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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2024

OR

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

COMMISSION FILE NUMBER 001-39202

Annovis Bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**26-2540421**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

101 Lindenwood Drive, Suite 225
Malvern, PA 19355
(Address of registrant's principal executive offices)

(484) 875-3192
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 $0.0001 per share	ANVS	New York Stock Exchange

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.

The number of outstanding shares of the registrant's common stock as of August 9, 2024 was: 13,054,018

ANNOVIS BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2024

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements

Annovis Bio, Inc.
Balance Sheets
(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,997,767	$ 5,754,720
Prepaid expenses and other current assets	1,048,688	4,453,544
Total assets	$ 5,046,455	$ 10,208,264
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,394,657	$ 1,292,837
Accrued expenses	662,682	2,986,273
Total current liabilities	4,057,339	4,279,110
Non-current liabilities:		
Warrant liability	2,235,000	13,680,000
Derivative liability	505,000	—
Total liabilities	6,797,339	17,959,110
Commitments and contingencies (Note 6)		
Stockholders' (deficit):		
Preferred stock - $0.0001 par value, 2,000,000 shares authorized and 0 shares issued and outstanding	—	—
Common stock - $0.0001 par value, 70,000,000 and 70,000,000 shares authorized and 11,721,480 and 10,519,933 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1,172	1,052
Additional paid-in capital	114,594,390	102,507,189
Accumulated deficit	(116,346,446)	(110,259,087)
Total stockholders' (deficit)	(1,750,884)	(7,750,846)
Total liabilities and stockholders' deficit	$ 5,046,455	$ 10,208,264

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 5,785,217	$ 8,262,167	$ 12,307,308	$ 16,048,223
General and administrative	1,977,421	1,497,533	3,265,137	3,681,193
Total operating expenses	7,762,638	9,759,700	15,572,445	19,729,416
Operating loss	(7,762,638)	(9,759,700)	(15,572,445)	(19,729,416)
Other income (expense):				
Interest income	25,978	222,578	70,146	455,113
Other financing costs (Note 7)	(1,346,060)	—	(1,346,060)	—
Change in fair value of warrants (Note 7)	4,062,308	—	10,761,000	—
Total other income, net	2,742,226	222,578	9,485,086	455,113
Loss before income taxes	(5,020,412)	(9,537,122)	(6,087,359)	(19,274,303)
Income taxes	—	—	—	—
Net loss	$ (5,020,412)	$ (9,537,122)	$ (6,087,359)	$ (19,274,303)
Net loss per share (Note 9)				
Basic	$ (0.44)	$ (1.07)	$ (0.56)	$ (2.25)
Diluted	$ (0.44)	$ (1.07)	$ (1.52)	$ (2.25)
Weighted-average number of common shares used in computing net loss per share				
Basic	11,307,759	8,951,309	10,966,412	8,575,239
Diluted	11,307,759	8,951,309	11,066,265	8,575,239

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Changes in Stockholders' (Deficit) Equity
(Unaudited)

	Common Stock		Additional Paid-In Capital	Total Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Three and Six Months Ended June 30, 2024					
Balance, December 31, 2023	10,519,933	$ 1,052	$ 102,507,189	$ (110,259,087)	$ (7,750,846)
Exercise of common stock warrants, inclusive of warrant reduction	60,000	6	1,223,994	—	1,224,000
Issuance of common stock under registered direct offering, net of issuance costs	431,366	43	3,874,957	—	3,875,000
Stock-based compensation expense	—	—	364,765	—	364,765
Net loss	—	—	—	(1,066,947)	(1,066,947)
Balance, March 31, 2024	11,011,299	$ 1,101	$ 107,970,905	$ (111,326,034)	$ (3,354,028)
Issuance of common stock under ELOC, net of issuance costs	710,181	71	5,026,973	—	5,027,044
Stock-based compensation expense	—	—	1,596,512	—	1,596,512
Net loss	—	—	—	(5,020,412)	(5,020,412)
Balance, June 30, 2024	11,721,480	$ 1,172	$ 114,594,390	$ (116,346,446)	$ (1,750,884)
Three and Six Months Ended June 30, 2023					
Balance, December 31, 2022	8,163,923	$ 816	$ 82,377,488	$ (54,054,774)	$ 28,323,530
Exercise of stock options	52,755	6	7,380	—	7,386
Stock-based compensation expense	—	—	1,542,338	—	1,542,338
Net loss	—	—	—	(9,737,181)	(9,737,181)
Balance, March 31, 2023	8,216,678	$ 822	$ 83,927,206	$ (63,791,955)	$ 20,136,073
Issuance of common stock, net of issuance costs	788,453	79	8,571,112	—	8,571,191
Exercise of stock options	7,142	1	999	—	1,000
Stock-based compensation expense	—	—	1,571,493	—	1,571,493
Net loss	—	—	—	(9,537,122)	(9,537,122)
Balance, June 30, 2023	9,012,273	$ 902	$ 94,070,810	$ (73,329,077)	$ 20,742,635

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (6,087,359)	$ (19,274,303)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,961,277	3,113,831
Change in fair value of warrants	(10,761,000)	—
Non-cash other financing costs	1,296,060	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,404,856	552,521
Accounts payable	2,101,820	(2,788,377)
Accrued expenses	(2,323,591)	(2,836,313)
Net cash used in operating activities	(10,407,937)	(21,232,641)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	8,110,984	8,571,191
Proceeds from exercise of warrants	540,000	—
Proceeds from exercise of stock options	—	8,386
Net cash provided by financing activities	8,650,984	8,579,577
Net decrease in cash and cash equivalents	(1,756,953)	(12,653,064)
Cash and cash equivalents, beginning of period	5,754,720	28,377,693
Cash and cash equivalents, end of period	$ 3,997,767	$ 15,724,629
Supplemental disclosure of cash flow information:		
Reduction in value of warrants related to exercises	$ 684,000	$ —
Cash paid for financing costs	$ 50,000	$ —

See accompanying notes to financial statements.

Annovis Bio, Inc.
Notes to Financial Statements
(Unaudited)

(1) Nature of Business, Going Concern and Management's Plan

Annovis Bio, Inc. (the "Company" or "Annovis") was incorporated on April 29, 2008, under the laws of the State of Delaware. Annovis is a clinical-stage drug platform company addressing neurodegeneration, such as Alzheimer's disease ("AD") and Parkinson's disease ("PD"). The toxic cascade in neurodegeneration begins with high levels of neurotoxic proteins, which lead to impaired axonal transport, inflammation, death of nerve cells and loss of cognition and motor function. The Company's lead product candidate, Buntanetap, is a small molecule administered orally that is designed to attack neurodegeneration by entering the brain and inhibiting the translation of multiple neurotoxic proteins, thereby impeding the toxic cascade. High levels of neurotoxic proteins lead to impaired axonal transport, which is responsible for the communication between and within nerve cells. When that communication is impaired, the immune system is activated and attacks the nerve cells, eventually killing them. The Company has shown in its clinical and pre-clinical studies that Buntanetap lowered neurotoxic protein levels, leading to improved axonal transport, reduced inflammation, lower nerve cell death and improved function.

