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, 2024**

☐ **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	**98-0608404**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

630 5th Avenue , 20th Floor , New York , NY US A 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).

☒ **Yes** ☐ **No**

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

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

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

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date: 84,641,537 shares of Common Stock outstanding as of May 9, 2024.

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ITEM 1. FINANCIAL STATEMENTS

Anavex Life Sciences Corp.

Condensed Consolidated Interim Financial Statements

March 31, 2024

(Unaudited)

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

	March 31, 2024 (Unaudited)	September 30, 2023
Assets		
Current		
Cash and cash equivalents	**$ 139,386**	$ 151,024
Incentive and tax receivables	**3,785**	2,709
Prepaid expenses and other current assets	**1,345**	653
Total Assets	**$ 144,516**	$ 154,386
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	**$ 3,726**	$ 4,322
Accrued liabilities - Note 4	4,915	7,295
Deferred grant income - Note 3	917	917
Total Liabilities	9,558	12,534
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:		
83,616,218 common shares (September 30, 2023 - 82,066,511)	**84**	82
Additional paid-in capital	447,345	434,839
Share proceeds receivable	**(234)**	—
Accumulated deficit	**(312,237)**	(293,069)
Total Stockholders' Equity	**134,958**	141,852
Total Liabilities and Stockholders' Equity	**$ 144,516**	$ 154,386

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,	
	2024	2023	**2024**	2023
Operating expenses				
General and administrative	**$ 2,790**	$ 2,883	**$ 5,399**	$ 6,200
Research and development	**9,729**	11,307	**18,413**	23,373
Total operating expenses	**12,519**	14,190	**23,812**	29,573
Operating loss	**(12,519)**	(14,190)	**(23,812)**	(29,573)

Other income				
Grant income	**—**	—	**—**	25
Research and development incentive income	**472**	750	**1,064**	1,483
Interest income, net	**1,756**	1,465	**3,764**	2,733
Other financing expense	**—**	(964)	**—**	(964)
Foreign exchange gain (loss)	**(150)**	(118)	**7**	247
Total other income, net	**2,078**	1,133	**4,835**	3,524
Net loss before provision for income taxes	**(10,441)**	(13,057)	**(18,977)**	(26,049)
Income tax expense, current	**(105)**	(50)	**(191)**	(30)
Net loss and comprehensive loss	**$ (10,546)**	$ (13,107)	**$ (19,168)**	$ (26,079)
Net Loss per share				
Basic and diluted	**$ (0.13)**	$ (0.17)	**$ (0.23)**	$ (0.33)
Weighted average number of shares outstanding				
Basic and diluted	82,464,226	78,304,363	82,269,965	78,138,940

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, 2024 and 2023
(in thousands, except share and per share amounts)
(Unaudited)

	Common Stock Shares	Par Value	Additional Paid-in Capital	Share proceeds Receivable	Accumulated Deficit	Total
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**
Balance, January 1, 2023	**78,032,135**	**$ 78**	**$ 393,582**	**$ —**	**$ (258,536)**	**$ 135,124**
Shares issued under 2023 Purchase Agreement						
Initial commitment shares	75,000	—	844	—	—	844
Purchase shares	2,075,000	2	18,151	—	—	18,153
Commitment shares	9,080	—	—	—	—	—
Shares issued pursuant to exercise of stock options	44,183	—	181	—	—	181
Share based compensation	—	—	3,970	—	—	3,970
Net loss	—	—	—	—	(13,107)	(13,107)
Balance, March 31, 2023	**80,235,398**	**$ 80**	**$ 416,728**	**$ —**	**$ (271,643)**	**$ 145,165**

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, 2024 and 2023
(in thousands, except share and per share amounts)
(Unaudited)

	Common Stock Shares	Par Value	Additional Paid-in Capital	Share proceeds Receivable	Accumulated Deficit	Total
Balance, October 1, 2023	**82,066,511**	**$ 82**	**$ 434,839**	**$ —**	**$ (293,069)**	**$ 141,852**
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	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**

Balance, October 1, 2022	77,942,815	$ 78	$ 387,977	$ —	$ (245,564)	142,491
Shares issued under 2023 Purchase Agreement						
Initial commitment shares	75,000	—	844	—		844
Purchase shares	2,075,000	2	18,151	—		18,153
Commitment shares	9,080	—	—	—		—
Shares issued pursuant to exercise of stock options	133,503	—	439	—	—	439
Share based compensation	—	—	9,317	—	—	9,317
Net loss	—	—	—	—	(26,079)	(26,079)
Balance, March 31, 2023	**80,235,398**	**$ 80**	**$ 416,728**	**$ —**	**$ (271,643)**	**145,165**

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)
(Unaudited)

