483 , $P = 0.0104$) as well as in both 50 mg (-0.465 , $P = 0.045$) and 30 mg (-0.502 , $P = 0.020$) groups at Week 48. Clinical Global Impression – Improvement (“CGI-I”) was also significantly improved vs. placebo (-0.278 , $P = 0.004$) as well as in both the 50 mg (-0.314 , $P = 0.008$) and the 30 mg (-0.248 , $P = 0.024$) groups at Week 48. The findings are supported by biomarkers, including plasma A β 42/40-ratio and reduction of brain atrophy. Blarcamesine significantly slowed brain atrophy in key regions of interest, including the whole brain by 37.6%, total grey matter by 63.5%, and lateral ventricles by 25.1%.

In the respective safety population, common treatment-emergent adverse events included dizziness, which was transient and mostly mild to moderate in severity, and occurred in 120 participants (35.8%) during titration and in 76 participants (25.2%) during maintenance with ANAVEX[®]2-73 and 10 (6.0%) during titration and 9 (5.6%) during maintenance with placebo.

In November 2024, we announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA), under the centralized procedure, for ANAVEX[®]2-73 for the treatment of Alzheimer’s disease and, in December 2024, the EMA accepted the submission for scientific review. The MAA, if approved, would allow direct market access throughout the European Union for oral ANAVEX[®]2-73 (blarcamesine) for the treatment of Alzheimer’s disease. A company seeking to market a new pharmaceutical product through the centralized procedure must file safety data and efficacy data as part of the MAA. After the EMA evaluates the MAA, it provides a recommendation to the European Commission (“EC”) and the EC then approves or denies the MAA. Throughout the scientific review process with the EMA, we may receive feedback or comments which, while not a conclusive decision, could suggest the application provided is insufficient to support the marketing authorization. We may not be able to sufficiently address these comments or requests. Alternatively, these comments or requests could lead us to decide, after consultation with our advisors or the regulatory authorities, to withdraw our MAA for blarcamesine. The Company plans to announce the results when the EMA review and decision-making is finished and does not plan to provide interim updates.

A long-term open label extension study of ANAVEX[®]2-73, referred to as the ATTENTION-AD trial, was initiated for patients who completed the 48-week Phase 2b/3 placebo-controlled trial referenced above. This trial extension for a duration of up to 96/144 additional weeks was completed in June 2024. The trial extension demonstrated that blarcamesine-treated patients continued to accrue benefit through up to 4 years, as measured by the clinical endpoints ADAS-Cog13 and ADCS-ADL. Delayed-start analysis of treatment with oral blarcamesine was significant, reflecting the importance of early treatment initiation. No new safety findings were observed with continued blarcamesine treatment over three years, confirming good comparative safety profile and no associated neuroimaging adverse events.

Parkinson’s Disease

In September 2016, we presented positive preclinical data for ANAVEX[®]2-73 in an animal model of Parkinson’s disease, which demonstrated significant improvements on behavioral, histopathological, and neuroinflammatory endpoints. The study was funded by the Michael J. Fox Foundation. Additional data announced in October 2017 indicated that ANAVEX[®]2-73 induced robust neurorestoration in experimental Parkinsonism. We believe the encouraging results we have gathered in this preclinical model, coupled with the favorable profile of this product candidate in the Alzheimer’s disease trial, support the notion that ANAVEX[®]2-73 has the potential to treat Parkinson’s disease dementia.

In October 2020, we completed a double-blind, randomized, placebo-controlled proof-of-concept Phase 2 trial with ANAVEX[®]2-73 in Parkinson’s disease dementia in Spain and Australia, to study the effect of the compound on both the cognitive and motor impairment of Parkinson’s disease. The trial enrolled approximately 132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEX[®]2-73 doses, 30 mg and 50 mg, or placebo. The ANAVEX[®]2-73 Phase 2 Parkinson’s disease dementia trial design incorporated genomic precision medicine biomarkers identified in the ANAVEX[®]2-73 Phase 2a Alzheimer’s disease trial.

The trial demonstrated that ANAVEX[®]2-73 was safe and well tolerated in oral doses up to 50 mg once daily. The results showed clinically meaningful, dose-dependent, and statistically significant improvements in the Cognitive Drug Research (“CDR”) computerized assessment system analysis. Treatment with ANAVEX[®]2-73 also resulted in clinically meaningful improvements as measured by the global composite score of Parkinson’s disease symptom severity, MDS-Unified Parkinson’s Disease Rating Scale (“MDS-UPDRS”) total score on top of standard of care including dopaminergic therapy, levodopa and other anti-PD medications after 14 weeks of treatment,

suggesting ANAVEX®2-73's potential capability of slowing and reversing symptoms that progress in Parkinson's disease. In addition, the trial confirmed the precision medicine approach of targeting SIGMAR1 as a genetic biomarker in response to ANAVEX®2-73 may result in improved clinical outcomes.

A 48-week OLE ANAVEX2-73-PDD-EP-001 Phase 2 trial was offered to participants after completion of the double-blind placebo-controlled ANAVEX2-73-PDD-001 Phase 2 trial discussed above. The OLE trial assessed safety, tolerability and efficacy, measuring among others, MDS-Unified Parkinson's Disease Rating Scale Parts I, II, III, REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ), CGI-I, as well as cognitive efficacy endpoint Montreal Cognitive Assessment (MoCA) over a 48-week period.

In March 2023, we reported the preliminary ANAVEX2-73-PDD-EP-001 OLE trial data, which demonstrated longitudinal beneficial effects of ANAVEX®2-73 on the pre-specified primary and secondary objectives. Preliminary analysis reveals that ANAVEX®2-73 was found to be generally safe and well tolerated, and safety findings in this trial were consistent with the known safety profile of ANAVEX®2-73. In respect to efficacy, across all efficacy endpoints, patients performed better while on ANAVEX®2-73. While all patients were on drug holiday due to COVID-19 between the DB EOT and the OLE Baseline, the respective efficacy endpoints, including the MDS-UPDRS Part II + III and CGI-I, measured at the end of trial of the double-blind study (DB EOT) and the OLE Baseline, were worsening, as expected in a progressive disease like Parkinson's. However, when patients resumed daily oral ANAVEX®2-73 treatment, a consistent improvement was observed during the extension phase from OLE Baseline through OLE Week 24, and OLE Week 48, respectively. These results are consistent with the pattern observed for all efficacy measures in the extension phase.

We anticipate conducting further clinical trials of ANAVEX®2-73 in Parkinson's disease dementia after submitting the results of the trial to regulatory authorities to obtain regulatory guidance.

Also with respect to Parkinson's disease, in January 2021, we were awarded a research grant of \$1.0 million from The Michael J. Fox Foundation for Parkinson's Research to explore utilization of PET imaging biomarkers to enable measurement of target engagement and pathway activation of the SIGMAR1 with clinically relevant doses including in people with Parkinson's disease.

Rett Syndrome

In February 2016, we presented positive preclinical data for ANAVEX®2-73 in Rett syndrome, a rare neurodevelopmental disease. The data demonstrated dose related significant improvements in an array of behavioral and gait paradigms in a mouse model with an MECP2-null mutation that causes neurological symptoms that mimic Rett syndrome. The study was funded by the International Rett Syndrome Foundation.

Our Rett syndrome program includes several clinical trials that were conducted in a range of patient age demographics and geographic regions, utilizing an oral liquid once-daily formulation of ANAVEX®2-73. The FDA has granted Orphan Drug Designation and the Rare Pediatric Disease (RPD) designation for the treatment of Rett syndrome. The RPD designation is intended to encourage the development of treatments for rare pediatric diseases. Additionally, the FDA has granted Fast Track designation for the ANAVEX®2-73 clinical development program for the treatment of Rett syndrome. The FDA Fast Track program is designed to facilitate and expedite the development and review of new drugs to address unmet medical needs in the treatment of serious and life-threatening conditions. An earlier application for a proposed Rett syndrome study in the United States resulted in the FDA requesting additional information. The resulting clinical hold and subsequent partial clinical hold have since been removed after the Company satisfactorily provided the additional information requested. At the present time, the Company does not plan to conduct a clinical trial in the United States. The following is a summary of clinical trials conducted by the Company in Rett Syndrome. The first Phase 2 trial, (ANAVEX®2-73-RS-001), took place in the United States, and was completed in December 2020. This trial was a randomized double-blind, placebo-controlled safety, tolerability, PK and efficacy trial of oral liquid ANAVEX®2-73 formulation in 25 adult female patients with Rett syndrome over a 7-week treatment period including ANAVEX®2-73-specific genomic precision medicine biomarkers. The primary endpoint of the trial was safety. The dosing of 5 mg ANAVEX®2-73 was well-tolerated and demonstrated dose-proportional PK. All secondary efficacy endpoints of the trial showed statistically significant and clinically meaningful response in the Rett Syndrome Behaviour Questionnaire ("RSBQ") response, when compared to placebo, in the intent to treat ("ITT") cohort (all participants, $p = 0.011$). 66.7% of ANAVEX®2-73 treated subjects showed a statistically significant improvement in RSBQ response as compared to 10% of the subjects on

placebo in the ITT cohort (all participants, $p = 0.011$). ANAVEX[®]2-73 treatment resulted in a sustained improvement in CGI-I response throughout the 7-week clinical trial, when compared to placebo in the ITT cohort (all participants, $p = 0.014$). Consistent with previous ANAVEX[®]2-73 clinical trials, patients carrying the common form of the SIGMAR1 gene treated with ANAVEX[®]2-73 experienced stronger improvements in the prespecified efficacy endpoints.

This clinical trial was funded, in part, by a financial grant from the International Rett Syndrome Foundation of \$0.6 million. No other clinical trials with ANAVEX[®]2-73 related to Rett syndrome have been conducted in the United States.

The second, international trial of ANAVEX[®]2-73 for the treatment of Rett syndrome, called the AVATAR trial, commenced in June 2019. This trial took place in Australia and the United Kingdom using a higher dose than the U.S. based Phase 2 trial for Rett syndrome. The trial was a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of ANAVEX[®]2-73 in 33 adult patients over a 7-week treatment period including ANAVEX[®]2-73 specific precision medicine biomarkers. Based upon the input from the successful U.S. Phase 2 Rett syndrome trial (ANAVEX[®]2-73-RS-001), we updated the endpoints for the AVATAR trial (ANAVEX[®]2-73-RS-002) to appropriately assess the clinically meaningful outcome following International Conference on Harmonization (ICH) guidelines. These updates were approved by the respective regulatory authorities in the U.K. and in Australia, respectively, where the AVATAR trial was conducted.

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The data from the AVATAR trial was released in February 2022. The clinical trial met all primary and secondary efficacy and safety endpoints, with consistent improvements in primary efficacy endpoint, RSBQ response ($p = 0.037$), and secondary efficacy endpoints, Anxiety, Depression, and Mood Scale (ADAMS) ($p = 0.010$) and CGI-I ($p = 0.037$) response. Efficacy endpoints demonstrated statistically significant and clinically meaningful reductions in Rett syndrome symptoms. Convenient once daily oral liquid doses of up to 30 mg of ANAVEX[®]2-73 were also well tolerated with good medication compliance. All patients who participated in the trial were eligible to receive ANAVEX[®]2-73 under a voluntary open label extension protocol and subsequent Compassionate Use Program.

The very first trial of ANAVEX[®]2-73 in pediatric Rett syndrome patients, the EXCELLENCE trial, completed enrollment in February 2023. This randomized, double-blind, placebo-controlled Phase 2/3 trial in pediatric patients with Rett syndrome included trial sites in Canada, Australia, and the United Kingdom. 92 pediatric patients with Rett syndrome between the ages of 5 through 17 years were treated daily with up to 30 mg ANAVEX[®]2-73. Participants were randomized 2:1 (ANAVEX[®]2-73:placebo) for 12 weeks, followed by a week 16 safety visit and topline results from this trial were announced in early January 2024.

After 12 weeks, the study showed improvement on the key co-primary endpoint RSBQ, which is a detailed 45-item questionnaire for assessing multiple Rett syndrome characteristics by the patients' caregivers. The other co-primary endpoint, the CGI-I, which represents a less granular assessment by the site investigators using a seven-point scoring (one="very much improved" to seven="very much worse"), was not met.

In an ad-hoc analysis, using the predefined mixed-effect model for repeated measure (MMRM) method, after 12 weeks of treatment, ANAVEX[®]2-73-treated patients improved LS Mean (SE) -12.93 (2.150) points on their RSBQ total score compared to LS Mean (SE) -8.32 (2.537) points in placebo-treated patients. The LS Mean difference (SE) of -4.61 (2.439) points between treated and placebo groups did not reach statistical significance ($n=77$; $p=0.063$). ANAVEX[®]2-73-treated patients demonstrated a rapid onset of action with improvements at 4 weeks after treatment with a RSBQ total score LS Mean (SE) -10.32 (2.086) points in the drug-treated group compared to a LS Mean (SE) -5.67 (2.413) points in placebo-treated patients. The LS Mean difference of -4.65 (2.233) points between treated and placebo groups was statistically significant ($n=77$; $p=0.041$).

The key secondary endpoint, the ADAMS, trended favorably. In the same analysis, scores for all RSBQ and ADAMS subscales improved over the course of the study. Collectively, the RSBQ and ADAMS demonstrated improvements in multiple areas, impacting positively in particular repetitive movements, nighttime disruptive behaviors, and social avoidance.

A preliminary review of the safety results indicates there were no new safety signals in the EXCELLENCE study, reinforcing the favorable and manageable safety profile observed with ANAVEX[®]2-73 to date.

All patients who participated in the trial were eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol, which was completed in June 2024.

A high enrollment rate in the Open Label Extension (“OLE”) of over 91% and the high level of requests for the Compassionate Use Program (93%) provide solid numerical evidence for the reported positive Real World Evidence (RWE) from patients with Rett syndrome under Compassionate Use Authorization. Families whose children were previously on drug or placebo in the placebo-controlled trial commented favorably on the improvement of their child’s daily life due to ANAVEX®2-73 treatment in the Compassionate Use Program.