Going Concern

Since its founding, the Company has been engaged in organizational activities, including raising capital, as well as research and development activities. The Company has not generated substantial revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. The Company is subject to those risks associated with any clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital.

The Company has a history of incurring net losses and anticipates incurring additional losses until such time, if ever, that it can generate significant revenue from its product candidates currently in development. The Company's primary source of capital has historically been the issuance of common stock and warrants to purchase common stock.

Since the Company's inception, the Company has incurred losses and negative cash flows from operations. At June 30, 2024, the Company had cash and cash equivalents of $4.0 million and an accumulated deficit of $116.3 million. The Company's net loss was $6.1 million and $19.3 million for the six months ended June 30, 2024 and 2023, respectively. In addition, the Company's operating loss was $15.6 million and $19.7 million for the six months ended June 30, 2024 and 2023, respectively. The Company follows the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 205-40, Presentation of Financial Statements-Going Concern, or ASC 205-40, which requires Management to assess the Company's ability to continue as a going concern for one year after the date its financial statements are issued. The Company expects that its existing balance of cash and cash equivalents as of June 30, 2024 is not sufficient to fund operations for the period through one year after the date of this filing and therefore Management has concluded that substantial doubt exists about the Company's ability to continue as a going concern. Management's plans to mitigate this risk include raising additional capital through equity financings, debt or other potential alternatives. Management's plans may also include the deferral of certain operating expenses unless and until additional capital is received. However, there can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company, or that the Company will be successful in deferring certain operating expenses. As such, Management concluded that such plans do not alleviate the aforementioned substantial doubt. If the Company is unable to raise sufficient additional capital or defer sufficient operating expenses, the Company may be compelled to reduce the scope of its operations.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation of Interim Unaudited Financial Statements

The accompanying interim financial statements of Annovis Bio, Inc. should be read in conjunction with the audited financial statements and notes thereto included in the Company's 2023 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 29, 2024. The interim financial statements included herein are unaudited. In the opinion of Management, these statements include all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of the financial position of Annovis at June 30, 2024, its results of operations for the three and six months ended June 30, 2024 and 2023 and its cash flows for the six months ended June 30, 2024 and 2023. These interim results of operations are not necessarily indicative of the results to be expected for a full year or any future period. The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and the rules and regulations of the SEC. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations relating to interim financial statements.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires Management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates.

Significant items subject to such estimates and assumptions include the accounting and fair value of equity instruments, common stock warrant liabilities, derivative liabilities, as well as accounting for research and development contracts, including clinical trial accruals. Future events and their effects cannot be predicted with certainty; accordingly, accounting estimates require the exercise of judgment. Accounting estimates used in the preparation of these financial statements change as new events occur, as more experience is acquired, as additional information is obtained and as the operating environment changes.

(c) Basic and Diluted Net Loss per Share

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants and stock options, which would result in the issuance of incremental shares of common stock. The computation of diluted net loss per shares does not include the conversion of securities that would have an anti-dilutive effect.

(d) Cash and Cash Equivalents

The Company considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. The Company has cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds, could have a significant adverse effect on the Company's financial condition, results of operations and cash flows.

(e) Issuance Costs Associated with Equity Issuances

Issuance costs incurred in connection with the Company's equity issuances, which primarily consist of direct incremental legal, printing, listing and accounting fees, are offset against proceeds received in the issuances and charged to additional paid-in capital in the period the equity issuance is completed. Issuance costs related to the Equity Line of Credit ("ELOC") Purchase Agreement are expensed as incurred as prescribed by ASC 815.

(f) Derivative Liability

The Company evaluates all features contained in financing agreements to determine if there are any embedded derivatives that require separate accounting from the underlying agreement under ASC 815 – *Derivatives and Hedging*. An embedded derivative that requires separation is accounted for as a separate liability or asset from the host agreement. The separated embedded derivative is accounted for at fair market value, with changes in fair value recognized in the statements of operations within the other financing costs line item. The Company determined that certain features under the ELOC Purchase Agreement (See Note 7 — Stockholders' (Deficit) Equity) collectively qualified as an embedded derivative. The derivative was accounted for separately from the underlying ELOC Purchase Agreement and is accounted for at fair value.

(g) Common Stock Warrants

On October 31, 2023, the Company completed an underwritten offering whereby the Company sold (i) 1,250,000 shares of common stock and (ii) warrants to purchase an aggregate of 1,250,000 shares of common stock at an exercise price of $9.00 per share ("Canaccord Warrants"). The warrants are liability classified as they contain certain cash settlement adjustment features that are outside of the Company's control or not deemed to be indexed to the Company's stock. The warrant liabilities are recorded at fair value regardless of the timing of the redemption feature, the redemption price, or the likelihood of redemption. These warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of change in fair value of warrant liability in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise, expiration, or other settlement of the warrants. The warrants are classified as Level 3 liabilities.

(h) Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under FASB ASC Topic 820, "Fair Value Measurements," equals or approximates the carrying amounts represented in the balance sheets, primarily due to their short-term nature, except for the derivative liabilities and warrant liabilities (see Note 3).

(i) Research and Development

Research and development costs are either expensed as incurred or recorded separately as a prepaid asset, and the expense recognized when the service is performed and are primarily comprised of personnel-related expenses and external research and development expenses incurred under arrangements with third parties, such as contract research organizations and consultants. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record net prepaid or accrued expenses related to these costs. Prepaid clinical expenses represent valid future economic benefits based on the Company's contracts with its vendors and are realized in the ordinary course of business.

(j) Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). The Company has issued stock-based compensation awards including stock options. ASC 718 requires all stock-based payments, including grants of stock options, to be recognized

in the financial statements based on their grant date fair values. The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options granted. The Company recognizes forfeitures as they occur.

Expense related to stock-based compensation awards granted with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Stock options have a contractual term of 10 years. Expense for stock-based compensation awards with performance-based vesting conditions is only recognized when the performance-based vesting condition is deemed probable to occur. Expense related to stock-based compensation awards are recorded to research and development expense or general and administrative expense based on the underlying function of the individual that was granted the stock-based compensation award.

Estimating the fair value of stock options requires the input of subjective assumptions, including the expected term of the stock option, stock price volatility, the risk-free interest rate, and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model represent Management's best estimates and involve a number of variables, uncertainties, assumptions, and the application of Management's judgment, as they are inherently subjective. If any assumptions change, the Company's stock-based compensation expense could be materially different in the future.

The assumptions used in the Company's Black-Scholes option-pricing model for stock options are as follows:

Expected Term. As Annovis does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term, the expected term of employee stock options subject to service-based vesting conditions is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin No. 107, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the stock option.