	Six months ended March 31,	
	2024	2023
Cash Flows used in Operating Activities		
Net loss	**$ (19,168)**	$ (26,079)
Adjustments to reconcile net loss to net cash used in operations:		
Non-cash financing related charges	**—**	845
Share-based compensation	**4,938**	9,317
Changes in working capital balances related to operations:		
Incentive and tax receivables	**(1,076)**	(1,545)
Prepaid expenses and deposits	**(692)**	(628)
Accounts payable	**(596)**	2,456
Accrued liabilities	**(2,380)**	878
Deferred grant income	**—**	473
Net cash used in operating activities	**(18,974)**	(14,283)
Cash Flows provided by Financing Activities		
Issuance of common shares	**7,178**	18,153
Proceeds from exercise of stock options	**158**	439
Net cash provided by financing activities	**7,336**	18,592
Increase (decrease) in cash and cash equivalents during the period	**(11,638)**	4,309
Cash and cash equivalents, beginning of period	**151,024**	149,158
Cash and cash equivalents, end of period	**$ 139,386**	$ 153,467
Supplemental Cash Flow Information		
Cash paid for state and local minimum income taxes	**$ 220**	$ 140

See Accompanying Notes to Condensed Consolidated Interim Financial Statements

Anavex Life Sciences Corp.
Notes to the Condensed Consolidated Interim Financial Statements
March 31, 2024
(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 lead compound ANAVEX ®2-73 is being developed to treat Alzheimer’s disease, Parkinson’s disease and potentially other central nervous system diseases, including rare diseases, such as Rett syndrome, a rare severe neurological monogenic disorder caused by mutations in the X-linked gene, methyl-CpG-binding protein 2 (“MECP2”).

Note 2 Basis of Presentation

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, 2023 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, 2023 filed with the SEC on November 27, 2023. The Company follows the same accounting policies in the preparation of interim reports.

Operating results for the six months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending September 30, 2024.

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 revenues 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. 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 income receivable, 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 consolidated 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, 2024 and September 30, 2023, the Company did not have any 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, 2024 loss per share excludes 15,755,114 (March 31, 2023: 15,001,613) potentially dilutive common shares related to outstanding options and warrants, as their effect was anti-dilutive.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 Other Income

Grant Income

As of March 31, 2024, 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 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 has been 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, 2024, the Company recognized $ 0 and $ 0 , respectively (2023: $ 0 and $ 25,000 , respectively) of this grant on its statements of operations as grant income. At March 31, 2024, an amount of $ 0.9 million (September 30, 2023: $ 0.9 million) of this grant is recorded as deferred grant income, representing the amount of this grant which has not yet been recognized to other income. The Company will recognize this income on its statement of operations as the relating 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, 2024 the Company recorded research and development incentive income of $ 0.5 million (AUD 0.7 million) and $ 1.1 million (AUD 1.6 million), respectively (2023: $ 0.7 million (AUD 1.1 million) and $ 1.5 million (AUD 2.2 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 on the consolidated statements of operations.

At March 31, 2024, Incentive and tax receivables includes $ 3.6 million (AUD 5.6 million) (September 30, 2023: $ 2.5 million (AUD 3.9 million)) relating to Australia R&D credits earned during the year 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-assess program whereby the Company must assess its eligibility each year to determine (i) if the entity is eligible (ii) if the 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 Australian Tax Office (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 such adjustment.

Currently, the Company's tax incentive claims from 2020 to 2023 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 4 Accrued Liabilities

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

	March 31, 2024	September 30, 2023
Accrued clinical site and patient visits costs	$ 1,209	$ 2,006
Accrued compensation and benefits	630	1,360
Fixed contract accruals	—	38
Milestone based contract accruals	1,545	1,267
All other accrued liabilities	1,531	2,624
Total accrued liabilities	**$ 4,915**	**$ 7,295**

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 (the "Board").

Preferred Stock

The Company's 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.

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 "Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (together the "Sales Agents"), pursuant to which the Company may offer and sell shares of common stock ("Shares") registered under an effective registration statement from time to time through the Sales Agents (the "Offering").

Upon delivery of a placement notice based on the Company's instructions and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell the Shares by methods deemed to be an "at the market" offering, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to the prior written consent of the Company. The Company is not obligated to make any sales of Shares under the Sales Agreement. The Company or Sales Agents may suspend or terminate the offering of Shares upon notice to the other party, subject to certain conditions. The Sales Agents will act as agent on a commercially reasonable efforts basis consistent with their normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of Nasdaq.

The Company has agreed to pay the Sales Agents commissions for their services of up to 3.0 % of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. The Company also agreed to provide the Sales Agents with customary indemnification and contribution rights. During the six months ended March 31, 2024 and 2023, no shares were sold pursuant to the Offering. At March 31, 2024, an amount of $ 142.4 million (September 30, 2023: $ 142.4 million) was registered pursuant to an effective registration statement. The Company currently is unable to sell shares of common stock under the Sales Agreement.

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, 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 $ 7.4 million and 3,707 commitment shares. During the six months ended March 31, 2023, the Company issued to Lincoln Park an aggregate of 2,159,080 shares of common stock under the 2023 Purchase Agreement, including 2,075,000 shares of common stock for an aggregate purchase price of $ 18.2 million, and 9,080 commitment shares and the 75,000 initial commitment shares.

At March 31, 2024, an amount of $ 114.7 million remained available under the 2023 Purchase Agreement.

Note 6 Commitments and Contingencies

Leases

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.