Other indications

We believe preclinical data from our studies also supports further research into the use of ANAVEX®2-73 as a potential platform drug for other neurodegenerative diseases beyond Alzheimer’s disease, Parkinson’s disease or Rett syndrome, more specifically, epilepsy, infantile spasms, Fragile X syndrome, Angelman syndrome, multiple sclerosis, and tuberous sclerosis complex (TSC). ANAVEX®2-73 demonstrated significant improvements in all of these indications in the respective preclinical animal models.

In a preclinical study sponsored by the Foundation for Angelman Syndrome, ANAVEX®2-73 was assessed in a mouse model for the development of audiogenic seizures. The results indicated that ANAVEX®2-73 administration significantly reduced audiogenic-induced seizures in mice. In a study sponsored by FRAXA Research Foundation regarding Fragile X syndrome, data demonstrated that ANAVEX®2-73 restored hippocampal brain-derived neurotrophic factor (BDNF) expression to normal levels. BDNF under-expression has been observed in many neurodevelopmental and neurodegenerative pathologies. BDNF signaling promotes maturation of both excitatory and inhibitory synapses. ANAVEX®2-73 normalization of BDNF expression could be a contributing factor for the positive preclinical data observed in both neurodevelopmental and neurodegenerative disorders like Angelman and Fragile X syndromes.

In addition, preclinical data to-date also indicates that ANAVEX®2-73 has the potential to demonstrate protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, may play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

In addition, preclinical data on ANAVEX®2-73 related to multiple sclerosis indicates that ANAVEX®2-73 may promote remyelination in multiple sclerosis disease. Further, our data also demonstrates that ANAVEX®2-73 has the potential to provide protection for oligodendrocytes and oligodendrocyte precursor cells (“OPCs”), as well as central nervous system neurons in addition to helping repair by increasing OPC proliferation and maturation in tissue culture.

In March 2018, we presented preclinical data of ANAVEX®2-73 in a genetic mouse model of tuberous sclerosis complex (“TSC”). TSC is a rare genetic disorder characterized by the growth of numerous benign tumors in many parts of the body with a high incidence of seizures. The preclinical data demonstrated that treatment with ANAVEX®2-73 significantly increased survival and reduced seizures in those mice.

ANAVEX®2-73 (blarcamesine)-specific Biomarkers

As part of some of our clinical trials, we have incorporated a genomic analysis to better understand potential populations for whom our clinical programs might benefit. A full genomic analysis of Alzheimer’s disease patients treated with ANAVEX®2-73 (blarcamesine) has helped us identify actionable genetic variants. A significant impact of the genomic biomarkers SIGMAR1, the direct target of ANAVEX®2-73 (blarcamesine) and COMT, a gene involved in memory function, on the drug response level was identified, leading to an early ANAVEX®2-73 (blarcamesine) specific biomarker hypothesis. We believe that *excluding* patients with SIGMAR1 identified biomarker variant (approximately 10%-20% of the population) in prospective studies would identify approximately 80%-90% patients that would display clinically significant improved functional and cognitive scores. The consistency between the identified DNA and RNA data related to ANAVEX®2-73 (blarcamesine), which are considered independent of Alzheimer’s disease pathology, as well as multiple endpoints and time-points, provides support for the potential precision medicine clinical development of ANAVEX®2-73 (blarcamesine) by using genetic biomarkers identified within the trial population itself to either confirm the mechanism of action of ANAVEX®2-73

(blarcamesine) or target patients who are most likely to respond to ANAVEX®2-73 (blarcamesine) treatment. We may in the future utilize such an approach in certain indications in which ANAVEX®2-73 (blarcamesine) is being studied.

ANAVEX®3-71

ANAVEX®3-71 is an orally available clinical drug candidate with a novel mechanism of action via SIGMAR1 activation and M1 muscarinic allosteric modulation, which has been shown to enhance neuroprotection and cognition in Alzheimer's disease models. ANAVEX®3-71 is a CNS-penetrable potential disease modifying treatment for cognitive impairments. We believe it is effective against the major Alzheimer's hallmarks in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, and also has beneficial effects on inflammation and mitochondrial dysfunctions. ANAVEX®3-71 indicates extensive therapeutic advantages in Alzheimer's and other protein-aggregation-related diseases given its ability to enhance neuroprotection and cognition via SIGMAR1 activation and M1 muscarinic allosteric modulation.

A preclinical study examined the response of ANAVEX®3-71 in aged transgenic animal models and showed a significant reduction in the rate of cognitive deficit, amyloid beta pathology and inflammation with the administration of ANAVEX®3-71. The FDA has granted Orphan Drug Designation to ANAVEX®3-71 for the treatment of FTD.

During pathological conditions ANAVEX®3-71 demonstrated the formation of new synapses between neurons (synaptogenesis) without causing an abnormal increase in the number of astrocytes. In neurodegenerative diseases such as Alzheimer's and Parkinson's disease, synaptogenesis is believed to be impaired. Additional preclinical data presented also indicates that in addition to reducing oxidative stress, ANAVEX®3-71 has the potential to demonstrate protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed to play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

In July 2020, we commenced the First-in-Human Phase 1 clinical trial of ANAVEX®3-71. The Phase 1 clinical trial was a prospective double-blind, randomized, placebo-controlled trial conducted in Australia. A total of 36 healthy male and female subjects were included. Single escalating doses of ANAVEX®3-71 were administered in order to evaluate the safety, tolerability, and PK of ANAVEX®3-71 and the effects of food and gender on its PK in healthy volunteers.

The trial met its primary and secondary endpoints of safety, with no serious adverse events ("SAEs") or dose-limiting toxicities observed. ANAVEX®3-71 was well tolerated in all cohorts receiving ANAVEX®3-71 in single doses ranging from 5 mg to 200 mg daily with no SAEs and no significant lab abnormalities in any subject. In the trial, ANAVEX®3-71 exhibited linear PK. Its pharmacokinetics was also dose proportional for doses up to 160 mg. Gender had no effect on the PK of the drug and food had no effect on the bioavailability of ANAVEX®3-71. The trial also met the secondary objective of characterizing the effect of ANAVEX®3-71 on electrocardiogram ("ECG") parameters. There were no clinically significant ECG parameters throughout the trial. Participant QTcF measures were normal across all dose groups with no difference between ANAVEX®3-71 and placebo.

In October 2023 a peer-reviewed publication in the journal *Neurobiology of Aging*, titled '*Early treatment with an M1 and sigma-1 receptor agonist prevents cognitive decline in a transgenic rat model displaying Alzheimer-like amyloid pathology*', featured the orally available small molecule ANAVEX®3-71 (AF710B). The preclinical study described the potential disease-modifying properties of ANAVEX®3-71 on Alzheimer's disease pathology as a possible drug candidate for a potential once daily oral preventive strategy for Alzheimer's disease.

In January 2024, in another peer-reviewed publication in the journal *Clinical Pharmacology in Drug Development*, entitled, '*Population-Based Characterization of the Pharmacokinetics and Food Effect of ANAVEX3-71, a Novel Sigma-1 Receptor and Allosteric M1 Muscarinic Receptor Agonist in Development for Treatment of Frontotemporal Dementia, Schizophrenia, and Alzheimer Disease*', reported the population-based characterization of the PK and food effect of ANAVEX®3-71 as part of the single ascending dose study in healthy participants with the primary objective of assessing dose proportionality of ANAVEX®3-71, and to characterize the effect of food on the PK of ANAVEX®3-71. The results from this PK evaluation demonstrated that ANAVEX®3-71, at single ascending doses of

5 to 200 mg, is linear, dose proportional, and time invariant. Food had no effect on the PK of ANAVEX®3-71. This data also expands the safety objectives met in this first-in-human study of ANAVEX®3-71, further supporting its drug development program.

Based on these results, and ANAVEX®3-71 pre-clinical profile, the Company intends to advance ANAVEX®3-71 into a biomarker-driven clinical development dementia program for the treatment of schizophrenia, FTD and Alzheimer's disease, evaluating longitudinal effect of treatment with ANAVEX®3-71. The first of these trials is being conducted in Schizophrenia.

Schizophrenia

In March 2024, we commenced the U.S. FDA-cleared ANAVEX®3-71-SZ-001 clinical trial: a double-blind, placebo-controlled Phase 2 trial in schizophrenia. The trial consists of two parts to explore multiple ascending doses in individuals with schizophrenia followed by a 28-day treatment period in a larger cohort. The trial will utilize standard clinical outcome measures for schizophrenia including the Positive and Negative Symptoms Scale (PANSS), and novel fluid and electrophysiological biomarkers will also be assessed, leveraging several advances in electroencephalography/event-related potential (EEG/ERP) biomarkers in schizophrenia developed in collaboration with the industry-led ERP Biomarker Qualification Consortium. In addition to the electrophysiological biomarkers, we are also applying novel neuroinflammatory, metabolomic, and transcriptomic biomarkers at the intersection of schizophrenia pathophysiology and ANAVEX®3-71's novel, dual mechanism of action.

Preliminary results from Part A of the ANAVEX®3-71-SZ-001 clinical trial, consisting of a multiple ascending dose study in 16 participants, demonstrated a dose-dependent effect of ANAVEX®3-71 on two key EEG biomarkers in patients with schizophrenia. The effects were most pronounced in the higher dose group indicating a dose-dependent pharmacodynamic effect. The observed changes reversed known electroencephalography (EEG) and ERP biomarker abnormalities associated with schizophrenia. These EEG biomarkers correlate with positive, negative, and cognitive symptoms of schizophrenia.

In May 2025 we announced the completion of enrollment of Part B of the placebo-controlled Phase 2 study, which includes more participants and a longer treatment duration, and will provide more comprehensive data on the efficacy and safety of ANAVEX®3-71 in schizophrenia. We expect to report top-line data of the Phase 2 ANAVEX®3-71-SZ-001 clinical trial in the second half of 2025.

ANAVEX®1-41

ANAVEX®1-41 is a sigma-1 agonist. Pre-clinical tests revealed significant neuroprotective benefits (i.e., protects nerve cells from degeneration or death) through the modulation of endoplasmic reticulum, mitochondrial and oxidative stress, which damages and impairs cell viability. In addition, in animal models, ANAVEX®1-41 prevented the expression of caspase-3, an enzyme that plays a key role in apoptosis (programmed cell death) and loss of cells in the hippocampus, the part of the brain that regulates learning, emotion and memory. These activities involve both muscarinic and SIGMAR1 systems through a novel mechanism of action.

Preclinical data presented also indicates that ANAVEX®1-41 has the potential to demonstrate protective effects of mitochondrial enzyme complexes during pathological conditions, which, if impaired, are believed to play a role in the pathogenesis of neurodegenerative and neurodevelopmental diseases.

ANAVEX®1066

ANAVEX®1066, a mixed sigma-1/sigma-2 ligand, is designed for the potential treatment of neuropathic and visceral pain. ANAVEX®1066 was tested in two preclinical models of neuropathic and visceral pain that have been extensively validated in rats. In the chronic constriction injury model of neuropathic pain, a single oral administration of ANAVEX®1066 dose-dependently restored the nociceptive threshold in the affected paw to normal levels while leaving the contralateral healthy paw unchanged. Efficacy was rapid and remained significant for two hours. In a model of visceral pain, chronic colonic hypersensitivity was induced by injection of an inflammatory agent directly into the colon and a single oral administration of ANAVEX®1066 returned the nociceptive threshold to

control levels in a dose-dependent manner. Companion studies in rats demonstrated the lack of any effects on normal gastrointestinal transit with ANAVEX®1066 and a favorable safety profile in a battery of behavioral measures.

ANAVEX®1037

ANAVEX®1037 is designed for the treatment of prostate and pancreatic cancer. It is a low molecular weight, synthetic compound exhibiting high affinity for sigma-1 receptors at nanomolar levels and moderate affinity for sigma-2 receptors and sodium channels at micromolar levels. In advanced pre-clinical studies, this compound revealed antitumor potential. It has also been shown to selectively kill human cancer cells without affecting normal/healthy cells and also to significantly suppress tumor growth in immune-deficient mice models. Scientific publications highlight the possibility that these ligands may stop tumor growth and induce selective cell death in various tumor cell lines. Sigma receptors are highly expressed in different tumor cell types. Binding by appropriate sigma-1 and/or sigma-2 ligands can induce selective apoptosis. In addition, through tumor cell membrane reorganization and interactions with ion channels, we believe our drug candidates may play an important role in inhibiting the processes of metastasis (spreading of cancer cells from the original site to other parts of the body), angiogenesis (the formation of new blood vessels) and tumor cell proliferation.

ANAVEX®1037 is currently in the pre-clinical and clinical testing stages of development, and there is no guarantee that the activity demonstrated in pre-clinical models will be shown in human testing.

We continue to identify and initiate discussions with potential strategic and commercial partners to most effectively advance our programs and increase stockholder value. Further, we may acquire or develop new intellectual property and assign, license, or otherwise transfer our intellectual property to further our goals.

Our Target Indications

We are developing compounds with potential application to two broad categories and several specific indications, including:

Central Nervous System Diseases

Alzheimer's disease – In 2024, an estimated 6.9 million Americans were suffering from Alzheimer's disease according to the Alzheimer's Association®. The Alzheimer's Association® estimates that the annual number of new cases of Alzheimer's and

- other dementias is projected to double by 2050. Medications on the market today treat only the symptoms of Alzheimer's disease and do not have the ability to stop its onset or its progression. We believe that there is an urgent and unmet need for both a disease modifying cure for Alzheimer's disease as well as for better symptomatic treatments.