Expected Volatility. The expected volatility is based on historical volatilities of Annovis and similar entities within the Company's industry for periods commensurate with the assumed expected term.

Risk-Free Interest Rate. The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

Expected Dividends. The expected dividend yield is 0% because Annovis has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

(k) Income Taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of June 30, 2024 and December 31, 2023, the Company had a full valuation allowance against its deferred tax assets.

The Company is subject to the provisions of ASC 740, Income Taxes, which prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. There are currently no open federal or state tax audits. The Company has not recorded any liability for uncertain tax positions at June 30, 2024 or December 31, 2023.

(l) Recent Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which improves income tax disclosures by requiring: (1) consistent categories and

greater disaggregation of information in the rate reconciliation, and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. The ASU indicates that all entities will apply the guidance prospectively with an option for retroactive application to each period presented in the financial statements. The Company has not yet determined the full impact ASU 2023-09 may have on its financial statement disclosures, but does not expect any material impact.

(3) Fair Value Measurements

The Company measures certain assets and liabilities at fair value in accordance with ASC 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy that serves to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

Level 3—Valuations based on unobservable inputs and models that are supported by little or no market activity.

The following table provides the carrying value and fair value of certain financial assets and liabilities of the Company measured at fair value on a recurring basis as of June 30, 2024 and December 31, 2023:

		Fair Value Measurement at June 30, 2024		
	Carrying Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 479,068	$ 479,068	$ —	$ —
Total assets measured and recorded at fair value	$ 479,068	$ 479,068	$ —	$ —
Liabilities:				
Derivative liability	$ 505,000	$ —	$ —	$ 505,000
Warrant liability	2,235,000	—	—	2,235,000
Total liabilities measured and recorded at fair value	$ 2,740,000	$ —	$ —	$ 2,740,000

		Fair Value Measurement at December 31, 2023		
	Carrying Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 5,136,677	$ 5,136,677	$ —	$ —
Total assets measured and recorded at fair value	$ 5,136,677	$ 5,136,677	$ —	$ —
Liabilities:				
Warrant liability	$ 13,680,000	$ —	$ —	$ 13,680,000
Total liabilities measured and recorded at fair value	$ 13,680,000	$ —	$ —	$ 13,680,000

The Company did not transfer any financial instruments into or out of Level 3 classification, during the three or six months ended June 30, 2024 and 2023.

(a) Canaccord Warrants

The common stock warrants issued in connection with the Company's equity raise in November 2023 ("Canaccord Warrants") were classified as liabilities at the time of issuance due to certain cash settlement adjustment features that are outside of the Company's control or not deemed to be indexed to the Company's stock. The Canaccord Warrant liability is remeasured each reporting period with the change in fair value recorded to other income (expense) in the statements of operations until the warrants are exercised, expired, reclassified, or otherwise settled. The fair value of the warrant liability is estimated using a Monte Carlo simulation model.

The estimated fair value of the Canaccord Warrants is determined using Level 3 inputs. Inherent in a Monte Carlo simulation model with the volatility calculated by back solving in a Monte Carlo simulation are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and other inputs. The Company estimates the volatility of its warrants based on implied volatility from the Company's traded warrants. The risk-free interest rate is based on the market yield of U.S. Treasuries over a term commensurate with the remaining term to expiration. Any changes in these assumptions can change the associated valuation significantly.

The following table provides quantitative information regarding Level 3 fair value measurements inputs as of their measurement dates:

	June 30, 2024	December 31, 2023
Exercise price	$ 9.00	$ 9.00
Closing stock price	$ 5.76	$ 18.70
Number of warrants	1,140,000	1,200,000
Phase 3 data probability of success	60 %	60 %
Volatility	70 %	55 %
Term (time to expiration in years)	4.34	4.84
Redemption hurdle price	$ 14.25	$ 14.25
Risk-free rate	4.4 %	3.9 %

The Canaccord Warrants have an exercise price of $9.00 per unit, and are redeemable at the Company's option, in whole or in part, at a redemption price equal to $0.001 per Warrant upon 30 days' prior written notice, at any time after:

- the Company's public announcement of Positive Topline Data (as defined in the Warrant Agreement) from its Phase 3 in patients with Parkinson's Disease; and

- the date on which (a) the closing price of the Company's common stock on the principal exchange or trading facility on which it is then traded has equaled or exceeded $14.25 and (b) the average daily trading value ("ADTV") of the Company's common stock is equal to or exceeds $2,000,000, for two consecutive Trading Days.

The common stock warrants are exercisable immediately and unless otherwise redeemed (as outlined above) by the Company, will expire on November 2, 2028, five years from the date of issuance. See Note 7 – Stockholders' (Deficit) Equity for additional background.

(b) ELOC Purchase Agreement

The Company entered into a Common Stock Purchase Agreement (the "ELOC Purchase Agreement") on April 25, 2024 with an Equity Line investor ("ELOC Purchaser"). Due to certain pricing and settlement provisions, the ELOC Purchase Agreement qualifies as a standby equity purchase agreement and includes an embedded put option. The put option derivative liability ("ELOC derivative liability") is recognized at inception and is accounted for on a fair value basis under the provisions of ASC 815 - *Derivatives and Hedging*. The fair value of the ELOC Purchase Agreement contemplated future purchase decisions based on economic considerations and relevant stock issuance rules/limitations and was initially determined using a Monte Carlo simulation.

The following table provides quantitative information regarding fair value measurements inputs used with respect to the ELOC derivative liability, as of their measurement dates:

	June 30, 2024	April 25, 2024
Closing stock price	$ 5.76	$ 13.60
Volatility	115 %	110 %
Term (time to expiration in years)	2.60	2.80
Risk-free rate	4.5 %	4.8 %

The change in fair value of the ELOC derivative liability was recorded within other financing costs within the statements of operations during the three and six month periods ended June 30, 2024.

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2024	December 31, 2023
Prepaid clinical expenses	$ 728,241	$ 4,391,219
Prepaid other	202,848	23,455
Prepaid insurance	110,104	18,074
Security deposits	7,495	20,796
	$ 1,048,688	$ 4,453,544

(5) Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2024	December 31, 2023
Payroll and related benefits	$ 387,435	$ 96,848
Accrued professional and clinical fees	275,247	2,889,425
	$ 662,682	$ 2,986,273

(6) Commitments and Contingencies

(a) Research & Development

The Company has entered into contracts with contract research organizations ("CROs") and contract manufacturers ("CMOs") related to the Company's clinical trials. These contracts generally require upfront payments, milestone payments, and pass through cost reimbursement, to be made. While the contracts are cancellable with (written) notice, the Company is obligated to make payments for services rendered through the termination date of the project with any applicable CRO/CMO.

(b) Leases

In November 2023, the Company entered into a short-term lease for office space, with an initial term of less than 12 months. Prior to entering into this lease, the Company was leasing its office facilities under a month-to-month short-term lease. Total rental expense, inclusive of both leases was $24,238 and $17,712 for the three months ended June 30, 2024 and 2023, respectively and $58,113 and $35,273 for the six months ended June 30, 2024 and 2023, respectively.