During the three and six months ended March 31, 2024 and 2023, operating lease costs were as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Operating lease costs	$ 31	$ 30	$ 61	$ 60

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.

During the three and six months ended March 31, 2024 and 2023, the Company made matching contributions under the 401(k) plan as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Contributions to 401(k) plan	$ 94	$ 56	$ 167	$ 100

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. The complaint is captioned Blum v. Anavex Life Sciences, Corp. et al., case number 1:24-cv-01910, and names the Company and Christopher Missling as Defendants. The complaint alleges violations of the Securities and Exchange Act of 1934 resulting from disclosures and statements made about certain clinical trials for ANAVEX®2-73. The Company believes the complaint is without merit. The Company is vigorously pursuing its defenses and a potential dismissal of all claims asserted in the lawsuit.

Share Purchase Warrants

At March 31, 2024 and September 30, 2023, the Company had 160,000 warrants outstanding at a weighted average exercise price of $ 3.72 as follows:

Number	Exercise Price	Expiry Date
150,000	$ 3.17	May 6, 2024
10,000	$ 12.00	April 21, 2026
160,000		

Stock–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 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 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 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. At March 31, 2024, 5,452,500 options had been issued under the 2022 Plan and 5,132,202 options were available for issue under the 2022 Plan.

The following summarizes information about stock option activity during the year ended September 30, 2023 and six months ended March 31, 2024:

	Number of Options	Weighted Average Exercise Price ($)	Weighted Average Grant Date Fair Value ($)	Aggregate intrinsic value ($)
Outstanding, September 30, 2022	13,169,616	6.61	4.96	62,267,309
Granted	1,959,000	9.30	6.60	—
Exercised	(759,753)	2.34	0.95	4,629,026
Forfeited	(257,083)	12.00	6.74	—
Outstanding, September 30, 2023	14,111,780	7.12	5.27	22,290,069
Granted	1,750,500	5.53	3.99	—
Exercised	(46,000)	3.43	2.60	125,170
Forfeited	(221,166)	13.84	9.06	—
Outstanding, March 31, 2024	15,595,114	6.85		12,480,916
Exercisable, March 31, 2024	9,955,616	5.38		12,440,416

The following summarizes information about stock options at March 31, 2024 by a range of exercise prices:

Range of exercises prices From	To	Number of outstanding options	Weighted average remaining contractual life (in years)	Weighted average exercise price	Number of vested options	Weighted average exercise price
$ 0.92	$ 3.00	3,243,060	4.22	2.38	3,243,060	$ 2.38
$ 3.01	$ 5.00	2,167,500	4.24	3.39	2,017,500	$ 3.28
$ 5.01	$ 9.00	6,790,554	6.62	6.58	3,436,472	$ 6.19
$ 9.01	$ 13.00	1,894,000	7.85	10.53	705,667	$ 11.06
$ 13.01	$ 25.00	1,500,000	6.97	18.12	552,917	$ 18.28
		15,595,114	5.97	6.85	9,955,616	5.38

The weighted average grant date fair value of options vested at March 31, 2024 was $ 4.07 (September 30, 2023: $ 3.94). At March 31, 2024, the weighted average contractual life of options outstanding was 6.0 years (September 30, 2023: 6.0 years) and for options exercisable was 4.5 years (September 30, 2023: 4.75 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, 2024.

During the three and six months ended March 31, 2024, the Company recognized stock-based compensation expense of $ 2.7 million and $ 4.9 million, respectively (2023: $ 4.0 million and $ 9.3 million, respectively) in connection with the issuance and vesting of stock options and warrants 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 statement of operations as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
General and administrative	$ 979	$ 1,257	$ 1,905	$ 3,000
Research and development	1,673	2,713	3,033	6,317
Total stock-based compensation	$ 2,652	$ 3,970	$ 4,938	$ 9,317

An amount of approximately $ 14.5 million in stock-based compensation is expected to be recorded over the remaining term of such options through fiscal 2026.

The fair value of each option award granted during the three and six months ended March 31, 2024 and 2023 is estimated on the date of grant using the Black Scholes option pricing model based on the following weighted average assumptions:

	2024	2023
Risk-free interest rate	4.28%	3.69%
Expected life of options (years)	5.74	5.61
Annualized volatility	84.84%	85.28%
Dividend rate	0.00%	0.00%

The fair value of stock compensation charges recognized during the three and six months ended March 31, 2024 and 2023 was determined with reference to the quoted market price of the Company's shares on the grant date.

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 products 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 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; 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 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 November 27, 2023. 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.