Parkinson's disease – Parkinson's disease is a progressive disease of the nervous system marked by tremors, muscular rigidity, and slow, imprecise movement. It is associated with degeneration of the basal ganglia of the brain and deficiency of the

- neurotransmitter dopamine. Parkinson's disease currently is estimated to afflict more than 10 million people worldwide, typically middle-aged and elderly people. The Parkinson's disease market is expected to reach \$11.5 billion by 2029, according to GlobalData.

Rett syndrome – Rett syndrome is a rare X-linked genetic neurological and developmental disorder that affects the way the brain develops, including protein transcription, which is altered and as a result leads to severe disruptions in neuronal homeostasis. It is considered a rare, progressive neurodevelopmental disorder and is caused by a single mutation in the MECP2 gene. Because

- males have a different chromosome combination from females, boys who have the genetic MECP2 mutation are affected in devastating ways. Most of them die before birth or in early infancy. For females who survive infancy, Rett syndrome leads to severe impairments, affecting nearly every aspect of the child's life; severe mental retardation, their ability to speak, walk and eat, sleeping problems, seizures and even the ability to breathe easily. Rett syndrome affects approximately 1 in every 10,000-15,000 females.

- Schizophrenia - Schizophrenia is a persistent and often disabling mental illness impacting how a person thinks, feels, and behaves, and affects nearly 24 million people worldwide, including 2.8 million people in the U.S., according to the World Health Organization. It is characterized by three symptom domains: positive symptoms (hallucinations and delusions), negative symptoms (difficulty enjoying life and withdrawal from others), and cognitive impairment (deficits in memory, concentration, and decision-making). In part due to limitations with current treatments, people living with schizophrenia often struggle to maintain employment, live independently, and manage relationships. While current treatments can be effective in managing select symptoms, approximately 34% of people do not respond to therapy, with an additional 50-60% experiencing only a partial improvement in symptoms or unacceptable side effects.

- Fragile X – Fragile X syndrome (FXS) is the most prevalent genetic form of intellectual disability and autism spectrum disorder, primarily affecting boys. As with most neurodevelopmental disorders, FXS is considered a condition of synaptic development and function. The disease has a range of clinical presentations depending on the specific genetic changes associated with an “expansion” of the FMR1 gene. The disease is characterized by deficits in long-term potentiation and homeostatic plasticity. FXS has been detected in all populations and ethnic groups. Researchers do not know the exact number for how many Americans could have full mutation FXS. Studies estimate that the disease affects approximately 1:4,000 males and 1:6,000 females. Worldwide, more than 1,400,000 people could be affected by FXS.

- Depression – Depression is a major cause of morbidity worldwide according to the World Health Organization. The global antidepressant drug market is projected to reach \$21 billion by 2030 according to Allied Market Research. Pharmaceutical treatment for depression has been historically dominated by blockbuster brands. However, the dominance of the leading brands is waning, largely due to an increase in the number of approvals for antidepressant drugs.

- Epilepsy – Epilepsy is a common chronic neurological disorder characterized by recurrent unprovoked seizures. These seizures are transient signs and/or symptoms of abnormal, excessive or synchronous neuronal activity in the brain. According to the Centers for Disease Control and Prevention, in 2015 epilepsy affected 3.4 million Americans. Today, epilepsy is often controlled, but not cured, with medications that are categorized as older traditional anti-epileptic drugs and second-generation anti-epileptic drugs. Because epilepsy afflicts sufferers in different ways, there is a need for drugs used in combination with both traditional anti-epileptic drugs and second generation anti-epileptic drugs.

- Neuropathic Pain – We define neuralgia, or neuropathic pain, as pain that is not related to activation of pain receptor cells in any part of the body. Neuralgia is more difficult to treat than some other types of pain because it does not respond well to normal pain medications. Special medications have become more specific to neuralgia and typically fall under the category of membrane stabilizing drugs or antidepressants.

Cancer

- Malignant Melanoma – Predominantly a skin cancer, malignant melanoma can also occur in melanocytes found in the bowel and the eye. Malignant melanoma accounts for a large majority of skin cancer deaths. The treatment includes surgical removal of the tumor, adjuvant treatment, chemo and immunotherapy, or radiation therapy. According to iHealthcareAnalyst, Inc. the worldwide malignant melanoma market is expected to grow to \$7.5 billion by 2029.

- Prostate Cancer – Specific to men, prostate cancer is a form of cancer that develops in the prostate, a gland in the male reproductive system. Cancer cells may metastasize from the prostate to other parts of the body, particularly the bones and lymph nodes. Drug therapeutics for prostate cancer are expected to increase to nearly \$10.1 billion by the end of 2030 according to Market Research Future.

- Pancreatic Cancer – Pancreatic cancer is a malignant neoplasm of the pancreas. In the United States, approximately 62,000 new cases of pancreatic cancer will be diagnosed this year and approximately 50,000 patients will die as a result of their cancer, according to the American Cancer Society. Sales predictions by Market Data Forecast predict that the market for the global pharmaceutical treatment of pancreatic cancer will increase to \$3.7 billion by 2027.

Patents, Trademarks and Intellectual Property

We hold ownership or exclusive rights to twenty-seven (27) issued U.S. patents, twenty-two (22) pending U.S. patent applications, and numerous PCT and ex-U.S. patent applications relating to our drug candidates, methods associated therewith, and to our research programs.

We own one issued U.S. patent entitled “ANAVEX®2-73 and certain anticholinesterase inhibitors composition and method for neuroprotection,” which claims a composition of matter of ANAVEX®2-73, a synergistic neuroprotective compound, combined with donepezil and other cholinesterase inhibitors. This patent is expected to expire in June 2034, absent any patent term extension for regulatory delays.

We own another issued U.S. patent entitled “A2-73 crystalline polymorph compositions of matter and methods of use thereof”. It claims crystals of A2-73 freebase or its fumarate salt, dosage forms and pharmaceutical formulations. This patent is expected to expire in July 2039, absent any patent term extension for regulatory delays.

We own five issued U.S. patents each with claims directed to crystalline forms of ANAVEX®2-73. The first of these five patents claims crystalline forms of ANAVEX®2-73, dosage forms and compositions containing crystalline ANAVEX®2-73, and methods of treatment for Alzheimer’s disease using them. This patent is expected to expire in July 2036, absent any patent term extension for regulatory delays. The second of these five patents claims pharmaceutical compositions containing a crystalline form of ANAVEX®2-73, and methods of treatment for Alzheimer’s disease using the compositions. This patent is expected to expire in June 2036, absent any patent term extension for regulatory delays. The third of these five patents claims pharmaceutical compositions containing a crystalline form of ANAVEX®2-73, and methods of treating for Alzheimer’s disease using the compositions. This patent is expected to expire in June 2037, absent any patent term extension for regulatory delays. The fourth patent claims method of making certain crystalline forms of ANAVEX®2-73. This patent is expected to expire in October 2036, absent any patent term extension for regulatory delays. The fifth patent claims crystalline forms of the dihydrogen phosphate salt of ANAVEX®2-73 and dosage forms (including transdermal and oral dosage forms) and pharmaceutical compositions containing the same. This patent is expected to expire in July 2039, absent any patent term extension for regulatory delays.

We also own three issued U.S. patents for seizure treatment. The first of these three patents claims methods and dosage forms for treating seizures, the dosage forms containing a low-dose anti-epilepsy drug combined with either: (i) ANAVEX®2-73 and its active metabolite ANAVEX®19-144; or (ii) ANAVEX®19-144. The second of these three patents further claims a combination seizure treatment involving administration of an anti-epilepsy drug combined with (i) ANAVEX®19-144, or (ii) ANAVEX®19-144 and ANAVEX®2-73. The third of these three patents claims a dosage form for seizure reduction, comprising (i) ANAVEX®19-144, (ii) ANAVEX®2-73, or (iii) a combination of ANAVEX®19-144 and ANAVEX®2-73; and optionally further comprising a low-dose anti-epilepsy drug. All three patents are expected to expire in October 2035, absent any patent term extension for regulatory delays.

We also own four issued U.S. patents with claims directed to treating neurodevelopmental disorders. These patents claim methods for treating a neurodevelopmental disorder, multiple sclerosis, their related biochemical and functional abnormalities, or loss-of-function associated with a neurodevelopmental disorder, by administering ANAVEX®2-73, ANAVEX®19-144, and/or ANAVEX®1-41 (another sigma receptor ligand similar to ANAVEX®2-73), or compositions thereof. All four patents are expected to expire in January 2037, absent any patent term extension for regulatory delays.

In addition, we own one issued U.S. patent with claims directed to methods of treating melanoma with a compound related to ANAVEX®2-73. This patent is expected to expire in February 2030, absent any patent term extension for regulatory delays.

We also own an issued U.S. patent that claims crystalline forms of ANAVEX®19-144, dosage forms and compositions containing the crystalline forms of ANAVEX®19-144, and methods of treatment for Alzheimer’s disease. This patent is expected to expire in July 2036, absent any patent term extension for regulatory delays.

Further, we own two issued U.S. patents with claims directed to methods of treating cardiac dysfunction with ANAVEX®2-73. These patents are expected to expire in July 2038, absent any patent term extension for regulatory delays. Additionally, we own three issued U.S. patents for the treatment of insomnia, anxiety, or agitation. The first of the three patents claims methods of treating insomnia or anxiety with ANAVEX®2-73, ANAVEX®19-144, and/or ANAVEX®1-41. This patent is expected to expire in September 2038. The second and third of the three patents claim dosage forms comprising any of, or any combination of ANAVEX®2-73, ANAVEX®19-144, and/or ANAVEX®1-41. These patents are expected to expire in July 2037, absent any patent term extension for regulatory delays.

Further, we own one issued U.S. patent with claims directed to a method of treating systolic hypertension using ANAVEX®2-73. This patent is expected to expire in July 2039, absent any patent term extension for regulatory delays. Additionally, we own one issued U.S. patent with claims directed to pharmaceutical dosage forms of the (-) enantiomer of ANAVEX®2-73. This patent is expected to expire in July 2036, absent any patent term extension for regulatory delays.

We also own three (3) issued U.S. patents related to ANAVEX®1066. The first of these three patents claims methods for treating or preventing pain using the (+) ANAVEX®1066 isomer. The second patent claims methods for treating or preventing pain using the (-) ANAVEX®1066 isomer. The third patent claims dosage forms and pharmaceutical compositions comprising the (+) ANAVEX®1066 isomer. All three patents are expected to expire in November 2036, absent any patent term extension for regulatory delays.

For ANAVEX®2-73, ANAVEX®19-144, ANAVEX®1-41, and ANAVEX®1066, we also have granted or pending applications in Australia, Canada, China, Europe, Japan, and Hong Kong, which are expected to expire after 2035.

With regard to ANAVEX®3-71, we own exclusive rights to two issued U.S. patents with claims respectively directed to the ANAVEX®3-71 compound and methods of treating various diseases including Alzheimer's with the same. These patents are expected to expire in April 2030, and January 2030, respectively, absent any patent term extension for regulatory delays. We also own exclusive rights to related patents or applications that are granted or pending in Australia, Canada, China, Europe, Japan, Korea, New Zealand, Russia, and South Africa, which are expected to expire in January 2030.

We also own other patent applications and certain granted foreign patents directed to enantiomers, crystals, formulations, uses, and patient selection methods that may provide additional protection for one or more of our product candidates.

We regard patents and other intellectual property rights as corporate assets. Accordingly, we attempt to optimize the value of intellectual property in developing our business strategy including the selective development, protection, and exploitation of our intellectual property rights. In addition to filings made with intellectual property authorities, we protect our intellectual property and confidential information by means of carefully considered processes of communication and the sharing of information, and by the use of confidentiality and non-disclosure agreements and provisions for the same in contractor's agreements. While no agreement offers absolute protection, such agreements provide some form of recourse in the event of disclosure, or anticipated disclosure.

Our intellectual property position, like that of many biomedical companies, is uncertain and involves complex legal and technical questions for which important legal principles are unresolved. For more information regarding challenges to our existing or future patents, see "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on December 23, 2024.

Financial Overview

The following discussion should be read in conjunction with our condensed consolidated interim financial statements and related notes thereto contained elsewhere in this report. Past operating results are not necessarily indicative of results that may occur in future periods. The discussion contains forward-looking statements, which involve a number of risks and uncertainties. See "Forward Looking Statements" included elsewhere in this report.

We are in the development stage and have not earned any revenue since our inception in 2004. We do not anticipate earning any revenues until we can establish an alliance with other companies to develop, co-develop, license, acquire or market our products.

Our operating costs consist primarily of research and development activities including the cost of clinical trials and clinical supplies as well as clinical drug manufacturing and formulation. Research and development expenses also include personnel related costs such as salaries and wages, and third-party contract research organization (CRO) expenses in support of these clinical trials. Personnel costs include salaries and wages, benefits, and non-cash share-based compensation charges associated with options and other equity awards granted to employees and consultants who are directly engaged in support of our research and development activities.

General and administrative expenses consist of personnel costs, expenses for outside professional services and expenses associated with operating as a public company. Personnel costs consist of salaries and wages, benefits and share-based compensation for general and administrative personnel. Outside professional services and public company expenses include expenses related to compliance and reporting, additional insurance expenses, audit and SOX compliance, expenses associated with patent research, applications and filings, investor and stockholder relations activities and other administrative expenses and professional services.

Comparison of the three- and six- months ended March 31, 2025 and 2024

Operating Expenses

Total operating expenses for the three months ended March 31, 2025 were \$12.5 million, compared to \$12.6 million for the comparable three months ended March 31, 2024. Total operating expenses for the six months ended March 31, 2025 were \$26.1 million, compared to \$24.0 million for the comparable six months ended March 31, 2024.

Our research and development expenses for the three months ended March 31, 2025 were \$9.9 million, as compared to \$9.7 million for the three months ended March 31, 2024. Our research and development expenses for the six months ended March 31, 2025 were \$20.3 million, compared to \$18.4 million in the comparable six months ended March 31, 2024.