(c) Employment Agreements

The Company has agreements with its executive officers that provide for severance payments to the employee upon termination of the agreement by the Company for any reason other than for cause, death, or disability or by the employee for good reason. The maximum aggregate severance payments under the agreements were estimated to be $1,114,104 at June 30, 2024.

(d) Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows.

(7) Stockholders' (Deficit) Equity

(a) Overview

The Company's Amended and Restated Certificate of Incorporation was adopted on January 31, 2020, in conjunction with the closing of the Company's initial public offering (the "IPO") and amended on June 15, 2023 to increase the authorized number of shares. Currently, there are two classes of stock authorized which are designated, respectively, common stock and preferred stock. The total number of shares which the Company is authorized to issue is 72,000,000, each with a par value of $0.0001 per share. Of these shares, 70,000,000 is designated as common stock and 2,000,000 is preferred stock.

(b) Common Stock

Dividends

Subject to the rights of holders of all classes of Company stock outstanding having rights that are senior to or equivalent to holders of common stock, the holders of the common stock are entitled to receive dividends when and as declared by the Board.

Liquidation

Subject to the rights of holders of all classes of stock outstanding having rights that are senior to or equivalent to holders of common stock as to liquidation, upon the liquidation, dissolution or winding up of the Company, the assets of the Company will be distributed to the holders of common stock.

Voting

The holders of common stock are entitled to one vote for each share of common stock held. There is no cumulative voting.

(c) Preferred Stock

Preferred stock may be issued from time to time by the Board in one or more series. There was no preferred stock issued or outstanding as of June 30, 2024 or December 31, 2023.

(d) IPO Warrants

In conjunction with the closing of the Company's Initial Public Offering ("IPO"), the Company granted its underwriters 100,000 warrants to purchase shares of Company common stock ("IPO Warrants") at an exercise price of $7.50 per share, which was 125% of the IPO price. The IPO Warrants have a five-year term and were exercisable as of January 29, 2021 and have been classified by the Company as a component of stockholders' equity. As of June 30, 2024 and December 31, 2023, 2,400 of the IPO Warrants were outstanding. No IPO Warrants were exercised during the three or six months ended June 30, 2024 or 2023.

(e) November 2023 Equity Offering and Warrant Issuance

On October 31, 2023, the Company entered into an underwritten offering with a Canaccord Genuity LLC whereby the Company sold (i) 1,250,000 shares of common stock and (ii) warrants ("Canaccord Warrants") to purchase an aggregate of 1,250,000 shares of common stock at an exercise price of $9.00 per share. The warrants are exercisable immediately on the date of issuance and will expire five years after the date of issuance. The Company received $6.83 million in net cash proceeds after deducting underwriter discount and fees, as well as other third-party costs. The Canaccord Warrants are liability classified as they contain certain cash settlement adjustment features that are outside of the Company's control or not deemed to be indexed to the Company's stock.

The following is a roll-forward of the Common Stock Warrant Liability from December 31, 2023 to June 30, 2024:

Warrant liability at December 31, 2023	13,680,000
Exercise of 60,000 warrants – January 2, 2024	(684,000)
Change in fair value of warrant liabilities	(6,698,692)
Warrant liability at March 31, 2024	6,297,308
Change in fair value of warrant liabilities	(4,062,308)
Warrant liability at June 30, 2024	2,235,000

(f) Warrant Summary

As of June 30, 2024, the Company had the following common stock warrants outstanding:

	Classification	Outstanding December 31, 2023	Granted	Exercised or Expired	Outstanding June 30, 2024	Exercise price per share	Expiration date
IPO Warrants	Equity	2,400	—	—	2,400	$ 7.50	January 29, 2026
Canaccord Warrants	Liability	1,200,000	—	(60,000)	1,140,000	$ 9.00	November 2, 2028

(g) March 15th Registered Direct Offering ("March RDO Round 1")

On March 15, 2024, the Company entered into a Securities Purchase Agreement with an institutional investor. Pursuant to the terms of the purchase agreement, the Company agreed to issue and sell an aggregate of 114,911 shares of Common Stock at $8.92 per share for aggregate gross proceeds of $1,025,000. Net of offering costs, proceeds from this offering were $925,000.

(h) March 21st Registered Direct Offering ("March RDO Round 2")

On March 21, 2024, the Company entered into a Securities Purchase Agreement with an institutional investor. Pursuant to the terms of the purchase agreement, the Company agreed to issue and sell an aggregate of 316,455 shares of Common Stock at $9.48 per share for aggregate gross proceeds of $3,000,000. Net of offering costs, proceeds from this offering were $2,950,000.

(i) ELOC Purchase Agreement

As described in Note 3, on April 25, 2024, the Company entered into an ELOC Purchase Agreement with an ELOC Purchaser, whereby the Company may offer and sell, from time to time at its sole discretion, and whereby the ELOC Purchaser has committed to purchase, up to 2,051,428 shares of shares of the Company's common stock. The term of the agreement runs until the expiration of the Company's active S-3 Registration Statement, if not earlier terminated or exhausted. Due to certain pricing and settlement provisions, the ELOC Purchase Agreement qualifies as a standby equity purchase agreement and includes an embedded put option and embedded forward option. The Company will therefore account for the ELOC Purchase Agreement as a derivative measured at fair value, with changes in the fair value recognized in the statements of operations within other financing costs. The Company initially recognized a derivative liability of $1.7 million related to the purchased put option at inception of the ELOC Purchase Agreement. The Company will expense the difference between the discounted purchase price of the settled forward and the fair value of shares on the date of settlement as a noncash financing issuance cost. The Company recognized $0.3 million of noncash financing costs during the three and six months ended June 30, 2024 related to the discounted purchase price of the settled forward and the underlying fair value of the shares issued.

Upon execution of the ELOC Purchase Agreement, the Company agreed to issue to the ELOC Purchaser 33,937 shares of Common Stock as commitment shares (the "Commitment Shares"). The fair value of the Commitment Shares was $0.5 million, which was expensed within other financing costs in the statements of operations during the three and six month periods ended June 30, 2024. The Company also incurred issuance costs of $50,000, consisting of legal costs incurred in connection with the ELOC Purchase Agreement, which were expensed within other financing costs in the statements of operations during the three and six month periods ended June 30, 2024. The ELOC Purchaser has agreed that during the term of the Purchase Agreement, neither it nor any of its affiliates will engage in any short sales or hedging transactions involving the Company's common stock.

In addition to the commitment shares referenced above, a total of 700,000 shares of the Company's common stock were issued under the ELOC Purchase Agreement during the three months ended June 30, 2024, for net proceeds of $4.2 million.