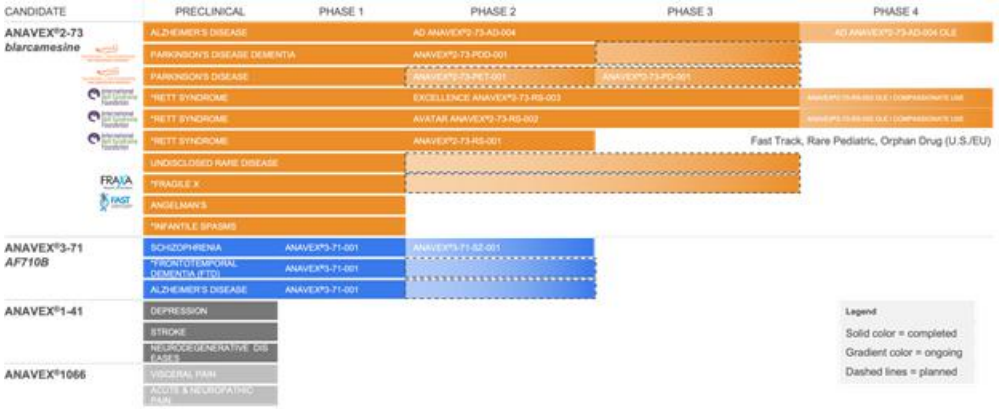
Our Current Business

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.

Our lead product candidate, ANAVEX ®2-73 (blarcamesine), is being developed to treat Alzheimer's disease, Parkinson's disease and potentially other central nervous system diseases, including rare diseases, such as Rett syndrome, a rare severe neurological monogenic disorder caused by mutations in the X-linked gene, methyl-CpG-binding protein 2 ("MECP2").

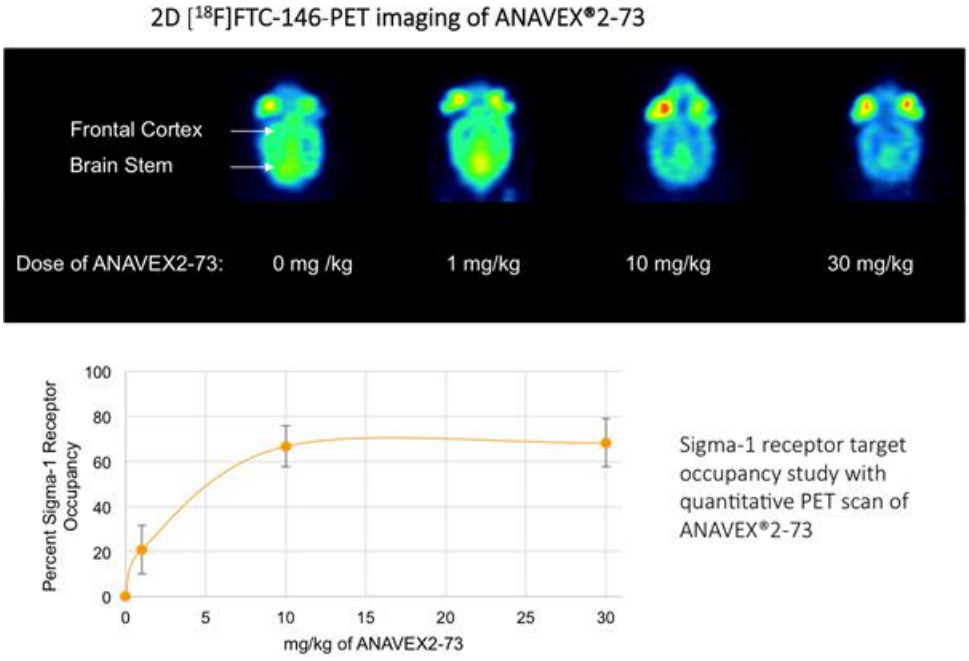
We currently have two core programs and two seed programs. Our core programs are at various stages of clinical and preclinical development, in neurodegenerative and neurodevelopmental diseases.

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. 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.



Source: Reyes S et al., 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.

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. In our clinical trials, 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 Alzheimer's disease as well as indications like Parkinson's disease dementia or Rett syndrome in which ANAVEX®2-73 (blarcamesine) is currently being studied.

Clinical Trials Overview

Alzheimer's Disease

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.

A larger Phase 2b/3 double-blind, placebo-controlled trial of ANAVEX®2-73 in Alzheimer's disease commenced in August 2018. The Phase 2b/3 trial enrolled 509 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 the primary 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 positive topline results from the Phase 2b/3 clinical trial.

ANAVEX®2-73 met the co-primary endpoints ADAS-Cog and ADCS-ADL and key secondary endpoint CDR-SB. ANAVEX®2-73 treatment slowed decline of cognition and function in patients with early Alzheimer's disease over 48 weeks. In addition, patients treated with ANAVEX®2-73 had 1.84 times higher odds, or likelihood, to improve cognitively compared to placebo, with an ADAS-Cog score threshold change of -0.5 points or better [Odds Ratio = 1.84 (p = 0.015)]. At clinically significant levels of improvement in function (ADCS-ADL score threshold change of +3.5 points or better), patients treated with ANAVEX®2-73 had 2.67 times higher odds, or likelihood, to improve function compared to placebo [Odds Ratio = 2.67 (p = 0.0255)]. Additionally, treatment with ANAVEX®2-73 reduced cognitive decline at end of treatment, measured with the ADAS-Cog, as compared to placebo, by 45%, representing a treatment difference in mean score change of -1.85 points (p=0.033). Compared to placebo, ANAVEX®2-73 reduced clinical decline of cognition and function by 27% with mean score difference of -0.42 points (p=0.040) as measured by the CDR-SB. ANAVEX®2-73 was generally safe and well tolerated. All statistical analyses were performed by outside consultancy companies.