The increase in research and development expenses during the three- and six-month periods is primarily related to the following:

- (i) an increase of approximately \$2.1 million in the three-month period and \$3.7 million in the six-month period over the comparable periods relating to expenditures on the ANAVEX®3-71-SZ-001 clinical trial, which trial commenced in the second quarter of fiscal 2024.
- (ii) an increase in personnel costs of \$0.9 million for the six-month period related to the addition of new consultants engaged to assist in the preparation of the submission of our Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA); and
- (iii) an increase of approximately \$1.2 million in the six-month period over the comparable period relating to manufacturing activities of ANAVEX®2-73 for potential commercial use, and to support the MAA.

These increases were partially offset by (i) a decrease of approximately \$0.6 million in the three-month period and \$1.2 million in the six-month period in expenditures over the comparable periods relating to our Alzheimer's program, as a result of the completion of the Phase 2b/3 clinical trial open label extension and (ii) a decrease in stock based compensation charges of \$0.8 million in the three-month period and \$0.9 million in the six-month period due to a change in estimates associated with milestone-based options.

The following table summarizes our research and development expenses for the three- and six-months ended March 31, 2025 and 2024 (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
Cost of external service providers	\$ 6,018	\$ 5,167	\$ 11,494	\$ 9,732
Personnel costs	3,010	2,862	6,674	5,610
Share based compensation	844	1,673	2,097	3,033
Other common costs	20	27	73	38
Total research and development costs	\$ 9,892	\$ 9,729	\$ 20,338	\$ 18,413

During the three- and six-months ended March 31, 2025 and 2024, external service provider costs by product candidate was as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
ANAVEX®2-73	\$ 3,232	\$ 4,180	\$ 6,752	\$ 7,991
ANAVEX®3-71	2,693	856	4,282	1,453
All other product candidates	44	61	286	66
Other external service provider costs	49	70	174	222
Total external service provider costs	<u>\$ 6,018</u>	<u>\$ 5,167</u>	<u>\$ 11,494</u>	<u>\$ 9,732</u>

General and administrative expenses were \$2.6 million for the three months ended March 31, 2025, as compared to \$2.9 million for the same quarter of fiscal 2024. General and administrative expenses were \$5.8 million for the six months ended March 31, 2025, as compared to \$5.6 million for the six months ended March 31, 2024. In both periods, increases in legal fees were offset by a decrease in stock based compensation charges.

Other income (net)

Net other income for the three-months ended March 31, 2025 was \$1.3 million, as compared to \$2.1 million for the comparable three-months ended March 31, 2024. The decrease in other income is primarily related to a decrease in interest income associated with a change in market wide rates and principal balances held, as well as decrease in research and development incentive income, as a result of the completion of the open label extensions of our Australian clinical trials.

Net other income for the six months ended March 31, 2025 was \$2.8 million as compared to \$4.8 million for the comparable six months ended March 31, 2024. The decrease in other income for the six-month period is also primarily related to a decrease in interest income associated with a change in market wide rates and principal balances held, as well as decrease in research and development incentive income, as a result of the completion of the open label extensions of our Australian clinical trials

Net loss

Net loss for the three-months ended March 31, 2025, was \$11.2 million, or \$0.13 per share, as compared to \$10.5 million, or \$0.13 per share in the comparative quarter of fiscal 2024.

Net loss for the six-months ended March 31, 2025, was \$23.3 million, or \$0.27 per share, as compared to \$19.2 million, or \$0.23 per share for the six-months ended March 31, 2024. The increase in net loss for the quarter and year-to-date periods is primarily related to an increase in research and development expenditures and a decrease in other income, as discussed above.

Liquidity and Capital Resources

Working Capital (in thousands)

	March 31, 2025	September 30, 2024
Current Assets	\$ 117,139	\$ 135,567
Current Liabilities	17,381	15,304
Working Capital	<u>\$ 99,758</u>	<u>\$ 120,263</u>

On March 31, 2025, we had net current assets of \$99.8 million, a decrease of approximately \$20.5 million from our year ended September 30, 2024. The decrease in net current assets primarily relates to cash utilized in operations during the period.

We intend to continue to use our capital resources to advance our clinical trials for ANAVEX®2-73 and ANAVEX®3-71, and to perform the work necessary to prepare for future development of our pipeline compounds.

Cash Flows

The following table summarizes cash flows during the six months ended March 31, 2025 and 2024 (in thousands):

	2025	2024
Net cash flows used in operating activities	\$ (17,976)	\$ (18,974)
Net cash flows provided by financing activities	1,560	7,336
Decrease in cash and cash equivalents	<u><u>\$ (16,416)</u></u>	<u><u>\$ (11,638)</u></u>

Cash flow used in operating activities

Net cash used in operating activities for the six-months ended March 31, 2025 was \$18.0 million, compared to \$19.0 million during the comparable period ended March 31, 2024. The principal reason for this is due to changes in working capital as a result of (i) the receipt of the annual research and development incentive tax refund during the current quarter, whereas such amount was received in third quarter of fiscal 2024 and (ii) an increase in accrued liabilities related to activities associated with a large manufacturing run for ANAVEX®2-73, which work was not yet invoiced at March 31, 2025.

Cash flow provided by financing activities

Cash flows from financing activities for the six-month period ended March 31, 2025 was \$1.6 million, compared to cash provided from financing activities of \$7.3 million during the comparable six-month period ended March 31, 2024.

During the six months ended March 31, 2025, we received \$1.6 million in cash from the exercise of stock options by our employees.

During the six months ended March 31, 2024, cash provided by financing activities was primarily attributable to cash received from the issuance of common shares at various market prices under the 2023 Purchase Agreement.

Other Financings

2023 Purchase Agreement

On February 3, 2023, the Company entered into a \$150,000,000 purchase agreement (the “2023 Purchase Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), pursuant to which the Company has the right to sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$150.0 million in value of its shares of Common Stock from time to time over a three-year period until February 3, 2026.

On any business day and subject to having an effective registration statement and subject to certain customary conditions, the Company may direct Lincoln Park to purchase up to 200,000 shares of Common Stock (such purchases, “Regular Purchases”). The amount of a Regular Purchase may increase under certain circumstances based on the market price of the Common Stock; provided, however, that Lincoln Park’s committed obligation under any Regular Purchase shall not exceed \$4.0 million. The purchase price of shares of Common Stock will be based on the then prevailing market prices of such shares at the time of sales as described in the 2023 Purchase Agreement. There are no limits on the price per share that Lincoln Park may pay to purchase Common Stock under the 2023 Purchase Agreement. In addition, if the Company has directed Lincoln Park to purchase the full amount of Common Stock available as a Regular Purchase on a given day, it may direct Lincoln Park to purchase additional amounts as “accelerated purchases” and “additional accelerated purchases,” each as set forth in the 2023 Purchase Agreement.

The 2023 Purchase Agreement limits the Company’s sale of shares of Common Stock to Lincoln Park to 15,606,426 shares of Common Stock, representing 19.99% of the shares of the Common Stock outstanding on the date of the 2023 Purchase Agreement unless (i) stockholder approval is obtained to issue more than such amount or (ii) the average price of all applicable sales of Common Stock to Lincoln Park under the 2023 Purchase Agreement equals or exceeds the lower of (A) the closing price of the Common Stock on the Nasdaq Capital Market immediately preceding the Execution Date or (B) the average of the closing price of the Common Stock on the Nasdaq Capital Market for the five Business Days immediately preceding the Execution Date.

The 2023 Purchase Agreement also prohibits the Company from directing Lincoln Park to purchase any shares of Common Stock if those shares, when aggregated with all other shares of Common Stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of Common Stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.

In consideration for entering into the 2023 Purchase Agreement, the Company issued to Lincoln Park 75,000 shares of Common Stock as a commitment fee (the “initial commitment shares”) during the year ended September 30, 2023 and agreed to issue up to 75,000 shares pro rata (collectively with the initial commitment shares, the “commitment shares”), when and if, Lincoln Park purchased, at the Company’s discretion, the \$150.0 million aggregate commitment.

During the six-months ended March 31, 2025, the Company did not issue any shares of common stock under the 2023 Purchase Agreement. During the six-month period ended March 31, 2024, the Company issued to Lincoln Park an aggregate of 1,503,707 shares of Common Stock under the 2023 Purchase Agreement, including 1,500,000 shares of Common Stock for an aggregate purchase price of \$7,411,700 and 3,707 commitment shares.

On March 31, 2025, there was an unused amount of \$110.8 million under the 2023 Purchase Agreement. The Company will need to obtain effectiveness of a new registration statement in order to access funds under the 2023 Purchase Agreement.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to our stockholders.

CRITICAL ACCOUNTING POLICIES

We prepare our condensed consolidated interim financial statements in accordance with accounting principles generally accepted in the United States of America and make estimates and assumptions that affect our reported amounts of assets, liabilities, revenue and expenses, and the related disclosures of contingent liabilities. We base our estimates on historical experience and other assumptions that we believe are reasonable in the circumstances. Actual results may differ from these estimates.

There have been no significant changes in the critical accounting policies and estimates described in our Annual Report on Form 10-K for the year ended September 30, 2024, as filed with the SEC on December 23, 2024.

RECENT ACCOUNTING PRONOUNCEMENTS

Please refer to Note 2 “Recent Accounting Pronouncements” in notes to our Condensed Consolidated Interim Financial Statements included in this Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS.

Not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer and our principal financial officer, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2025.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2025, there were no changes to our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a 15(d) or 15d 15 (d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is subject to claims and legal proceedings that arise during the course of business. The Company is currently subject to the following lawsuits:

On March 13, 2024, a shareholder class action complaint was filed in the United States District Court for the Southern District of New York (the "Initial Action"). The complaint was captioned Blum v. Anavex Life Sciences, Corp. et al., case number 1:24-cv-01910, and it named the Company and Christopher Missling as Defendants. The complaint alleged violations of the Securities and Exchange Act of 1934 associated with disclosures and statements made with respect to certain clinical trials for ANAVEX®2-73 related to Rett syndrome (the "March 2024 Complaint"). At a hearing on or about June 13, 2024, the Court named another purported Company shareholder, Quintessa Huey, as lead plaintiff with respect to the March 2024 Complaint. An Amended Complaint was filed by the appointed lead plaintiff on July 12, 2024, which asserts allegations related to purported violations of Section 10(b) of the Securities Exchange Act tied to disclosures associated with the same clinical trials related to Rett Syndrome, and which names the Company and Christopher Missling as defendants. The Amended Complaint seeks unspecified damages, as well as costs, including counsel and expert witness fees, on behalf of a class of investors who purchased stock of the Company on the NASDAQ during the period February 1, 2022 through January 1, 2024. The defendants filed a motion to dismiss the complaint. The motion to dismiss is fully-briefed and awaiting a decision by the Court.

On May 8, 2024, a similar complaint was filed in the same court by Kenneth Downing (case no. 1:2024-cv-03529), a purported shareholder of the Company, against the same defendants as the March 2024 Complaint. The defendants filed a motion to dismiss the complaint. Plaintiff Downing voluntarily dismissed his complaint subsequent to the filing of the motion to dismiss.

On or about May 13, 2024, a derivative lawsuit was filed against the Company (as nominal defendant), Christopher Missling, and members of the Company's Board of Directors in the U.S. District Court for the District of Nevada by another purported shareholder named Denise Deangelis. The complaint asserts various common law claims (including breach of fiduciary duty) and violation of Section 14(a) of the Securities Exchange Act regarding the same or similar allegations at issue in the two purported class action lawsuits related to disclosures and statements made about certain clinical trials related to Rett Syndrome. On January 22, 2025, pursuant to a stipulation of the parties, the Court entered an order staying this purported derivative lawsuit until the motion to dismiss filed by defendants in the above-referenced class action (Quintessa Huey) lawsuit is decided by the U.S. District Court for the Southern District of New York.

On February 14, 2025, another derivative lawsuit asserting state law breach of fiduciary duty and unjust enrichment claims based upon similar allegations was filed against the Company (as nominal defendant), Christopher Missling, and members of the Company's Board of Directors in the Supreme Court for the State of New York, County of New York, by another purported shareholder named Evan Levitan. The parties to that action also have stipulated to a stay of the proceeding until the Court rules on the motion to dismiss in the putative class action lawsuit pending in the U.S. District Court for the Southern District of New York. The New York state court has not yet entered an order pursuant to the stipulation of the parties.

We know of no other material pending legal or governmental proceedings, other than ordinary routine litigation incidental to our business, to which our Company or our subsidiaries are a party or of which any of their property is subject. There are no other proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, or any associate of such persons, is an adverse party or has a material interest adverse to our or our subsidiaries' interest.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors discussed in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2024, filed with the SEC on December 23, 2024 except the following:

Risks Related to the Discovery and Development of Our Current and Future Product Candidates

The marketing approval process for pharmaceutical products is a lengthy, complex and highly regulated process and we cannot predict the outcome of any interactions with the regulatory authorities or when we will receive marketing approval, if at all.

The regulatory approval processes of the EMA, the FDA, and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and the approval process can vary significantly depending on the regulatory authority. Relevant health authorities may, at the time of the filing of the application for a marketing authorization, or later during their review, impose requirements that can evolve over time, including requiring additional clinical trials, and such authorities may delay or refuse to grant approval. A finding that our Phase 2b/3 ANAVEX2-73-AD-004 clinical trial is insufficient to support the current marketing authorization in Alzheimer's disease could lead us to decide, after consultation with regulatory authorities, to voluntarily withdraw our MAA for blarcamesine.

In recent years, health authorities have become increasingly focused on product safety and on the risk/benefit profile of pharmaceutical products, which could lead to more burdensome and costly approval processes and negatively affect our ability to obtain regulatory approval for products under development. For example, the U.S. Food and Drug Administration (the "FDA") and the European Medicines Agency (the "EMA"), have been implementing strict requirements for approval, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety.