Under ELOC the Purchase Agreement, on any business day (the "Purchase Date"), if the Company's stock price is greater than or equal to $5.00 per share, the Company may direct the ELOC Purchaser to purchase common stock. The ELOC Purchaser's committed obligation under any single Fixed Purchase shall not exceed the lower of 25,000 shares of Common Stock or $250,000 ("Fixed Purchases").

In addition, the Company may also direct the ELOC Purchaser, on any trading day in which the Company has submitted a Fixed Purchase notice for the maximum amount allowed for such Fixed Purchase, to purchase an additional amount of the Company's common stock (a "VWAP Purchase"). The ELOC Purchaser's committed obligation under any single VWAP Purchase shall not exceed a number of shares of Common Stock equal to the lesser of (i) 300% of the number of Shares directed by the Company to be purchased by the Investor pursuant to the corresponding Fixed Purchase Notice and (ii) 30% of the trading volume in the Company's Common Stock on the NYSE during the applicable VWAP Purchase Period on the applicable VWAP Purchase Date ("VWAP Purchase Maximum Amount").

The Company may also direct the ELOC Purchaser, on any trading day for which a VWAP Purchase has been completed and all of the shares have been placed, to purchase an additional amount of the Company's common stock (an "Additional VWAP Purchase"). The ELOC Purchaser's committed obligation under any single Additional VWAP Purchase shall be the lesser of (i) 300% of the number of Shares directed by the Company to be purchased by the Investor pursuant to the corresponding Fixed Purchase Notice and (ii) a number of Shares equal to (A) the Additional VWAP Purchase Share Percentage multiplied by (B) the trading volume of shares of Common Stock traded during the applicable Additional VWAP Purchase Period on the applicable Additional VWAP Purchase Date for such Additional VWAP Purchase ("Additional VWAP Purchase Maximum Amount") and collectively the ("Maximum Amounts"). The applicable pricing structure for each purchase type is outlined below:

The purchase price per share for Fixed Purchases ("Fixed Purchase Price") equals 95% of the lesser of:

- the daily volume weighted average price of the Company's Common Stock on the NYSE for the five (5) Trading Days immediately preceding the applicable Fixed Purchase Date for such Fixed Purchase; and
- the Closing Sale Price of a share of Common Stock on the applicable Fixed Purchase Date for such Fixed Purchase during the full Trading Day on the NYSE on such applicable Purchase Date.

The purchase price per share for VWAP Purchases ("VWAP Purchase Price") equals 95% of the lesser of:

- the Closing Sale Price of the Common Stock on the applicable VWAP Purchase Date; and
- the VWAP during the applicable VWAP Purchase Period.

The purchase price per share for Additional VWAP Purchases ("Additional VWAP Purchase Price") equals 95% of the lesser of:

- the VWAP for the applicable Additional VWAP Purchase Period during the applicable Additional VWAP Purchase Date for such Additional VWAP Purchase; and
- the Closing Sale Price of the Common Stock on such applicable Additional VWAP Purchase Date for such Additional VWAP Purchase Period.

The following is a roll-forward of the ELOC derivative liability from date of execution to June 30, 2024:

Fair value at April 25, 2024	1,697,500
Settlements and changes in fair value of ELOC derivative liability	(1,192,500)
Fair value at June 30, 2024	505,000

(8) Stock-Based Compensation

The Company's 2019 Equity Incentive Plan (the "2019 Plan") became effective on January 31, 2020, succeeding the Company's previous equity incentive plan. No new options may be issued under the previous plan, although shares subject to grants which are cancelled or forfeited will again be available under the 2019 Plan.

Effective June 1, 2021, the 2019 Plan was amended to increase the number of shares authorized to be issued from 1,000,000 to 2,000,000. Effective June 12, 2024, the 2019 Plan was amended to increase the number of shares authorized from 2,000,000 to 3,000,000. As of June 30, 2024, 735,572 shares were available for future grants.

Stock-based compensation expense was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 997,779	$ 644,353	$ 1,233,519	$ 1,413,455
Research and development	598,733	927,140	727,758	1,700,376
	$ 1,596,512	$ 1,571,493	$ 1,961,277	$ 3,113,831

During the three and six months ended June 30, 2024, the Company granted 361,600 stock options to various executives, employees and Board Members.

There were no stock options exercised during the three and six months ended June 30, 2024. Stock options exercised during the three and six months ended June 30, 2023 were 7,142. As of June 30, 2024, there were 2,254,747 options outstanding, of which 1,940,066 were vested and exercisable. As of December 31, 2023, there were 1,954,774 options outstanding, of which 1,600,577 were vested and exercisable.

(9) Net Loss Per Share

The Company analyzes the potential dilutive effect of stock options and warrants under the treasury stock method (as applicable), during periods of income, or during periods in which income is recognized related to changes in fair value of its liability-classified securities.

The following table sets forth the computation of basic and diluted net loss per common share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss per share – Basic:				
Numerator				
Net loss	$ (5,020,412)	$ (9,537,122)	$ (6,087,359)	$ (19,274,303)
Denominator				
Weighted-average common shares outstanding, basic	11,307,759	8,951,309	10,966,412	8,575,239
Basic net loss per common share	$ (0.44)	$ (1.07)	$ (0.56)	$ (2.25)
Net loss per share – Diluted:				
Numerator				
Net loss	$ (5,020,412)	$ (9,537,122)	$ (6,087,359)	$ (19,274,303)
Less: gain from change in fair value applicable to dilutive liability-classified warrants	—	—	(10,761,000)	—
Numerator for diluted net loss per share	$ (5,020,412)	$ (9,537,122)	$ (16,848,359)	$ (19,274,303)
Denominator				
Denominator for basic net loss per share	11,307,759	8,951,309	10,966,412	8,575,239
Plus: incremental shares underlying “in the money” liability-classified warrants outstanding	—	—	99,853	—
Denominator for diluted net loss per share	11,307,759	8,951,309	11,066,265	8,575,239
Diluted net loss per common share	$ (0.44)	$ (1.07)	$ (1.52)	$ (2.25)

Potentially dilutive securities, whose effect would have been antidilutive, were excluded from the computation of diluted earnings per share for each of the three and six months ended June 31, 2024 and 2023. Total antidilutive securities that were excluded from the computation of diluted weighted-average shares outstanding were as follows:

	June 30,	
	2024	2023
Stock options	2,254,747	1,709,150
ELOC shares remaining	1,317,491	—
Warrants	2,400	2,400

(10) Income Taxes

The Company’s income tax benefit (expense) was $0 for the three and six months ended June 30, 2024 and 2023. The Company has recorded a valuation allowance to reduce its net deferred tax asset to an amount that is more likely than not to be realized in future years. Accordingly, the benefit of the net operating loss (“NOL”) that would have been recognized in the three and six months ended June 30, 2024 and 2023 was offset by changes in the valuation allowance.

Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code as well as similar state provisions. The Company has completed financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code or could result in a change in control in the future.

As of June 30, 2024, and December 31, 2023, the Company had not recorded any liability for uncertain tax positions, accrued interest or penalties thereon, and no amounts have been recognized in the Company’s statements of operations.