In September 2023, we provided additional data demonstrating that the clinical effect was complemented by two independent biomarkers. A significant reduction in pathological amyloid beta levels in plasma, as well as a significant slowing in the rate of pathological brain atrophy on Magnetic Resonance Imaging (MRI) scans. Validated biomarkers of amyloid beta pathology, plasma Aβ42/40 ratio increased significantly (P = 0.048), demonstrating strong anti-amyloid effects of ANAVEX®2-73 in Alzheimer's disease patients, while MRI revealed significant reduction in brain volume loss, including whole brain (P = 0.0005), comparing treatment to placebo.

Furthermore, all pre-specified clinical endpoints were further 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, since the differences in the least-squares mean (LSM) change from baseline to 48 weeks between the ANAVEX®2-73 and placebo groups were −1.783 [95% CI, −3.314 to −0.251]; (P = 0.0226) for ADAS-Cog13, and −0.456 [95% CI, −0.831 to −0.080]; (P = 0.0175) for CDR-SB in patients with early Alzheimer's disease.

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.

A subsequent long-term open label extension study of ANAVEX®2-73, entitled the ATTENTION-AD trial was initiated for patients who have completed the 48-week Phase 2b/3 placebo-controlled trial referenced above. This trial extension for an additional 96 weeks is currently ongoing, and provides an opportunity to evaluate longer term safety and efficacy of ANAVEX®2-73 in persons with Alzheimer'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 and 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 ("Rettsyndrome.org"). In January 2017, we were awarded a financial grant from Rettsyndrome.org of a minimum of $0.6 million to cover some of the costs

of a multicenter Phase 2 clinical trial of ANAVEX®2-73 for the treatment of Rett syndrome. This award was received in quarterly instalments which commenced during fiscal 2018.

In March 2019, we commenced the first Phase 2 clinical trial in a planned Rett syndrome program of ANAVEX ®2-73 for the treatment of Rett syndrome. The clinical trials are being conducted in a range of patient age demographics and geographic regions, utilizing an oral liquid once-daily formulation of ANAVEX®2-73.

The first Phase 2 trial, (ANAVEX ®2-73-RS-001), which took place in the United States, 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 Clinical Global Impression Improvement (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.

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.

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.

A high enrollment rate in the 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.

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 Phase 2 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 Open Label Extension ("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), Clinical Global Impression – Improvement (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. The two endpoints, MDS-UPDRS Part II + III and CGI-I measured in this study are the planned primary and key secondary endpoints in our forthcoming pivotal 6-month Parkinson's disease study.

In January 2021, we were awarded a research grant of $1.0 million from The Michael J. Fox Foundation for Parkinson's Research to develop ANAVEX®2-73 for the treatment of Parkinson's disease. The award will 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.

Schizophrenia, Frontotemporal Dementia and Alzheimer's disease

In July 2020, we commenced the First-in-Human Phase 1 clinical trial of ANAVEX ®3-71. ANAVEX®3-71 was previously granted orphan drug designation for the treatment of Frontotemporal Dementia ("FTD") by the FDA. ANAVEX®3-71 is an orally administered small molecule targeting sigma-1 and M1 muscarinic receptors that is designed to be beneficial for neurodegenerative diseases. In preclinical studies, ANAVEX®3-71 demonstrated disease-modifying activity against the major hallmarks of Alzheimer's disease in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, as well as beneficial effects on mitochondrial dysfunction and neuroinflammation.

The Phase 1 clinical trial was a prospective double-blind, randomized, placebo-controlled trial 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's pre-clinical profile, we intend 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.

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.

Our Pipeline

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

Our proprietary SIGMACEPTOR™ Discovery Platform produced small molecule drug candidates with unique modes of action, based on our understanding of sigma receptors. 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 play a role in modulating the cellular response to viral infection and ameliorate pathogenesis.

Compounds that have been subjects of our research include the following:

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 in an oral liquid once-daily formulation for rare diseases such as Rett syndrome as well as an oral once-daily capsule formulation for diseases such as Alzheimer's disease.

In Rett syndrome, administration of ANAVEX ®2-73 in liquid form resulted in both significant and dose-related improvements in an array of behavioral paradigms in the MECP2 HET Rett syndrome disease model. In addition, in a further experiment sponsored by Rettsyndrome.org, ANAVEX ®2-73 was evaluated in automatic visual response and respiration tests in 7-month-old mice, an age at which advanced pathology is evident. Vehicle-treated MECP2 mice demonstrated fewer automatic visual responses than wild-type mice. Treatment with ANAVEX ®2-73 for four weeks significantly increased the automatic visual response in the MECP2 Rett syndrome disease mice. Additionally, chronic oral dosing daily for 6.5 weeks of ANAVEX ®2-73 starting at ~5.5 weeks of age was conducted in the MECP2 HET Rett syndrome disease mouse model assessed the different aspects of muscular coordination, balance, motor learning and muscular strengths, some of the core deficits observed in Rett syndrome. Administration of ANAVEX ®2-73 resulted in both significant and dose related improvements in an array of these behavioral paradigms in the MECP2 HET Rett syndrome disease model.