Obtaining and maintaining regulatory approval of blarcamesine or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of those product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of blarcamesine and any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from each other, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., including Canada, and certain jurisdictions in the EU, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional preclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have experience in obtaining regulatory approval in international markets or within the United States. If we fail to comply with the regulatory requirements in international or domestic markets and/or obtain and maintain applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of blarcamesine or any future product candidates will be harmed.

Risks Related to Our Business

Changes in U.S. and international trade policies may adversely impact our business and operating results.

The U.S. government has made statements and taken actions that have led to certain changes and may lead to additional changes to U.S. and international trade policies. For example, President Trump has imposed or signaled to impose a series of tariffs on certain products manufactured outside the United States, including pharmaceutical products and raw materials and components for pharmaceutical products, and it is unknown whether and to what extent additional tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. Such unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the import and export of materials and products used in our drug development. For example, we have already faced increased costs associated with our imports of drug products due to newly imposed tariffs on Canada. These policies may also affect the demand for our product candidates, the competitive position of our product candidates, and clinical manufacturing and future commercial activities. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or if the U.S. government takes retaliatory trade actions due to the ongoing trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the period covered by this Quarterly Report on Form 10-Q, we have not sold any equity securities that were not registered under the Securities Act of 1933 that were not previously reported in a Current Report on Form 8-K.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Insider Trading Plans

None of our directors or Section 16 officers informed us of the adoption, modification or termination of a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement” (in each case, as defined in Item 408(a) of Regulation S-K) during the three-month period ended March 31, 2025.

ITEM 6. EXHIBITS

Exhibit Number	Description
(3)	Articles of Incorporation and Bylaws
3.1	Articles of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K for the year ended September 30, 2021 filed on November 24, 2021)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on April 14, 2023)
(31)	Rule 13a-14(a)/15(d)-14(a)Certifications
31.1*	Certification of Christopher Missling, PhD.
31.2*	Certification of Sandra Boenisch
(32)	Section 1350 Certifications
32.1**	Certification of Christopher Missling, PhD and Sandra Boenisch.
(101)	XBRL
101.INS*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE

101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

* Filed herewith.

** Furnished herewith.

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.

ANAVEX LIFE SCIENCES CORP.

/s/Christopher Missling, PhD

Christopher Missling, PhD
Chief Executive Officer
(Principal Executive Officer)
Date: May 13, 2025

/s/Sandra Boenisch

Sandra Boenisch, CPA, CGA
Principal Financial Officer
(Principal Financial and Accounting Officer)
Date: May 13, 2025

CERTIFICATION

I, Christopher Missling, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended March 31, 2025 of Anavex Life Sciences Corp. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) 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 Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: May 13, 2025

/s/Christopher Missling, PhD

Christopher Missling, PhD

Chief Executive Officer, President and Secretary

(Principal Executive Officer)

CERTIFICATION

I, Sandra Boenisch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended March 31, 2025 of Anavex Life Sciences Corp. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) 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 Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: May 13, 2025

/s/Sandra Boenisch

Sandra Boenisch, CPA, CGA
Principal Financial Officer, Treasurer
(Principal Financial and Accounting Officer)

**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 Anavex Life Sciences Corp. (the “Company”) on Form 10-Q for the three months ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, in the capacities and on the date indicated below, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of our knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2025

/s/Christopher Missling, PhD

Christopher Missling, PhD
Chief Executive Officer, President, Secretary
(Principal Executive Officer)

/s/Sandra Boenisch

Sandra Boenisch, CPA, CGA
Principal Financial Officer, Treasurer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Cover - shares

6 Months Ended

Mar. 31, 2025

May 13, 2025

Cover [Abstract]

<u>Document Type</u>	10-Q
<u>Amendment Flag</u>	false
<u>Document Quarterly Report</u>	true
<u>Document Transition Report</u>	false
<u>Document Period End Date</u>	Mar. 31, 2025
<u>Document Fiscal Period Focus</u>	Q2
<u>Document Fiscal Year Focus</u>	2025
<u>Current Fiscal Year End Date</u>	--09-30
<u>Entity File Number</u>	001-37606
<u>Entity Registrant Name</u>	ANAVEX LIFE SCIENCES CORP.
<u>Entity Central Index Key</u>	0001314052
<u>Entity Tax Identification Number</u>	98-0608404
<u>Entity Incorporation, State or Country Code</u>	NV
<u>Entity Address, Address Line One</u>	630 5th Avenue
<u>Entity Address, Address Line Two</u>	20th Floor
<u>Entity Address, City or Town</u>	New York
<u>Entity Address, State or Province</u>	NY
<u>Entity Address, Country</u>	US
<u>Entity Address, Postal Zip Code</u>	10111
<u>City Area Code</u>	844
<u>Local Phone Number</u>	689-3939
<u>Title of 12(b) Security</u>	Common Stock Par Value \$0.001
<u>Trading Symbol</u>	AVXL
<u>Security Exchange Name</u>	NASDAQ
<u>Entity Current Reporting Status</u>	Yes
<u>Entity Interactive Data Current</u>	Yes
<u>Entity Filer Category</u>	Non-accelerated Filer
<u>Entity Small Business</u>	true
<u>Entity Emerging Growth Company</u>	false
<u>Entity Shell Company</u>	false
<u>Entity Common Stock, Shares Outstanding</u>	85,371,852

**Condensed Consolidated
Interim Balance Sheets
(Unaudited) - USD (\$)
\$ in Thousands**

**Mar. 31, Sep. 30,
2025 2024**

Current

<u>Cash and cash equivalents</u>	\$ 115,771	\$ 132,187
<u>Incentive and tax receivables</u>	666	2,449
<u>Prepaid expenses and other current assets</u>	702	931
<u>Total Assets</u>	117,139	135,567
<u>Current Liabilities</u>		
<u>Accounts payable</u>	6,997	9,627
<u>Accrued liabilities - Note 3</u>	9,555	4,835
<u>Deferred grant income - Note 4</u>	829	842
<u>Total Liabilities</u>	17,381	15,304
<u>Capital stock Authorized:10,000,000 preferred stock, par value \$0.001 per share</u>		
<u>Capital stock Authorized:200,000,000 common stock, par value \$0.001 per share 84,985,449 common shares (September 30, 2024 - 84,795,517)</u>	85	85
<u>Additional paid-in capital</u>	459,051	456,249
<u>Accumulated deficit</u>	(359,378)	(336,071)
<u>Total Stockholders' Equity</u>	99,758	120,263
<u>Total Liabilities and Stockholders' Equity</u>	\$ 117,139	\$ 135,567

**Condensed Consolidated
Interim Balance Sheets
(Unaudited) (Parenthetical) -
\$ / shares**

Mar. 31, 2025 Sep. 30, 2024

Statement of Financial Position [Abstract]

<u>Preferred stock, shares authorized</u>	10,000,000	10,000,000
<u>Preferred stock, par value</u>	\$ 0.001	\$ 0.001
<u>Common stock, shares authorized</u>	200,000,000	200,000,000
<u>Common stock, par value</u>	\$ 0.001	\$ 0.001
<u>Common stock, shares issued</u>	85,333,652	84,795,517
<u>Common stock, shares outstanding</u>	85,333,652	84,795,517

Condensed Consolidated Interim Statements of Operations and Comprehensive Loss (Unaudited) - USD (\$) \$ in Thousands	3 Months Ended		6 Months Ended	
	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024
<u>Operating expenses</u>				
<u>General and administrative</u>	\$ 2,621	\$ 2,895	\$ 5,767	\$ 5,590
<u>Research and development</u>	9,892	9,729	20,338	18,413
<u>Total operating expenses</u>	12,513	12,624	26,105	24,003
<u>Operating loss</u>	(12,513)	(12,624)	(26,105)	(24,003)
<u>Other income (expense)</u>				
<u>Grant income</u>			12	
<u>Research and development incentive income</u>	96	472	508	1,064
<u>Interest income, net</u>	1,210	1,756	2,604	3,764
<u>Foreign exchange gain (loss)</u>	11	(150)	(326)	7
<u>Total other income, net</u>	1,317	2,078	2,798	4,835
<u>Net loss and comprehensive loss</u>	\$ (11,196)	\$ (10,546)	\$ (23,307)	\$ (19,168)
<u>Net Loss per share</u>				
<u>Net Loss per share, Basic</u>	\$ (0.13)	\$ (0.13)	\$ (0.27)	\$ (0.23)
<u>Net Loss per share, Diluted</u>	\$ (0.13)	\$ (0.13)	\$ (0.27)	\$ (0.23)
<u>Weighted average number of shares outstanding</u>				
<u>Weighted average number of shares outstanding, Basic</u>	85,073,769	82,464,226	84,938,400	82,269,965
<u>Weighted average number of shares outstanding,</u>	85,073,769	82,464,226	84,938,400	82,269,965
<u>Diluted</u>				

Condensed Consolidated Interim Statements of Cash Flows (Unaudited) - USD (\$) \$ in Thousands	6 Months Ended
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Mar. 31, 2025 Mar. 31, 2024

Cash Flows used in Operating Activities

<u>Net loss</u>	\$ (23,307)	\$ (19,168)
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Adjustments to reconcile net loss to net cash used in operations:

<u>Share based compensation</u>	3,504	4,938
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Changes in working capital balances related to operations:

<u>Incentive and tax receivables</u>	1,783	(1,076)
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<u>Prepaid expenses and deposits</u>	229	(692)
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<u>Accounts payable</u>	(4,893)	(596)
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<u>Accrued liabilities</u>	4,720	(2,380)
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<u>Deferred grant income</u>	(12)	
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<u>Net cash used in operating activities</u>	(17,976)	(18,974)
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Cash Flows provided by Financing Activities

<u>Issuance of common shares</u>		7,178
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<u>Proceeds from exercise of stock options</u>	1,560	158
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<u>Net cash provided by (used in) financing activities</u>	1,560	7,336
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<u>Decrease in cash and cash equivalents during the period</u>	(16,416)	(11,638)
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<u>Cash and cash equivalents, beginning of period</u>	132,187	151,024
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<u>Cash and cash equivalents, end of period</u>	115,771	139,386
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Supplemental Cash Flow Information

<u>Cash paid for state and local franchise taxes</u>	36	220
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<u>Common stock issued upon cashless exercise of stock option</u>	\$ 460	
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Condensed Consolidated Interim Statements of Changes in Stockholders' Equity - USD (\$) \$ in Thousands	Common Stock [Member]	Additional Paid- in Capital [Member]	Share Proceeds Receivable [Member]	Retained Earnings [Member]	Total
<u>Beginning balance, value at Sep. 30, 2023</u>	\$ 82	\$ 434,839		\$ (293,069)	\$ 141,852
<u>Balance at beginning, shares at Sep. 30, 2023</u>	82,066,511				
<u>Purchase shares</u>	\$ 2	7,410	(234)		7,178
<u>Purchase shares, shares</u>	1,500,000				
<u>Commitment shares</u>					
<u>Commitment shares, shares</u>	3,707				
<u>exercise of stock options</u>		158			158
<u>exercise of stock options, shares</u>	46,000				
<u>Share based compensation</u>		4,938			4,938
<u>Net loss</u>				(19,168)	(19,168)
<u>Ending balance, value at Mar. 31, 2024</u>	\$ 84	447,345	(234)	(312,237)	134,958
<u>Balance at ending, shares at Mar. 31, 2024</u>	83,616,218				
<u>Beginning balance, value at Dec. 31, 2023</u>	\$ 82	437,184		(301,691)	135,575
<u>Balance at beginning, shares at Dec. 31, 2023</u>	82,086,511				
<u>Purchase shares</u>	\$ 2	7,410	(234)		7,178
<u>Purchase shares, shares</u>	1,500,000				
<u>Commitment shares</u>					
<u>Commitment shares, shares</u>	3,707				
<u>exercise of stock options</u>		99			99
<u>Shares issued pursuant to exercise of stock options, shares</u>	26,000				
<u>Share based compensation</u>		2,652			2,652
<u>Net loss</u>				(10,546)	(10,546)
<u>Ending balance, value at Mar. 31, 2024</u>	\$ 84	447,345	(234)	(312,237)	134,958
<u>Balance at ending, shares at Mar. 31, 2024</u>	83,616,218				
<u>Beginning balance, value at Sep. 30, 2024</u>	\$ 85	456,249		(336,071)	120,263
<u>Balance at beginning, shares at Sep. 30, 2024</u>	84,795,517				
<u>cashless exercise of stock option</u>	\$ 1	459			460
<u>cashless exercise of stock option, shares</u>	500,000				

<u>and taxes</u>	\$ (1)	(2,721)	(2,722)
<u>Shares withheld related to cashless exercise of stock option and taxes, shares</u>	(282,497)		
<u>exercise of stock options</u>	1,560		1,560
<u>Shares issued pursuant to exercise of stock options, shares</u>	320,632		
<u>Share based compensation</u>	3,504		3,504
<u>Net loss</u>		(23,307)	(23,307)
<u>Ending balance, value at Mar. 31, 2025</u>	\$ 85	459,051	(359,378) 99,758
<u>Balance at ending, shares at Mar. 31, 2025</u>	85,333,652		
<u>Beginning balance, value at Dec. 31, 2024</u>	\$ 85	459,012	(348,182) 110,915
<u>Balance at beginning, shares at Dec. 31, 2024</u>	84,985,449		
<u>exercise of stock options</u>	852		852
<u>Shares issued pursuant to exercise of stock options, shares</u>	130,700		
<u>exercise of stock option</u>	\$ 1	459	460
<u>exercise of stock option, shares</u>	500,000		
<u>exercise of stock option and taxes</u>	\$ (1)	(2,721)	(2,722)
<u>exercise of stock option and taxes, shares</u>	(282,497)		
<u>Share based compensation</u>	1,449		1,449
<u>Net loss</u>		(11,196)	(11,196)
<u>Ending balance, value at Mar. 31, 2025</u>	\$ 85	\$ 459,051	\$ (359,378) \$ 99,758
<u>Balance at ending, shares at Mar. 31, 2025</u>	85,333,652		

Pay vs Performance Disclosure - USD (\$) \$ in Thousands	3 Months Ended Mar. 31, 2025	6 Months Ended Mar. 31, 2024

Pay vs Performance Disclosure [Table]

Net Income (Loss) \$ (11,196) \$ (10,546) \$ (23,307) \$ (19,168)

**Insider Trading
Arrangements**

**6 Months Ended
Mar. 31, 2025**

Trading Arrangements, by Individual [Table]

<u>Rule 10b5-1 Arrangement Adopted</u>	false
<u>Non-Rule 10b5-1 Arrangement Adopted</u>	false
<u>Rule 10b5-1 Arrangement Terminated</u>	false
<u>Non-Rule 10b5-1 Arrangement Terminated</u>	false

Business Description

**6 Months Ended
Mar. 31, 2025**

**Organization, Consolidation
and Presentation of
Financial Statements
[Abstract]**

Business Description

Note 1 Business Description

Business

Anavex Life Sciences Corp. (“Anavex” or the “Company”) is a clinical stage biopharmaceutical company engaged in the development of differentiated therapeutics by applying precision medicine to central nervous system (“CNS”) diseases with high unmet need. Anavex analyzes genomic data from clinical trials to identify biomarkers, which are used in the analysis of its clinical trials for the treatment of neurodegenerative and neurodevelopmental diseases.