(11) Subsequent Events

On July 1, 2024 the Company entered into a Consulting Agreement (the "2024 Consulting Agreement"), pursuant to which Mark White, a director of the Company, agreed to serve as a consultant to the Company. Pursuant to the 2024 Consulting Agreement, Mr. White will be paid an hourly consulting rate, payable monthly. Additionally, Mr. White received an award of 20,000 non-qualified stock options. The grant price for the options was $5.27 per share, the closing price on the date of grant. The stock options awarded under the 2024 Consulting Agreement will vest in quarterly increments during the term of his consulting agreement, which terminates on December 31, 2024. Vesting is dependent on Mr. White's continued service over that period.

Between July 2, 2024 and July 9, 2024, 831,667 of the Company's Canaccord warrants were exercised at $9.00 per share. The exercises resulted in gross proceeds of $7.5 million. Warrant commissions payable to Canaccord for these exercises totaled $0.4 million.

Subsequent to June 30, 2024, 300,000 shares of common stock were sold under the ELOC through August 6, 2024, for net proceeds of $2.8 million.

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

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our cash and cash equivalents balance, runway and needs as well as financing plans;
- our business strategies;
- the timing of regulatory submissions;
- our ability to obtain and maintain regulatory approval of our existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain;
- risks relating to the timing and costs of clinical trials and the timing and costs of other expenses;
- risks related to market acceptance of products;
- risks associated with our reliance on third-party organizations;
- our competitive position;
- assumptions regarding the size of the available market, product pricing and timing of commercialization of our product candidates;
- our intellectual property position and our ability to maintain and protect our intellectual property rights;
- our results of operations, financial condition, liquidity, prospects, and growth strategies;
- the industry in which we operate; and
- the trends that may affect the industry or us.

You should refer to Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Those factors are updated, as applicable, in "Factors that May Affect Future Results" below. As a result of the risks, uncertainties and assumptions described above and elsewhere, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the

significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to new information, actual results or changes in our expectations, except as required by law.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with: (i) the interim financial statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our annual financial statements for the 2023 fiscal year, which are included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Company Overview

We are a clinical stage, drug platform company addressing neurodegeneration, such as Alzheimer's disease ("AD") and Parkinson's disease ("PD"). We are developing our lead product candidate, Buntanetap, which is designed to address AD, PD, and potentially other chronic neurodegenerative diseases. Buntanetap is a synthetically produced small molecule, orally administered, brain penetrant compound. In several studies, Buntanetap was observed to inhibit the synthesis of neurotoxic proteins - APP/Aβ ("APP"), tau/phospho-tau ("tau") and α-Synuclein ("αSYN") - that are one of the main causes of neurodegeneration. High levels of neurotoxic proteins lead to impaired axonal transport, which is responsible for the communication between and within nerve cells. When that communication is impaired, the immune system is activated and attacks the nerve cells, eventually killing them. We have observed in our clinical studies in early AD and early PD patients and pre-clinical studies in mice and rats that Buntanetap lowered neurotoxic protein levels leading to improved axonal transport, reduced inflammation, lower nerve cell death and improved affected function.

In 2021, we completed two Phase 1/2 clinical studies: one in 14 early AD patients, and one in 54 early PD patients (together, the "AD/PD Trials"). In the AD/PD Trials, early AD patients were defined as those with a Mini Mental State Examination ("MMSE") score between 19 and 28 and early PD patients as those patients at Hoehn & Yahr stages 1, 2 or 3. MMSE is a brief screening instrument used to assess cognitive function, with total scores ranging from 0 to 30 and a lower score indicating greater disease severity, while the Hoehn & Yahr scale is a medical assessment used to measure staging of the functional disability associated with PD, where a higher stage indicates greater disease severity. In collaboration with the Alzheimer's Disease Cooperative Study ("ADCS"), we also conducted a trial in 16 early AD patients (the "ADCS Trial"). In the ADCS Trial, early AD patients were defined as those patients with an MMSE score between 19 and 28. At the completion of the ADCS Trial, the data showed that Buntanetap is a translational inhibitor in humans just like in animals, and we further observed that there was statistical improvement in cognition in early AD patients, just like in the AD/PD Trials.

All three clinical trials above were double-blind, placebo-controlled studies.

We designed the studies by applying our understanding of the underlying neurodegenerative disease states and measured both target and pathway validation in the spinal fluid of patients to determine whether patients improved following treatment. In addition to meeting their primary endpoints of safety and tolerability and secondary endpoint of pharmacokinetics of Buntanetap, our AD/PD Trials met exploratory endpoints of measures of biomarkers and improvements in cognition in AD patients, and in function in PD patients. We believe that the AD/PD Trials represent the first double-blind placebo-controlled studies that showed improvements in AD patients, as measured by ADAS-Cog, and in PD patients, as measured by UPDRS. Following completion of the AD/PD Trials, we submitted our data to the U.S. Food and Drug Administration ("FDA") and requested direction to further pursue the development of Buntanetap in early PD patients. With the FDA's guidance, we initiated a Phase 3 study in early PD patients in August 2022 (our "Phase 3 PD Study"). In the Phase 3 PD Study, early PD patients were defined as those at Hoehn & Yahr

stages 1, 2 or 3 and OFF times of less than two hours per day. OFF time refers to when PD motor and/or non-motor symptoms occur between medication doses. We also submitted a proposed protocol for the treatment of moderate AD to the FDA, and after receiving permission to proceed, we initiated a Phase 2/3 study in mild to moderate AD patients in February 2023 (our "Phase 2/3 AD Study"). In the Phase 2/3 AD Study, mild to moderate AD patients were defined as those with an MMSE score between 14 and 24.

Our Phase 3 PD Study and Phase 2/3 AD Study each had built in interim analyses.

Our Phase 3 PD Study incorporated an interim analysis at two months, the results of which were disclosed on March 31, 2023. The pre-planned interim analysis was conducted by our data analytics provider based on 132 patients from all cohorts collectively for which baseline and two-month data was available. Based on the results of the interim analysis, we proceeded with the Phase 3 PD Study as planned in accordance with the previously established protocol. The study was completed on December 4, 2023 and we released the topline PD Study efficacy data on July 2, 2024. The data showed that in two subgroups, Buntanetap improved UPDRS 2, 3, 2+3 and total. It also showed that in the whole ITT population Buntanetap stopped the loss of cognition and that in the 12% of patients that already had cognitive issues, Buntanetap improved cognition in a dose-dependent, statistically significant way. We expect to discuss the PD data with the FDA in the fall of 2024. During that meeting we plan to propose continued development of Buntanetap in an 18-month disease-modifying trial.