In May 2016 and June 2016, the FDA granted Orphan Drug Designation to ANAVEX ®2-73 for the treatment of Rett syndrome and infantile spasms, respectively. In November 2019, the FDA granted ANAVEX ®2-73 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.

Further, in February 2020, the FDA 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.

For Parkinson's disease, data demonstrates significant improvements and restoration of function in a disease modifying animal model of Parkinson's disease. Significant improvements were seen on all measures tested: behavioral, histopathological, and neuroinflammatory endpoints. 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, to study the effect of the compound on both the cognitive and motor impairment of Parkinson's disease. The Phase 2 trial enrolled approximately 132 patients for 14 weeks, randomized 1:1:1 to two different ANAVEX®2-73 doses, 30mg and 50mg, 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 50mg once daily. The results showed clinically meaningful, dose-dependent, and statistically significant improvements in the CDR computerized assessment system analysis. We anticipate conducting further clinical trials of ANAVEX®2-73 in Parkinson's disease dementia after submitting the results of the trial to the FDA to obtain regulatory guidance.

In Alzheimer's disease animal models, ANAVEX ®2-73 has shown pharmacological, histological and behavioral evidence as a potential neuroprotective, anti-amnesic, anti-convulsive and anti-depressive therapeutic agent, due to its potent affinity to SIGMAR1 and moderate affinities to M1-4 type muscarinic receptors. In addition, ANAVEX®2-73 has shown a potential dual mechanism which may impact amyloid, tau pathology and inflammation. In a transgenic Alzheimer's disease animal model Tg2576, ANAVEX ®2-73 induced a statistically significant neuroprotective effect against the development of oxidative stress in the mouse brain, as well as significantly increased the expression of functional and synaptic plasticity markers that is apparently amyloid-beta independent. It also statistically alleviated the learning and memory deficits developed over time in the animals, regardless of sex, both in terms of spatial working memory and long-term spatial reference memory.

Based on the results of pre-clinical testing, we initiated and completed a Phase 1 single ascending dose (SAD) clinical trial of ANAVEX ®2-73. In this Phase 1 SAD trial, the maximum tolerated single dose was defined per protocol as 55-60 mg. This dose is above the equivalent dose shown to have positive effects in mouse models of Alzheimer's disease. There were no significant changes in laboratory or ECG parameters. ANAVEX ®2-73 was well tolerated below the 55-60 mg dose with only mild adverse events in some subjects. Observed adverse events at doses above the maximum tolerated single dose included headache and dizziness, which were moderate in severity and reversible. These side effects are often seen with drugs that target CNS conditions, including Alzheimer's disease.

In November 2016, we completed a Phase 2a clinical trial for ANAVEX ®2-73, for the treatment of Alzheimer's disease. The open-label randomized trial was designed to assess the safety and exploratory efficacy of ANAVEX®2-73 in 32 patients with mild-to-moderate Alzheimer's disease. The Phase 2a trial met both primary and secondary objectives of the trial.

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. On July 2, 2018, the Human Research Ethics Committee in Australia approved the initiation of our Phase 2b/3, double-blind, randomized, placebo-controlled 48-week safety and efficacy trial of ANAVEX®2-73 for the treatment of early Alzheimer's disease. Clinical trial sites in Canada, the United Kingdom, the Netherlands and Germany were also added. This Phase 2b/3 trial design incorporates inclusion of genomic precision medicine biomarkers identified in the ANAVEX®2-73 Phase 2a trial.

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, more recently, 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 ("OL's") and oligodendrocyte precursor cells ("OPC's"), 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®3-71

ANAVEX®3-71 is a 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 in very small doses 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. In April 2016, the FDA 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 Phase 1 clinical trial of ANAVEX ®3-71. The trial took place in Australia and was a double-blind, randomized, placebo-controlled, Phase 1 trial to evaluate safety and tolerability, and PK of oral escalating doses of ANAVEX®3-71 including effects of food and gender in healthy volunteers. The trial met its primary and secondary endpoints of safety, respectively, with no serious adverse events (SAEs) or dose-limiting toxicities observed, as more fully described above under *Clinical Trials Overview – Schizophrenia, Frontotemporal Dementia and Alzheimer's disease* .

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. We believe the results of this clinical trial and preclinical study could serve as a basis for advancing into respective registration trials in the U.S.

The first of these trials, the ANAVEX ®3-71-SZ-001 clinical trial, commenced in March 2024 and is more fully described above under *Clinical Trials Overview – Schizophrenia.*

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 SIGMAR1 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 2023, an estimated 6.7 million Americans aged 65 and older suffered from Alzheimer's disease. 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 a 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 30% of people do not respond to therapy, with an additional 50% experiencing only a partial improvement in symptoms or unacceptable side effects, according to the World Health Organization.