The Company’s focus is on developing innovative treatments for Alzheimer’s disease, Parkinson’s disease, schizophrenia, neurodevelopmental, neurodegenerative, and rare diseases, including Rett syndrome, and other central nervous system (CNS) disorders.

Basis of Presentation

**6 Months Ended
Mar. 31, 2025**

Organization, Consolidation and Presentation of Financial Statements [Abstract]

Basis of Presentation

Note 2 Basis of Presentation

These accompanying unaudited condensed consolidated interim financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) and accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim reporting. Accordingly, certain information and note disclosures normally included in the annual financial statements in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the disclosures are adequate to make the information presented not misleading.

These accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, which in the opinion of management are necessary for fair presentation of the information contained herein. The consolidated balance sheet as of September 30, 2024 was derived from the audited annual financial statements but does not include all disclosures required by U.S. GAAP. The accompanying unaudited condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s annual report on Form 10-K for the year ended September 30, 2024 filed with the SEC on December 23, 2024. The Company follows the same accounting policies in the preparation of interim reports.

Operating results for the six months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending September 30, 2025.

Certain immaterial amounts from prior periods have been reclassified to conform to the current year’s presentation.

Liquidity

All of the Company’s potential drug compounds are in the clinical development stage and the Company cannot be certain that its research and development efforts will be successful or, if successful, that its potential drug compounds will ever be approved for sales to pharmaceutical companies or generate commercial revenues. To date, we have not generated any revenue from our operations. The Company expects the business to continue to experience negative cash flows from operations for the foreseeable future and cannot predict when, if ever, our business might become profitable.

Management believes that the current working capital position will be sufficient to meet the Company’s working capital requirements beyond the next 12 months after the date that these condensed consolidated interim financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trials are uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company’s expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company’s research and development programs and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials.

Other than our rights related to the 2023 Purchase Agreement (as defined below in Note 5), there can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. The Company will need to obtain

effectiveness of a new registration statement in order to access the funds under the 2023 Purchase Agreement. If the Company is not able to obtain the additional financing on a timely basis, if and when it is needed, it will be forced to delay or scale down some or all of its research and development activities.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company regularly evaluates estimates and assumptions related to accounting for research and development costs, incentive and tax receivables, valuation and recoverability of deferred tax assets, share based compensation, and loss contingencies. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

Principles of Consolidation

These unaudited condensed consolidated interim financial statements include the accounts of Anavex Life Sciences Corp. and its wholly-owned subsidiaries, Anavex Australia Pty Limited ("Anavex Australia"), a company incorporated under the laws of Australia, Anavex Germany GmbH, a company incorporated under the laws of Germany, and Anavex Canada Ltd., a company incorporated under the laws of the Province of Ontario, Canada. All inter-company transactions and balances have been eliminated.

Fair Value Measurements

The fair value hierarchy under GAAP is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - observable inputs other than Level 1, quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; and

Level 3 - assets and liabilities whose significant value drivers are unobservable by little or no market activity and that are significant to the fair value of the assets or liabilities.

At March 31, 2025 and September 30, 2024, the Company did not have any Level 2 or Level 3 assets or liabilities.

Basic and Diluted Loss per Share

Basic income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the sum of (1) the weighted-average number of common shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the diluted net loss per share calculation, options and warrants are

potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

As of March 31, 2025 loss per share excludes 15,710,622 (March 31, 2024: 15,755,114) potentially dilutive common shares related to outstanding options and warrants, as their effect was anti-dilutive.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued ASU No. 2023-07, “Segment Reporting: Improvements to Reportable Segment Disclosures.” This guidance requires disclosure of incremental segment information on an annual and interim basis. This amendment is effective for our fiscal year ending September 30, 2025 and our interim periods within the fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes: Improvements to Income Tax Disclosures.” This guidance requires consistent categories and greater disaggregation of information in the rate reconciliation and disclosures of income taxes paid by jurisdiction. This amendment is effective for our fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

Accrued Liabilities

**6 Months Ended
Mar. 31, 2025**

Accrued Liabilities**Accrued Liabilities****Note 3 Accrued Liabilities**

The principal components of accrued liabilities consist of (in thousands):

	March 31, 2025	September 30, 2024
Accrued investigator payments	\$ 1,459	\$ 860
Accrued compensation and benefits	2,200	1,527
Milestone-based contract accruals	4,332	557
All other accrued liabilities	1,564	1,891
Total accrued liabilities	\$ 9,555	\$ 4,835

Other Income

**6 Months Ended
Mar. 31, 2025**

Other Income

Other Income

Note 4 Other Income

Grant income

As of March 31, 2025, the Company had received a \$1.0 million research grant awarded by the Michael J. Fox Foundation for Parkinson's Research. The grant will be used to fund a clinical trial of the Company's lead compound, ANAVEX®2-73 (blarcamesine) related to Parkinson's disease. Of the total, \$0.5 million was received during the year ended September 30, 2023 and \$0.5 million was received during the year ended September 30, 2021.

The grant income was deferred when received and is being amortized to other income as the related research and development expenditures are incurred. During the three and six months ended March 31, 2025, the Company recognized \$0 and \$12,275, respectively (three and six months ended March 31, 2024: \$0) of this grant on its statements of operations within grant income. At March 31, 2025 an amount of \$0.8 million (September 30, 2024: \$0.8 million) of this grant is recorded as deferred grant income, representing the amount of this grant which has not yet been amortized to other income. The Company will recognize this income on its statements of operations as the related expenditures are incurred to offset the income.

Research and development incentive income

Research and development incentive income represents the income earned by Anavex Australia of the Australia R&D credit. This cash incentive is received by Anavex Australia, upon filing of a claim in connection with Anavex Australia's annual income tax return.

During the three and six months ended March 31, 2025, the Company recorded research and development incentive income of \$0.1 million (AUD 0.2 million) and \$0.5 million (AUD 0.8 million), respectively (2024: \$0.5 million (AUD 0.7 million) and \$1.1 million (AUD 1.6 million), respectively) in respect of the Australia R&D credit for eligible research and development expenses incurred during the period. This amount is included within Other income (expense) on the condensed consolidated interim statements of operations and comprehensive loss.

At March 31, 2025, Incentive and tax receivables includes \$0.5 million (AUD 0.8 million) (September 30, 2024: \$2.3 million (AUD 3.3 million)) relating to Australia R&D credits earned during the period that are expected to be reimbursed upon filing of the Company's annual claim under this program.

The Australia R&D credit program is a self-assessment program whereby the Company must assess its eligibility each year to determine (i) if the entity is eligible (ii) if specific R&D activities are eligible and (iii) if the individual R&D expenditures have nexus to such R&D activities. The Company evaluates its eligibility under the tax incentive program as of each balance sheet date based on the most current and relevant data available. Anavex Australia is able to continue to claim the R&D tax incentive for as long as it remains eligible and continues to incur eligible research and development expenditures.

Although the Company believes that it has complied with all the relevant conditions of eligibility under the program for all periods claimed, the ATO has the right to review the Company's qualifying programs and related expenditures for a period of four years. If such a review were to occur, the ATO may have different interpretations of certain eligibility requirements. If the ATO disagreed with the Company's assessments and any related subsequent appeals, it could require adjustment to and repayment of current or previous years' claims already received. Additionally, if the Company was unable to demonstrate a reasonably arguable position taken on such claims, the ATO could also assess penalties and interest on any such adjustments.

Currently, the Company's tax incentive claims from 2020 to 2024 are open to potential review by the ATO. Additionally, the period open for review is indefinite if the ATO suspects fraud. The Company has not provided any allowance for any such potential adjustments, should they occur in the future.

Equity Offerings

**6 Months Ended
Mar. 31, 2025**

Equity Offerings

Equity Offerings

Note 5 Equity Offerings

Common Stock

Common shares are voting and are entitled to dividends as declared at the discretion of the Board of Directors.

Preferred Stock

The Company's Board of Directors (the "Board") has the authority to issue preferred stock in one or more series and to fix the rights, preferences, privileges, restrictions and the number of shares constituting any series or the designation of the series.

2023 Purchase Agreement

On February 3, 2023, the Company entered into a \$150.0 million purchase agreement (the "2023 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company has the right to sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$150.0 million in value of its shares of common stock from time to time over a three-year period until February 3, 2026.

In consideration for entering into the 2023 Purchase Agreement, the Company issued to Lincoln Park 75,000 shares of common stock as a commitment fee (the "initial commitment shares") and agreed to issue up to an additional 75,000 shares pro rata, when and if, Lincoln Park purchased, at the Company's discretion, the \$150.0 million aggregate commitment. The Company determined the fair value of the initial commitment shares was \$0.8 million with reference to the closing price of the Company's shares on the Purchase Agreement date. In addition, the Company incurred third party expenses of \$0.1 million in connection with entering into the Purchase Agreement. These amounts were expensed to other financing expense on the statements of operations during the year ended September 30, 2023.

During the six months ended March 31, 2025, the Company did not issue any shares of common stock under the 2023 Purchase Agreement (2024: an aggregate of 1,503,707 shares of common stock including 1,500,000 shares for an aggregate purchase price of \$7.4 million and 3,707 commitment shares).

At March 31, 2025, there was an unused amount of \$110.8 million under the 2023 Purchase Agreement. The Company will need to obtain effectiveness of a new registration statement in order to access funds under the 2023 Purchase Agreement.

2020 Sales Agreement

The Company entered into a Controlled Equity Offering Sales Agreement on July 6, 2018, which was amended and restated on May 1, 2020 (the "2020 Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (together the "Sales Agents"), pursuant to which the Company could offer and sell shares of common stock registered under an effective registration statement from time to time through the Sales Agents (the "Offering").

During the six months ended March 31, 2024, no shares were sold pursuant to the Offering.

On July 24, 2024, the Company terminated the 2020 Sales Agreement.

Stock Options

During the three and six months ended March 31, 2025, the Company issued a net 217,503 shares of common stock to the Company's Chief Executive Officer upon a net exercise of an option to purchase 500,000 shares of common stock at an exercise price of \$0.92 per share. In connection with the exercise, the Company withheld 47,745 shares of common stock as consideration of the exercise price of \$0.46 million and 234,752 shares of common stock as consideration for the payment of \$2.3 million in connection with tax withholding obligations associated with the exercise. The shares withheld were based upon a market price of \$9.63 per share as determined by reference to the average high and low sales price reported on the Nasdaq stock exchange on the date of exercise. At March 31, 2025, the amount of \$2.3 million in connection with the tax withholding obligations was included in accounts payable on the consolidated balance sheets.

Commitments and Contingencies

6 Months Ended Mar. 31, 2025

Commitments and Contingencies Disclosure [Abstract]

Commitments and Contingencies

Note 6 Commitments and Contingencies

Lease

The Company leases office space under an operating lease with an initial term of 12 months or less. Under the terms of the office lease, the Company is required to pay its proportionate share of operating costs.

Anavex Life Sciences Corp.

The operating lease costs were as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
	Operating lease costs	\$ 33	\$ 31	\$ 66

Employee 401(k) Benefit Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers all United States based employees. United States based employees eligible to participate in the plan may contribute up to the current statutory limits under the Internal Revenue Service regulations. The 401(k) plan permits the Company to make additional matching contributions on behalf of contributing employees.

The Company made matching contributions under the 401(k) plan as follows (in thousands):

	Three Months Ended March 31,		Six Months ended March 31	
	2025	2024	2025	2024
	Contributions to 401(k) plan	\$ 67	\$ 94	\$ 115

Litigation

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's consolidated financial statements. The Company does not believe that any of such pending claims and legal proceedings will have a material adverse effect on its consolidated financial statements.

On March 13, 2024, a shareholder class action complaint was filed in the United States District Court for the Southern District of New York and it named the Company and an officer of the Company as Defendants. The complaint was amended on July 12, 2024 (the "Initial Action"). The complaint alleged violations of the Securities and Exchange Act of 1934 associated with disclosures and statements made with respect to certain clinical trials for ANAVEX®2-73 related to Rett syndrome. The complaint seeks unspecified damages, as well as costs, including counsel and expert witness fees, on behalf of a class of investors. The Company believes the lawsuit is without merit and the Company denies any liability or wrongdoing and has filed a motion to

dismiss the complaint, which is awaiting a decision by the Court. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

On May 8, 2024, a similar complaint was filed in the same court by Kenneth Downing, a purported shareholder of the Company, against the same defendants. The Company believed that this lawsuit was also without merit and filed a motion to dismiss the complaint. Plaintiff Downing voluntarily dismissed this complaint subsequent to the filing of the motion to dismiss.