For the AD Study, we disclosed the results of the interim analysis on October 23, 2023, and similar to our PD study, based on the outcome of the interim analysis we proceeded with the study as planned. The Phase 2/3 AD study was completed on February 13, 2024 and on April 29, 2024, we announced topline efficacy data. The data showed that in early AD patients Buntanetap improved ADAS-Cog11 in a dose-dependent fashion and was statistically significant from placebo and from baseline. We have reported the data to the FDA and asked for an end-of-Phase 2 meeting for AD. We expect to discuss the AD data with the FDA in the fall of 2024. We are also proposing continued development of Buntanetap in an 18-month disease-modifying trial, focused on biomarker-positive early AD patients. We presented the data at AAIC 2024 and further plan to publish it in a peer-reviewed journal.

By the end of 2026, our goal is to have conducted the required pivotal studies for Buntanetap and to be able to file two new drug applications ("NDAs") with the FDA.

We believe that we are the only company developing a drug for AD and PD that inhibits more than one neurotoxic protein and has a mechanism of action designed to restore nerve cell axonal and synaptic activity. By improving brain function, our goal is to treat memory loss and dementia associated with AD, as well as body and brain function associated with PD. Based on pre-clinical and clinical data collected to date, we believe that Buntanetap has the potential to be the first drug to interfere with the underlying mechanism of neurodegeneration, potentially enabling Buntanetap to be the only drug to improve cognition in AD and motor function in PD. The industry has encountered challenges in specifically targeting one neurotoxic protein, be it APP, tau or αSYN, indicating that doing so only modestly or does not change the course of neurodegeneration. Our goal is to develop a disease-modifying drug ("DMD") for patients with neurodegeneration by leveraging our clinical and pre-clinical data to inhibit the four most relevant neurotoxic proteins. Studies have found that AD and PD are the most common neurodegenerative diseases in the U.S. and accordingly, these diseases present two unmet needs of the aging population and two potentially large U.S. markets if a DMD is developed and approved.

Funding Requirements

We have never been profitable and have incurred net losses since inception. Our accumulated deficit at June 30, 2024 was $116,346.4 thousand. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

We do not have sufficient capital on hand to fund our operations for the next 12 months and will need to raise additional capital to meet our obligations as they become due. We believe that our cash and cash equivalents as of June 30, 2024, combined with warrant exercise proceeds from July 2024 and proceeds from share issuances under our ELOC Purchase Agreement (both discussed below), will be sufficient to fund our operating expenses and capital expenditure requirements until we initiate additional FDA approved studies for AD and PD, which we expect to take place after the planned end-of-study meetings, in the second half of 2024. We will need to raise substantial additional capital to complete the development and commercialization of our product candidates through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. However, there can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital or defer sufficient operating expenses, we may be compelled to reduce the scope of our operations.

In order to fund operations and additional clinical trials, we plan to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds other than our ELOC Purchase Agreement, which was announced on April 25, 2024 and is discussed further below. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes the results of our operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 5,785.2	$ 8,262.2	$ (2,477.0)
General and administrative	1,977.4	1,497.5	479.9
Total operating expense	7,762.6	9,759.7	(1,997.1)
Other income (expense):			
Other financing costs	(1,346.1)	—	(1,346.1)
Change in fair value of warrants	4,062.3	—	4,062.3
Interest income	26.0	222.6	(196.6)
Other income (expense), net	2,742.2	222.6	2,519.7
Net loss	$ (5,020.4)	$ (9,537.1)	$ 4,516.7

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2024 were $5,785.2 thousand, compared to $8,262.2 thousand for the three months ended June 30, 2023. The $2,477.0 thousand decrease was primarily attributable to decreased contract research expenditures of $5,310.4 thousand given timing of study costs with respect to our Phase 3 study in early PD patients and Phase 2/3 in AD patients, offset by an increase of $2,398.4 thousand for increased contract manufacturing and drug substance costs for future planned clinical supply, as well as an increase of $471.7 thousand resulting from various biostatistical and bioanalytical projects and associated with the completed PD and AD clinical studies.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2024 were $1,977.4 thousand, compared to $1,497.5 thousand for the three months ended June 30, 2023. The $479.9 thousand increase was primarily

attributable to increased stock-based compensation expense of $353.4 thousand resulting from the vesting of stock options which were granted during the second quarter of 2024, as well as an increase of $115.5 thousand for professional fees associated with costs incurred by our external auditor and other external accounting consultants.

Financing Costs

Financing costs were $1,346.1 thousand for the three months ended June 30, 2024. We did not incur any financing costs for the three months ended June 30, 2023. The $1,346.1 thousand increase was attributable to issuance costs as well as changes in derivative fair value associated with our ELOC financing with the ELOC Purchaser, described further below.

Change in Fair Value of Warrants

Change in fair value of warrants was a gain of $4,062.3 thousand for the three months ended June 30, 2024. There was no change in fair value for the three months ended June 30, 2023. The $4,062.3 thousand increase was attributable to the fair value remeasurement with respect to our liability-classified Canaccord Warrants during the second quarter of 2024. The associated gain recorded in the Statements of Operations was primarily driven by the decrease in our stock price during the second quarter of 2024, which caused the fair value of the liability to decrease.

Interest Income

Interest income was $26.0 thousand for the three months ended June 30, 2024. Interest income was $222.6 thousand for the three months ended June 30, 2023. The decrease of $196.6 thousand was the result of lower cash and cash equivalent balances when compared to the prior year period.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes the results of our operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 12,307.3	$ 16,048.2	$ (3,740.9)
General and administrative	3,265.1	3,681.2	(416.1)
Total operating expense	15,572.4	19,729.4	(4,157.0)
Other income (expense):			
Other financing costs	(1,346.1)	—	(1,346.1)
Change in fair value of warrants	10,761.0	—	10,761.0
Interest income	70.1	455.1	(385.0)
Other income (expense), net	9,485.0	455.1	9,029.9
Net loss	$ (6,087.4)	$ (19,274.3)	$ 13,186.9

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2024 were $12,307.3 thousand, compared to $16,048.2 thousand for the six months ended June 30, 2023. The decrease of $3,740.9 thousand primarily attributable to a decrease of $7,032.1 thousand in contract research expenditures, given timing of study costs with respect to our Phase 3 study in early PD patients and Phase 2/3 in AD patients, offset by an increase of $2,253.3 thousand for increased contract manufacturing and drug substance costs for future planned clinical supply, as well as an increase of $1,364.8 thousand resulting from various biostatistical and bioanalytical projects and associated with the completed PD and AD clinical studies.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2024 were $3,265.1 thousand, compared to $3,681.2 thousand for the six months ended June 30, 2023. The $416.1 thousand decrease was primarily attributable to a $507.3 thousand decrease in professional fees, resulting from lower legal and PR/IR costs incurred to date in 2024, offset by an increase of $213.4 thousand in employee related costs, primarily from increased headcount year-over-year.

Financing Costs

Financing costs were $1,346.1 thousand for the six months ended June 30, 2024. We did not incur any financing costs for the six months ended June 30, 2023. The $1,346.1 thousand increase was attributable to issuance costs as well as changes in derivative fair value associated with our ELOC financing with the ELOC Purchaser, described further below.