- 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 1:6,000-8,000 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-five (25) U.S. patents, twenty-four U.S. patent applications, and various PCT or 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 directed to a novel and 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 one 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 four issued U.S. patents each with claims directed to crystalline forms of ANAVEX®2-73. The first of these four 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 four 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 four 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 fourth of these four patents claims method of making certain crystalline forms ANAVEX®2-73. This patent is expected to expire in October 2036, 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 one issued U.S. patent with claims directed to methods of treating cardiac dysfunction with ANAVEX®2-73. This patent is expected to expire in July 2038, absent any patent term extension for regulatory delays. Additionally, we own two issued U.S. patent for the treatment of insomnia, anxiety, or agitation. The first of the two 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 of the two patents claims a dosage form comprising any of, or any combination of ANAVEX®2-73, ANAVEX®19-144, and/or ANAVEX®1-41. This patent is expected to expire in July 2038, 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 (-) 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 two patents claims methods for treating or preventing pain using (+) ANAVEX®1066 isomer. The second patent claims methods for treating or preventing pain using (-) ANAVEX ®1066 isomer. The third patent claims dosage forms and pharmaceutical compositions comprising (+) 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 November 27, 2023.

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 stock-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 stock-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, 2024 and 2023

Operating Expenses

Total operating expenses for the quarter ended March 31, 2024 were $12.5 million, compared to $14.2 million for the comparable quarter ended March 31, 2023. Total operating expenses for the six-month period ended March 31, 2024 were $23.8 million, compared to $29.6 million for the comparable six month period ended March 31, 2023.

Our research and development expenses for the three months ended March 31, 2024 were $9.7 million, as compared to $11.3 million for the three months ended March 31 2023. Our research and development expenses for the six months ended March 31, 2024 were $18.4 million, as compared to $23.4 million for the comparable six month period ended March 31 2023.

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

(i) a decrease in stock-based compensation expense of $1.0 million in the three-month period and $3.3 million in the six-month period, as a result of the vesting of previous option awards and the extended timeline of milestone based vesting awards.

(ii) a decrease of approximately $1.3 million in the three-month period and $2.1 million in the six-month period in expenditures over the comparable periods relating to our Rett syndrome program as a result of the completion of the EXCELLENCE trial and the respective extension trial under the AVATAR trial.

(iii) a decrease of approximately $1.1 million in the six-month period in expenditures over the comparable period relating to our Alzheimer's program as a result of the completion of the Phase 2b/3 clinical trial in the comparable period.

These decreases were partially offset by an increase of $0.5 million in both the three- and six-month periods relating to expenditures on the ANAVEX ®3-71-SZ-001 clinical trial, which trial commenced in the current period.

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

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023

Cost of external service providers	$ 5,167	$ 6,165	$ 9,732	$ 12,219
Personnel costs	2,862	2,407	5,610	4,788
Stock-based compensation	1,673	2,713	3,033	6,317
Other common costs	27	22	38	49
Total research and development costs	$ 9,729	$ 11,307	$ 18,413	$ 23,373

During the three- and six-months ended March 31, 2024 and 2023, external service providers cost by product candidate was as follows (in thousands):

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
ANAVEX®2-73	$ 4,180	$ 5,510	$ 7,991	$ 10,750
ANAVEX®3-71	856	528	1,453	1,240
All other product candidates	61	3	66	3
Other external service provider costs	70	124	222	226
Total external service provider costs	$ 5,167	$ 6,165	$ 9,732	$ 12,219

General and administrative expenses were $2.8 million for the three months ended March 31, 2024, as compared to $2.9 million for the same quarter of fiscal 2023. General and administrative expenses were $5.4 million for the six months ended March 31, 2024, as compared to $6.2 million for the same period of fiscal 2023.The primary reason for the decrease in general and administrative expenses was a reduction in stock-based compensation charges of $0.3 million for the three month period and $1.1 million for the six month period, as a result of the vesting of previous option awards and the extended timeline of milestone based vesting awards.

We expect to see our research and development expenditures increase from current levels as we advance our clinical programs, including ongoing extension trials of our Alzheimer's and Rett syndrome programs, advancement of ANAVEX®3-71 trial in Schizophrenia, planned advancement of ANAVEX®2-73 for Parkinson's disease, planned initiation of an ANAVEX®2-73 for a Fragile X clinical trial, and as we continue to add additional staffing to manage and support these clinical initiatives.

Other income (net)

The net amount of other income for the three months ended March 31, 2024 was $2.1 million as compared to $1.1 million for the comparable three months ended March 31, 2023. The net amount of other income for the six months ended March 31, 2024 was $4.8 million as compared to $3.5 million for the comparable six month period ended March 31, 2023. The increase in other income for the quarter is primarily related to a one-time financing charge of $0.9 million recognized in the comparable three- and six-month periods associated with entering into the 2023 Purchase Agreement (as described below).

Net loss

Net loss for the three months ended March 31, 2024, was $10.5 million, or $0.13 per share, as compared to $13.1 million, or $0.17 per share in the comparative quarter of fiscal 2023. The net loss for the six months ended March 31, 2024 was $19.2 million, or $0.23 per share, as compared to $26.1 million, or $0.33 per share in the comparative six month period. The decrease in net loss for the quarter is primarily related to a decrease in research and development expenditures and an increase in other income, as discussed above.