On or about May 13, 2024, a derivative lawsuit was filed against the Company (as nominal defendant), an officer of the Company, and members of the Company's Board of Directors in the U.S. District Court for the District of Nevada by another purported shareholder. The complaint asserts various common law claims (including breach of fiduciary duty) and violation of Section 14(a) of the Securities Exchange Act regarding the same or similar allegations at issue in the purported class action lawsuit related to disclosures and statements made about certain clinical trials related to Rett Syndrome. On January 22, 2025, pursuant to a stipulation of the parties, the Court entered an order staying this purported derivative lawsuit until the motion to dismiss filed by defendants in the Initial Action is decided by the U.S. District Court for the Southern District of New York. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

On February 14, 2025, another derivative lawsuit asserting state law breach of fiduciary duty and unjust enrichment claims based upon similar allegations was filed against the Company (as nominal defendant), an officer of the Company, and members of the Company's Board of Directors in the Supreme Court for the State of New York, County of New York, by another purported shareholder named Evan Levitan. The parties to that action also have stipulated to a stay of the proceeding until the Court rules on the motion to dismiss in the putative class action lawsuit pending in the U.S. District Court for the Southern District of New York. The New York state court has not yet entered an order pursuant to the stipulation of the parties. No amount has been recorded in these condensed consolidated interim financial statements for any loss contingencies associated with this lawsuit as the Company believes that it is not probable that any loss will occur.

We know of no other material pending legal or governmental proceedings, other than ordinary routine litigation incidental to our business, to which our Company or our subsidiaries are a party or of which any of their property is subject. There are no other proceedings in which any of our directors, officers or affiliates, or any registered or beneficial stockholder holding more than 5% of our shares, or any associate of such persons, is an adverse party or has a material interest adverse to our or our subsidiaries' interest.

Share Purchase Warrants

At March 31, 2025 and September 30, 2024, the Company had 10,000 share purchase warrants outstanding exercisable at \$12.00 per share until April 21, 2026.

Share-based Compensation Plan

2015 Stock Option Plan

On September 18, 2015, the Company's Board approved a 2015 Omnibus Incentive Plan (the "2015 Plan"), which provided for the grant of stock options and restricted stock awards to directors, officers, employees and consultants of the Company.

The maximum number of our common shares reserved for issue under the 2015 Plan was 6,050,553 shares, subject to adjustment in the event of a change of the Company's capitalization.

2019 Stock Option Plan

On January 15, 2019, the Board approved the 2019 Omnibus Incentive Plan (the “2019 Plan”), which provides for the grant of stock options and restricted stock awards to directors, officers, employees, consultants and advisors of the Company.

The maximum number of our common shares reserved for issue under the 2019 Plan was 6,000,000 shares, subject to adjustment in the event of a change of the Company’s capitalization.

During the year ended September 30, 2022, 406,453 options previously available under the 2019 Plan and the 2015 Plan became available under the 2022 Plan (as defined below).

2022 Stock Option Plan

On March 25, 2022, the Board approved the 2022 Omnibus Incentive Plan (the “2022 Plan”). The 2022 Plan was approved by stockholders on May 24, 2022. Under the terms of the 2022 Plan, 10,000,000 additional shares of Common Stock will be available for issuance under the 2022 Plan, in addition to the shares available under the 2019 Plan and the 2015 Plan. Any awards outstanding under a previous stock option plan will remain subject to and be paid under such plan, and any shares subject to outstanding awards under a previous plan that subsequently cease to be subject to such awards (other than by reason of settlement of the awards in shares) will automatically become available for issuance under the 2022 Plan.

The 2022 Plan provides that it may be administered by the Board, or the Board may delegate such responsibility to a committee. The exercise price will be determined by the Board at the time of grant shall be at least equal to the fair market value on such date. If the grantee is a 10% stockholder on the grant date, then the exercise price shall not be less than 110% of fair market value of the Company’s shares of common stock on the grant date. Stock options may be granted under the 2022 Plan for an exercise period of up to ten years from the date of grant of the option or such lesser periods as may be determined by the Board, subject to earlier termination in accordance with the terms of the 2022 Plan. As at March 31, 2025, 6,751,000 options had been issued under the 2022 Plan and 3,978,702 options were available for issue under the 2022 Plan.

The following summarizes information about stock option activity during the six months ended March 31, 2025:

	Number of Options	Weighted Average Exercise Price (\$)	Weighted Average Grant Date Fair Value (\$)	Aggregate intrinsic value (\$)
Outstanding, September 30, 2024	15,037,754	6.80	5.12	15,825,791
Granted	1,483,500	8.58	6.22	—
Exercised	(820,632)	2.46	1.89	6,785,518
Outstanding, March 31, 2025	15,700,622	7.19	5.39	38,630,198
Exercisable, March 31, 2025	10,346,086	6.03	4.68	34,276,704

The following summarizes information about stock options at March 31, 2025 by a range of exercise prices:

Range of exercises prices	Number of outstanding	Weighted average remaining contractual life (in	Weighted average exercise	Number of vested	Weighted average exercise

From	To	options	years)	price	options	price
\$ 0.92	\$ 3.00	2,400,150	3.92	\$ 2.69	2,400,150	\$ 2.69
\$ 3.01	\$ 5.00	2,197,500	3.44	\$ 3.41	2,027,916	\$ 3.31
\$ 5.01	\$ 9.00	8,028,972	6.36	\$ 6.95	4,297,519	\$ 6.39
\$ 9.01	\$ 13.00	1,609,000	6.81	\$ 10.29	998,834	\$ 10.42
\$ 13.01	\$ 25.00	1,465,000	5.97	\$ 18.18	621,667	\$ 18.34
		<u>15,700,622</u>	<u>5.59</u>	<u>\$ 7.19</u>	<u>10,346,086</u>	<u>\$ 6.03</u>

The weighted average per share fair value of options vested at March 31, 2025 was \$4.68 (September 30, 2024: \$4.34). At March 31, 2024, the weighted average contractual life of options outstanding was 5.59 years (September 30, 2024: 5.48 years) and for options exercisable was 4.16 years (September 30, 2024: 4.03 years).

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the quoted market price of the Company's stock for the options that were in-the-money at March 31, 2025.

The Company recognized share-based compensation expense of \$1.4 million and \$3.5 million during the three and six months ended March 31, 2025, respectively (three and six months ended March 31, 2024: \$2.7 million and \$4.9 million, respectively) in connection with the issuance and vesting of stock options in exchange for services. These amounts have been included in general and administrative expenses and research and development expenses on the Company's condensed consolidated interim statements of operations as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
General and administrative	\$ 605	\$ 979	\$ 1,407	\$ 1,905
Research and development	844	1,673	2,097	3,033
Total share-based compensation	\$ 1,449	\$ 2,652	\$ 3,504	\$ 4,938

An amount of approximately \$14.5 million in share-based compensation is expected to be recorded over the remaining term of such options and warrants through fiscal 2029.

The fair value of each stock option award is estimated on the date of grant using the Black Scholes option pricing model. The fair value of share-based compensation charges recognized during the three and six months ended March 31, 2025 was determined with reference to the quoted market price of the Company's shares on the grant date and based on the following weighted average assumptions:

	2025	2024
Risk-free interest rate	3.98%	4.28%
Expected life of options (years)	5.56	5.74
Annualized volatility	86.49%	84.84%
Dividend rate	0.00%	0.00%

Subsequent Events

**6 Months Ended
Mar. 31, 2025**

Subsequent Events **[Abstract]**

Subsequent Events

Note 7 Subsequent Events

The Company evaluates subsequent events occurring between the most recent balance sheet date and the date the financial statements are available to be issued in order to determine whether the subsequent events are to be recorded and/or disclosed in the Company's financial statements and footnotes. The financial statements are considered to be available to be issued at the time they are filed with the Securities and Exchange Commission (SEC).

On April 17, 2025, the Board approved, subject to stockholder approval, an amendment to the 2022 Plan (the "Amendment"). The Amendment, if approved by stockholders, will increase the number of shares of common stock reserved for issuance under the 2022 Plan by 4,000,000 shares. In addition, the Amendment will establish a minimum vesting period of one year for all awards granted under the Plan and limit the discretion to accelerate the vesting of awards upon a separation from service, with limited exceptions permitted. Finally, the Amendment would prohibit liberal share recycling provisions.

**Basis of Presentation
(Policies)**

**Organization, Consolidation
and Presentation of
Financial Statements**

[Abstract]

Liquidity

**6 Months Ended
Mar. 31, 2025**

Liquidity

All of the Company's potential drug compounds are in the clinical development stage and the Company cannot be certain that its research and development efforts will be successful or, if successful, that its potential drug compounds will ever be approved for sales to pharmaceutical companies or generate commercial revenues. To date, we have not generated any revenue from our operations. The Company expects the business to continue to experience negative cash flows from operations for the foreseeable future and cannot predict when, if ever, our business might become profitable.

Management believes that the current working capital position will be sufficient to meet the Company's working capital requirements beyond the next 12 months after the date that these condensed consolidated interim financial statements are issued. The process of drug development can be costly, and the timing and outcomes of clinical trials are uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the design, timing and duration of future clinical trials, the progress of the Company's research and development programs and the level of financial resources available. The Company has the ability to adjust its operating plan spending levels based on the timing of future clinical trials.

Other than our rights related to the 2023 Purchase Agreement (as defined below in Note 5), there can be no assurance that additional financing will be available to us when needed or, if available, that it can be obtained on commercially reasonable terms. The Company will need to obtain effectiveness of a new registration statement in order to access the funds under the 2023 Purchase Agreement. If the Company is not able to obtain the additional financing on a timely basis, if and when it is needed, it will be forced to delay or scale down some or all of its research and development activities.

Use of Estimates

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company regularly evaluates estimates and assumptions related to accounting for research and development costs, incentive and tax receivables, valuation and recoverability of deferred tax assets, share based compensation, and loss contingencies. The Company bases its estimates and assumptions on current facts, historical experience, and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

Principles of Consolidation

Principles of Consolidation

These unaudited condensed consolidated interim financial statements include the accounts of Anavex Life Sciences Corp. and its wholly-owned subsidiaries, Anavex Australia Pty Limited ("Anavex Australia"), a company incorporated under the laws of Australia, Anavex Germany

GmbH, a company incorporated under the laws of Germany, and Anavex Canada Ltd., a company incorporated under the laws of the Province of Ontario, Canada. All inter-company transactions and balances have been eliminated.

Fair Value Measurements

Fair Value Measurements

The fair value hierarchy under GAAP is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - observable inputs other than Level 1, quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and model-derived prices whose inputs are observable or whose significant value drivers are observable; and

Level 3 - assets and liabilities whose significant value drivers are unobservable by little or no market activity and that are significant to the fair value of the assets or liabilities.

At March 31, 2025 and September 30, 2024, the Company did not have any Level 2 or Level 3 assets or liabilities.

Basic and Diluted Loss per Share

Basic and Diluted Loss per Share

Basic income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted income/(loss) per common share is computed by dividing net income/(loss) available to common stockholders by the sum of (1) the weighted-average number of common shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the diluted net loss per share calculation, options and warrants are potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

As of March 31, 2025 loss per share excludes 15,710,622 (March 31, 2024: 15,755,114) potentially dilutive common shares related to outstanding options and warrants, as their effect was anti-dilutive.

Recent Accounting Pronouncements

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued ASU No. 2023-07, “Segment Reporting: Improvements to Reportable Segment Disclosures.” This guidance requires disclosure of incremental segment information on an annual and interim basis. This amendment is effective for our fiscal year ending September 30, 2025 and our interim periods within the fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes: Improvements to Income Tax Disclosures.” This guidance requires consistent categories and greater disaggregation of information in the rate reconciliation and disclosures of income taxes paid by jurisdiction. This amendment is effective for our fiscal year ending September 30, 2026. The Company is currently assessing the impact of this guidance on its disclosures.