Change in Fair Value of Warrants

Change in fair value of warrants was a gain of $10,761.0 thousand for the six months ended June 30, 2024. There was no change in fair for the six months ended June 30, 2023. This increase was attributable to the fair value remeasurement with respect to our liability-classified Canaccord Warrants during 2024. The associated gain recorded in Results of Operations was primarily driven by the decrease in our stock price during 2024, which caused the fair value of the liability to decrease.

Interest Income

Interest income was $70.1 thousand for the six months ended June 30, 2024. Interest income was $455.1 thousand for the six months ended June 30, 2023. The decrease of $385.0 thousand was the result of lower cash and cash equivalent balances when compared to the prior year period.

Liquidity and Capital Resources

Since our inception in 2008, we have devoted most of our cash resources to research and development and general and administrative activities. We have financed our operations primarily with the proceeds from the sale of common stock and warrants. To date, we have not generated any revenue from the sale of products, and we do not anticipate generating any revenue from the sale of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of June 30, 2024, our principal source of liquidity was our cash and cash equivalents, which totaled $3,997.8 thousand. We do not believe that our cash on hand will be sufficient to fund our operations for at least twelve months beyond the date of this filing.

2024 ELOC Purchase Agreement

On April 25, 2024, we entered into an ELOC Purchase Agreement with the ELOC Purchaser, whereby we may offer and sell, from time to time at our sole discretion, and whereby the ELOC Purchaser has committed to purchase, up to 2,051,428 shares of shares of our common stock. The term of the agreement runs until the expiration of our active S-3 Registration Statement, unless earlier terminated or exhausted.

Upon execution of the ELOC Purchase Agreement, we agreed to issue 33,937 shares of common stock as commitment shares to the ELOC Purchaser. In addition to the commitment shares referenced above, we sold 700.0 thousand shares of our common stock under the purchase agreement and received net proceeds of $4,236.0 thousand. No shares were issued under the purchase agreement prior to the second quarter of 2024. The ELOC Purchaser has agreed that during the term of the Purchase Agreement, neither it nor any of its affiliates will engage in any short sales or hedging transactions involving the Company’s common stock.

March 2024 Registered Direct Offerings

On both March 15, 2024 and March 21, 2024, we entered into separate securities purchase agreements with an institutional investor. When aggregating the results of both purchase agreements, we issued 431.4 thousand shares for net proceeds of $3,875.0 thousand.

April 2023 Private Placement

On April 7, 2023, we sold 84.5 thousand shares of common stock in a private placement to individual members of our Board of Directors and management, for net proceeds of $1,065.0 thousand.

March 2023 ATM

On March 31, 2023, we entered into an ATM Equity Offering Sales Agreement with BofA Securities, Inc. and ThinkEquity LLC, as sales agents, pursuant to which the Company could offer and sell, shares of the Company's common stock from time to time, having an aggregate offering price of up to $50,000.0 thousand. Prior to termination of the Sales Agreement, the Company sold 704.0 thousand shares, for net proceeds of $7,506.2 thousand.

Cash Flows

The following table provides a summary of our cash flows for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Total net cash provided by (used in):		
Operating activities	$ (10,408.0)	$ (21,232.6)
Financing activities	8,651.0	8,579.6
Net (decrease) in cash and cash equivalents	$ (1,757.0)	$ (12,653.0)

Operating Activities

Cash used in operating activities was $10,408.0 thousand for the six months June 30, 2024, compared to $21,232.6 thousand for the six months ended June 30, 2023. The decrease in cash used in operations was primarily driven by decreases in operating expenditures associated with clinical trial expenses, given timing of study costs with respect to our Phase 3 study in early PD patients and Phase 2/3 in AD patients.

Contingent upon continued achievement of our fundraising requirements, we expect cash used in operating activities to continue to be elevated during and after 2024, due to expected operating losses associated with continued development of our product candidates, including clinical trial expenses for our planned disease-modifying studies.

Financing Activities

Cash provided by financing activities was $8,651.0 thousand for the six months ended June 30, 2024, compared to $8,579.6 thousand for the six months ended June 30, 2023. During the six months ended June 30, 2024, cash provided by financing activities primarily consisted of proceeds of $540.0 thousand from warrant exercises and a combined $3,875.0 thousand received from our March registered direct offerings and $4,236.0 thousand of proceeds from share issuances under our ELOC Purchase Agreement. During the six months ended June 30, 2023, cash provided by financing activities primarily consisted of $1,065.0 thousand in proceeds from our April 2023 Private Placement and $7,506.2 thousand in proceeds from our March 2023 ATM.

Contractual Obligations and Other Commitments

This item is not required for smaller reporting companies.

Factors that May Affect Future Results

You should refer to Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023 for a discussion of important factors that may affect our future results.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with GAAP requires us to use judgment in making certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in our financial statements and accompanying notes. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require difficult, subjective and complex judgments by Management in order to make estimates about the effect of matters that are inherently uncertain. During the three and six month periods ended June 30, 2024, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the 2023 fiscal year, which we included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

This item is not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Management, with the participation of our principal executive officer who is also our interim principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and Management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer/interim principal financial officer has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that the information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our Management, including our principal executive officer/interim principal financial officer, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any legal proceedings that we believe could have a material adverse effect on our business, operating results or financial condition and are not aware of any pending or threatened legal proceedings against us.

Item 1A. Risk Factors

Risk factors that may affect our business and financial results are discussed within Item 1A "Risk Factors" of our annual report on Form 10-K filed with the SEC on March 29, 2024 ("2023 Form 10-K"). There have been no material changes to the disclosures relating to this item from those set forth in our 2023 Form 10-K.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant. (Incorporated by reference to Exhibit 3.1 to Form 8-K filed February 6, 2020.)
3.2	Amended and Restated Bylaws of the Registrant. (Incorporated by reference to Exhibit 3.2 to Form 8-K filed February 6, 2020.)
10.1	Common Stock Purchase Agreement dated as of April 25, 2024 between Annovis Bio, Inc. and the ELOC Purchaser. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed April 26, 2024.)
10.2	Registration Rights Agreement dated as of April 25, 2024 between Annovis Bio, Inc. and the ELOC Purchaser. (Incorporated by reference to Exhibit 10.2 to Form 8-K filed April 26, 2024.)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

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.

Annovis Bio, Inc.

Signature	Title	Date
/s/ Maria Maccecchini Maria Maccecchini	President and Chief Executive Officer (Principal Executive Officer and Interim Principal Financial Officer)	August 14, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Maria Maccecchini, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Annovis Bio, Inc.;

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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my 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: August 14, 2024

/s/ Maria Maccecchini
Maria Maccecchini
President and Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial 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 Annovis Bio, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Maria Maccecchini, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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 operation of the Company.

Date: August 14, 2024

/s/ Maria Maccecchini
Maria Maccecchini
President and Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial Officer)