Liquidity and Capital Resources

Working Capital (in thousands)

	March 31, 2024	September 30, 2023
Current Assets	$ 144,516	$ 154,386
Current Liabilities	9,558	12,534
Working Capital	$ 134,958	$ 141,852

At March 31, 2024, we had net current assets of $144.5 million, a decrease of $10.0 million from September 30, 2023. The decrease in net current assets primarily relates to a decrease in cash and cash equivalents of $11.6 million due to cash utilized in operations, partially offset by $7.2 million in cash generated under the 2023 Purchase Agreement. Over the period, our net working capital position decreased by $6.9 million to $135.0 million.

During the first six months of fiscal 2024, we utilized cash and cash equivalents of $19.0 million to fund our operations, compared to $14.3 million during the same period of fiscal 2023. Our cash position was $139.4 million at March 31, 2024 compared to $151.0 million at our fiscal year ended September 30, 2023.

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, 2024 and 2023 (in thousands):

	2023	2023
Net cash flows used in operating activities	$ (18,974)	$ (14,283)
Net cash flows from financing activities	7,336	18,592
Increase/ (decrease) in cash and cash equivalents	$ (11,638)	$ 4,309

Cash flow used in operating activities

Net cash used in operating activities for the six months ended March 31, 2024 was $19.0 million, compared to $14.3 million during the comparable period ended March 31, 2023. The principal reason for this increase in net cash used in operating activities in the current period is due to a net decrease (pay down) of $3.0 million in accounts payable and accrued liabilities during the six-month period ended March 31, 2024, as compared to a net increase of $3.3 million in accounts payable and accrued liabilities in the comparable six-month period.

Cash flow provided by financing activities

Cash provided by financing activities for the six-month period ended March 31, 2024 was $7.3 million, compared to $18.6 million during the comparable six-month period ended March 31, 2023. Cash provided by financing activities in both periods is 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 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-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. During the six-month period ended March 31, 2023, the Company issued to Lincoln Park an aggregate of 2,159,080 shares of Common Stock under the 2023 Purchase Agreement, including 2,075,000 shares of Common Stock for an aggregate purchase price of $18,152,000, 9,080 commitment shares as well as the 75,000 initial commitment shares.

At March 31, 2024, an amount of $114.7 million remained available under the 2023 Purchase Agreement.

Controlled Equity Offering Sales Agreement

On May 1, 2020, we entered into an Amended and Restated Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and SVB Leerink LLC (the "Sales Agents"), pursuant to which we may offer and sell shares of Common Stock registered under an effective registration statement from time to time through the Sales Agents (the "At-the-Market Offering").

Upon delivery of a placement notice based on our instructions and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell shares of Common Stock by methods deemed to be an "at the market offering", in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including negotiated transactions, subject to our prior written consent. We are not obligated to make any sales of shares under the Sales Agreement. We or the Sales Agents may suspend or terminate the At-the-Market Offering upon notice to the other party, subject to certain conditions. The Sales Agents will act as agents on a commercially reasonable efforts basis consistent with their normal trading and sales practices, applicable state and federal law, and rules and regulations and the rules of Nasdaq.

We have agreed to pay the Sales Agents' commissions for their services of 3.0% of the gross proceeds from the sale of shares of Common Stock pursuant to the Sales Agreement. We have also agreed to provide the Sales Agents with customary indemnification and contribution rights.

No shares were sold during the six months ended March 31, 2024 and 2023 under the Sales Agreement. The Company currently is unable to sell shares of Common Stock under the Sales 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, 2023, as filed with the SEC on November 27, 2023.

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.

There have been no material changes in our exposure to market risk from that disclosed in Item 7A of our Annual Report on Form 10-K for the year ended September 30, 2023.

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, 2024.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2024, 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

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 complaint is captioned Blum v. Anavex Life Sciences, Corp. et al., case number 1:24-cv-01910, and names the Company and Christopher Missling as Defendants. The complaint alleges violations of the Securities and Exchange Act of 1934 resulting from disclosures and statements made about certain clinical trials for ANAVEX®2-73. The Company believes the complaint is without merit. The Company is vigorously pursuing its defenses and a potential dismissal of all claims asserted in the lawsuit.

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, 2023, filed with the SEC on November 27, 2023.

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

During the quarter ended March 31, 2024, no director or Section 16 officer adopted , modified, or terminated any “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).

ITEM 6. EXHIBITS

Exhibit Number	Description
(3)	**Articles of Incorporation and Bylaws**
3.1	Articles of Incorporation (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	Bylaws (incorporated by reference 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 9, 2024

/s/Sandra Boenisch

Sandra Boenisch, CPA, CGA
Principal Financial Officer
(Principal Financial and Accounting Officer)
Date: May 9, 2024

Exhibit 31.1

CERTIFICATION

I, Christopher Missling, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended March 31, 2024 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 9, 2024

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

Exhibit 31.2

CERTIFICATION

I, Sandra Boenisch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the three months ended March 31, 2024 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 9, 2024

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

Exhibit 32.1

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

In connection with the Quarterly Report of Anavex Life Sciences Corp. (the "Company") on Form 10-Q for the three months ended March 31, 2024 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 9, 2024

/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.