Accrued Liabilities (Tables)**6 Months Ended
Mar. 31, 2025****Accrued Liabilities****Schedule of principal components of accrued liabilities**

	March 31, 2025	September 30, 2024
Accrued investigator payments	\$ 1,459	\$ 860
Accrued compensation and benefits	2,200	1,527
Milestone-based contract accruals	4,332	557
All other accrued liabilities	1,564	1,891
Total accrued liabilities	\$ 9,555	\$ 4,835

Commitments and Contingencies (Tables)

Commitments and Contingencies Disclosure [Abstract]

Schedule of operating lease costs

	6 Months Ended Mar. 31, 2025			
	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
Operating lease costs	\$ 33	\$ 31	\$ 66	\$ 61

Schedule of contributions under the plan

	Three Months Ended March 31,		Six Months ended March 31	
	2025	2024	2025	2024
	\$ 67	\$ 94	\$ 115	\$ 167
Contributions to 401(k) plan				

Schedule of stock option activity

	Number of Options	Weighted Average Exercise Price (\$)	Weighted Average Grant Date Fair Value (\$)	Aggregate intrinsic value (\$)
Outstanding, September 30, 2024	15,037,754	6.80	5.12	15,825,791
Granted	1,483,500	8.58	6.22	—
Exercised	(820,632)	2.46	1.89	6,785,518
Outstanding, March 31, 2025	15,700,622	7.19	5.39	38,630,198
Exercisable, March 31, 2025	10,346,086	6.03	4.68	34,276,704

Schedule of summarizes information about stock options

Range of exercises prices	Number of outstanding options	Weighted average remaining contractual life (in years)	Weighted average exercise price	Number of vested options	Weighted average exercise price		
		From	To	options	price	options	price
\$ 0.92	\$ 3.00	2,400,150	3.92	\$ 2,400,150	\$ 2.69	2,400,150	\$ 2.69
\$ 3.01	\$ 5.00	2,197,500	3.44	\$ 3,411,916	\$ 3.41	2,027,916	\$ 3.31
\$ 5.01	\$ 9.00	8,028,972	6.36	\$ 6,954,297,519	\$ 6.95	4,297,519	\$ 6.39
\$ 9.01	\$ 13.00	1,609,000	6.81	\$ 10.29998,834	\$ 10.29	998,834	\$ 10.42
\$ 13.01	\$ 25.00	1,465,000	5.97	\$ 18.18621,667	\$ 18.18	621,667	\$ 18.34
		15,700,622	5.59	\$ 7.1910,346,086	\$ 7.19	10,346,086	\$ 6.03

Schedule of general and administrative expenses and research and development expenses

	Three months ended March 31,		Six months ended March 31,	
	2025	2024	2025	2024
General and administrative	\$ 605	\$ 979	\$ 1,407	\$ 1,905
Research and development	844	1,673	2,097	3,033
Total share-based compensation	\$ 1,449	\$ 2,652	\$ 3,504	\$ 4,938

Schedule of weighted average assumptions for fair value of each option award

	2025	2024
Risk-free interest rate	3.98%	4.28%
Expected life of options (years)	5.56	5.74
Annualized volatility	86.49%	84.84%

Dividend rate

0.00%

0.00%

Basis of Presentation (Details Narrative) - shares	Mar. 31, 2025	Mar. 31, 2024
<u>Organization, Consolidation and Presentation of Financial Statements [Abstract]</u>		
<u>Dilutive common shares</u>	15,710,622	15,755,114

Accrued Liabilities (Details)

- USD (\$) Mar. 31, 2025 Sep. 30, 2024

\$ in Thousands

Accrued Liabilities

<u>Accrued investigator payments</u>	\$ 1,459	\$ 860
<u>Accrued compensation and benefits</u>	2,200	1,527
<u>Milestone-based contract accruals</u>	4,332	557
<u>All other accrued liabilities</u>	1,564	1,891
<u>Total accrued liabilities</u>	\$ 9,555	\$ 4,835

Other Income (Details Narrative) - USD (\$)	3 Months Ended		6 Months Ended		12 Months Ended		
	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024	Sep. 30, 2024	Sep. 30, 2023	Sep. 30, 2021

[Defined Benefit Plan Disclosure](#)

[\[Line Items\]](#)

<u>Research and development incentive income</u>						\$ 500,000	\$ 500,000
<u>Non operating income from grant</u>	\$ 0	\$ 0	\$ 12,275	\$ 0			
<u>Deferred grant income</u>			800,000			\$ 800,000	
<u>Research and development incentive income</u>	100,000	500,000	500,000	1,100,000			
<u>Incentive and tax receivables</u>	500,000		500,000			2,300,000	

[Australia, Dollars](#)

[Defined Benefit Plan Disclosure](#)

[\[Line Items\]](#)

<u>Research and development incentive income</u>	200,000	\$ 700,000	800,000	\$	
<u>Incentive and tax receivables</u>	\$ 800,000		800,000	\$	

[Michael J Fox Foundation](#)

[\[Member\]](#)

[Defined Benefit Plan Disclosure](#)

[\[Line Items\]](#)

<u>Research and development incentive income</u>		\$	
		1,000,000.0	

Equity Offerings (Details Narrative) - USD (\$) \$ / shares in Units, \$ in Thousands	6 Months Ended			
	Feb. 03, 2023	Mar. 31, 2025	Mar. 31, 2024	Sep. 30, 2023

**Collaborative Arrangement and Arrangement Other than
Collaborative [Line Items]**

<u>Fair value of the initial commitment</u>	\$ 800
<u>Incurred expenses</u>	\$ 100
<u>Aggregate common shares</u>	1,503,707 1,500,000
<u>Aggregate purchase price</u>	\$ 7,400
<u>Commitment shares</u>	3,707
<u>[custom:SharesOfCommonStockIssued]</u>	217,503
<u>[custom:OptionToPurchaseShares]</u>	500,000
<u>[custom:ExercisePrice]</u>	\$ 0.92
<u>[custom:WthheldShares]</u>	47,745
<u>[custom:ExercisePriceConsideration]</u>	\$ 460
<u>[custom:CommonStockAsConsideration]</u>	234,752
<u>[custom:WithholdingObligationsExercise]</u>	\$ 2,300
<u>[custom:AccountsPayable]</u>	2,300

Purchase Agreement 2023 [Member] | Lincoln Park Capital Fund L
L C [Member]

**Collaborative Arrangement and Arrangement Other than
Collaborative [Line Items]**

<u>Value of shares obligated to purchase</u>	\$ 150,000
<u>Share issued for offering, shares</u>	75,000
<u>Pro rata basic number of shares obligated to purchase</u>	75,000
<u>Proceeds from issuance or sale of equity</u>	\$ 150,000
<u>Amount of shares remain available</u>	\$ 110,800

Commitments and Contingencies (Details) - USD (\$) \$ in Thousands	3 Months Ended		6 Months Ended	
	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024
<u>Commitments and Contingencies Disclosure</u>				
[Abstract]				
<u>Operating lease costs</u>	\$ 33	\$ 31	\$ 66	\$ 61

Commitments and Contingencies (Details 1) - USD (\$) \$ in Thousands	3 Months Ended		6 Months Ended	
	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024
<u>Commitments and Contingencies Disclosure</u>				
<u>[Abstract]</u>				
<u>Contributions to 401(k) plan</u>	\$ 67	\$ 94	\$ 115	\$ 167

Commitments and Contingencies (Details 2) - Equity Option [Member]	6 Months Ended Mar. 31, 2025
	USD (\$) \$ / shares shares

Offsetting Assets [Line Items]

<u>Number of options, Outstanding beginning balance shares</u>	15,037,754
<u>Weighted average exercise price, Outstanding beginning balance</u>	\$ 6.80
<u>Weighted average grant date fair value, Outstanding beginning balance</u>	\$ 5.12
<u>Aggregate intrinsic value, Outstanding beginning balance \$</u>	\$ 15,825,791
<u>Number of options, Granted shares</u>	1,483,500
<u>Weighted average exercise price, Granted</u>	\$ 8.58
<u>Weighted average grant date fair value, Granted</u>	\$ 6.22
<u>Number of options, Exercised shares</u>	(820,632)
<u>Weighted average exercise price, Exercised</u>	\$ 2.46
<u>Weighted average grant date fair value, Exercised</u>	\$ 1.89
<u>Aggregate intrinsic value, Exercised \$</u>	\$ 6,785,518
<u>Number of options, Outstanding beginning balance shares</u>	15,700,622
<u>Weighted average exercise price, Outstanding ending balance</u>	\$ 7.19
<u>Weighted average grant date fair value, Outstanding ending balance</u>	\$ 5.39
<u>Aggregate intrinsic value, Outstanding ending balance \$</u>	\$ 38,630,198
<u>Number of options, Exercisable shares</u>	10,346,086
<u>Weighted average exercise price, Exercisable</u>	\$ 6.03
<u>Weighted average grant date fair value, Exercisable</u>	\$ 4.68
<u>Aggregate intrinsic value, Exercisable \$</u>	\$ 34,276,704

Commitments and Contingencies (Details 3) - Equity Option [Member] - \$ / shares	6 Months Ended	
	Mar. 31, 2025	Sep. 30, 2024
<u>Offsetting Assets [Line Items]</u>		
<u>Number of outstanding options</u>	15,700,622	15,037,754
<u>Weighted average remaining contractual life (in years)</u>	5 years 7 months 2 days	
<u>Weighted average exercise price</u>	\$ 7.19	\$ 6.80
<u>Number of vested options</u>	10,346,086	
<u>Weighted average exercise price options vested</u>	\$ 6.03	
<u>Option Price 1 [Member]</u>		
<u>Offsetting Assets [Line Items]</u>		
<u>Range of exercise prices, lower range limit</u>	0.92	
<u>Range of exercise prices, upper range limit</u>	\$ 3.00	
<u>Number of outstanding options</u>	2,400,150	
<u>Weighted average remaining contractual life (in years)</u>	3 years 11 months 1 day	
<u>Weighted average exercise price</u>	\$ 2.69	
<u>Number of vested options</u>	2,400,150	
<u>Weighted average exercise price options vested</u>	\$ 2.69	
<u>Option Price 2 [Member]</u>		
<u>Offsetting Assets [Line Items]</u>		
<u>Range of exercise prices, lower range limit</u>	3.01	
<u>Range of exercise prices, upper range limit</u>	\$ 5.00	
<u>Number of outstanding options</u>	2,197,500	
<u>Weighted average remaining contractual life (in years)</u>	3 years 5 months 8 days	
<u>Weighted average exercise price</u>	\$ 3.41	
<u>Number of vested options</u>	2,027,916	
<u>Weighted average exercise price options vested</u>	\$ 3.31	
<u>Option Price 3 [Member]</u>		
<u>Offsetting Assets [Line Items]</u>		
<u>Range of exercise prices, lower range limit</u>	5.01	
<u>Range of exercise prices, upper range limit</u>	\$ 9.00	
<u>Number of outstanding options</u>	8,028,972	
<u>Weighted average remaining contractual life (in years)</u>	6 years 4 months 9 days	
<u>Weighted average exercise price</u>	\$ 6.95	
<u>Number of vested options</u>	4,297,519	
<u>Weighted average exercise price options vested</u>	\$ 6.39	
<u>Option Price 4 [Member]</u>		
<u>Offsetting Assets [Line Items]</u>		
<u>Range of exercise prices, lower range limit</u>	9.01	
<u>Range of exercise prices, upper range limit</u>	\$ 13.00	
<u>Number of outstanding options</u>	1,609,000	
<u>Weighted average remaining contractual life (in years)</u>	6 years 9 months 21 days	
<u>Weighted average exercise price</u>	\$ 10.29	

<u>Number of vested options</u>	998,834
<u>Weighted average exercise price options vested</u>	\$ 10.42
<u>Option Price 5 [Member]</u>	
Offsetting Assets [Line Items]	
<u>Range of exercise prices, lower range limit</u>	13.01
<u>Range of exercise prices, upper range limit</u>	\$ 25.00
<u>Number of outstanding options</u>	1,465,000
<u>Weighted average remaining contractual life (in years)</u>	5 years 11 months 19 days
<u>Weighted average exercise price</u>	\$ 18.18
<u>Number of vested options</u>	621,667
<u>Weighted average exercise price options vested</u>	\$ 18.34

Commitments and Contingencies (Details 4) - USD (\$) \$ in Thousands	3 Months Ended		6 Months Ended	
	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024
<u>Loss Contingencies [Line Items]</u>				
<u>Total share based compensation</u>	\$ 1,449	\$ 2,652	\$ 3,504	\$ 4,938
<u>General and Administrative Expense [Member]</u>				
<u>Loss Contingencies [Line Items]</u>				
<u>Total share based compensation</u>	605	979	1,407	1,905
<u>Research and Development Expense [Member]</u>				
<u>Loss Contingencies [Line Items]</u>				
<u>Total share based compensation</u>	\$ 844	\$ 1,673	\$ 2,097	\$ 3,033

Commitments and Contingencies (Details 5)	6 Months Ended	
	Mar. 31, 2025	Mar. 31, 2024

Commitments and Contingencies Disclosure [Abstract]

<u>Risk-free interest rate</u>	3.98%	4.28%
<u>Expected life of options (years)</u>	5 years 6 months 21 days	5 years 8 months 26 days
<u>Annualized volatility</u>	86.49%	84.84%
<u>Dividend rate</u>	0.00%	0.00%

Commitments and Contingencies (Details Narrative) - USD (\$) \$ / shares in Units, \$ in Millions	3 Months Ended	6 Months Ended	12 Months Ended				
	Mar. 25, 2022	Mar. 31, 2025	Mar. 31, 2024	Mar. 31, 2025	Mar. 31, 2024	Sep. 30, 2024	Sep. 30, 2022
<u>Share-Based Compensation</u>							
<u>Arrangement by Share-Based Payment</u>							
<u>Award [Line Items]</u>							
<u>Warrants outstanding</u>		10,000		10,000			
<u>Warrants outstanding weighted average exercise price</u>		\$ 12.00		\$ 12.00			
<u>Expiry Date</u>		Apr. 21, 2026		Apr. 21, 2026			
<u>Option issued</u>				6,751,000			
<u>Weighted average grant date fair value of options vested</u>				\$ 4.68		\$ 4.34	
<u>Weighted average contractual life of options exercisable</u>				5 years 7 months 2 days		5 years 5 months 23 days	
<u>Weighted average contractual life of options exercisable</u>				4 years 1 month 28 days		4 years 10 days	
<u>Share based compensation expense</u>	\$ 3.5	\$ 4.9	\$ 1.4		\$ 2.7		
<u>Remaining stock based compensation</u>	\$ 14.5		\$ 14.5				
<u>Stock Option Plan 2015 [Member]</u>							
<u>Share-Based Compensation</u>							
<u>Arrangement by Share-Based Payment</u>							
<u>Award [Line Items]</u>							
<u>Maximum number of common shares reserved for future issuance</u>		6,050,553		6,050,553			
<u>Stock Option Plan 2019 [Member]</u>							
<u>Share-Based Compensation</u>							
<u>Arrangement by Share-Based Payment</u>							
<u>Award [Line Items]</u>							
<u>Additional shares of common stock available for issuance</u>				6,000,000			
<u>Stock Option Plan 2022 [Member]</u>							
<u>Share-Based Compensation</u>							
<u>Arrangement by Share-Based Payment</u>							
<u>Award [Line Items]</u>							
<u>Additional shares of common stock available for issuance</u>		10,000,000					
<u>Option granted</u>							406,453
<u>Option available issue</u>		3,978,702		3,978,702			

**Subsequent Events (Details
Narrative)** **Apr. 17, 2025**
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Subsequent Event [Member]

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