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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 September 30, 2023

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.)

1055 Westlakes Drive, Suite 300
Berwyn, PA 19312
(Address of registrant's principal executive offices)

(610) 727-3913
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 November 6, 2023 was: 10,262,273.

ANNOVIS BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2023

EXPLANATORY NOTE

As disclosed in our Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 31, 2023 (the "Filing Date" and "Form 10-K"), Annovis Bio, Inc. ("Annovis," the "Company," "our," "us" and "we") restated (the "Restatement") our previously issued (i) unaudited condensed balance sheets as of March 31, 2022, June 30, 2022 and September 30, 2022, (ii) unaudited condensed statements of operations and comprehensive loss for the three months ended March 31, 2022, three and six months ended June 30, 2022, and three and nine months ended September 30, 2022, and (iii) unaudited condensed statements of cash flows for the three months ended March 31, 2022, six months ended June 30, 2022 and nine months ended September 30, 2022, in each of the Quarterly Reports on Form 10- Q for the quarterly periods ended March 31, 2022, June 30, 2022 and September 30, 2022.

See Note 12 – Restatement of Previously Issued Unaudited Condensed Financial Statements, to the Financial Statements in the Form 10-K for additional information related to the restatement and additional information related to the restatement of the Condensed Financial Statements for the three and nine months ended September 30, 2022.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements

Annovis Bio, Inc.
Balance Sheets
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,354,942	$ 28,377,693
Prepaid expenses and other current assets	3,868,164	7,644,376
Total current assets	10,223,106	36,022,069
Total assets	$ 10,223,106	$ 36,022,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,926,397	$ 3,961,254
Accrued expenses	1,638,499	3,737,285
Total current liabilities	3,564,896	7,698,539
Total liabilities	3,564,896	7,698,539
Commitments and contingencies (Note 7)		
Stockholders' equity:		
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 35,000,000shares authorized and 9,012,273 and 8,163,923 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	902	816
Additional paid-in capital	94,703,001	82,377,488
Accumulated deficit	(88,045,693)	(54,054,774)
Total stockholders' equity	6,658,210	28,323,530
Total liabilities and stockholders' equity	$ 10,223,106	$ 36,022,069

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Operations and Comprehensive Loss
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,837,650	$ 4,123,538	$ 29,885,874	$ 10,307,142
General and administrative	1,025,621	2,361,299	4,706,813	7,403,817
Total operating expenses	14,863,271	6,484,837	34,592,687	17,710,959
Operating loss	(14,863,271)	(6,484,837)	(34,592,687)	(17,710,959)
Other income:				
Interest income, net	146,655	52,886	601,768	108,559
Total other income	146,655	52,886	601,768	108,559
Loss before income taxes	(14,716,616)	(6,431,951)	(33,990,919)	(17,602,400)
Income tax expense (benefit)	—	—	—	—
Net loss	$ (14,716,616)	$ (6,431,951)	$ (33,990,919)	$ (17,602,400)
Basic and diluted loss per common share	$ (1.63)	$ (0.79)	$ (3.90)	$ (2.16)
Weighted average number of common shares outstanding, basic and diluted	9,012,273	8,163,923	8,722,518	8,161,787

See accompanying notes to financial statements.

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

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Three and Nine Months Ended September 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 and comprehensive 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 and comprehensive loss	—	—	—	(9,537,122)	(9,537,122)
Balance, June 30, 2023	9,012,273	$ 902	$ 94,070,810	$ (73,329,077)	$ 20,742,635
Stock-based compensation expense	—	—	632,191	—	632,191
Net and comprehensive loss	—	—	—	(14,716,616)	(14,716,616)
Balance, September 30, 2023	9,012,273	$ 902	$ 94,703,001	$ (88,045,693)	$ 6,658,210
Three and Nine Months Ended September 30, 2022					
Balance, December 31, 2021	8,100,570	$ 810	$ 73,220,361	$ (28,726,207)	$ 44,494,964
Exercise of stock options	63,353	6	4,607	—	4,613
Stock-based compensation expense	—	—	3,434,944	—	3,434,944
Net and comprehensive loss	—	—	—	(5,234,063)	(5,234,063)
Balance, March 31, 2022	8,163,923	$ 816	$ 76,659,912	$ (33,960,270)	$ 42,700,458
Stock-based compensation expense	—	—	1,903,761	—	1,903,761
Net and comprehensive loss	—	—	—	(5,936,386)	(5,936,386)
Balance, June 30, 2022	8,163,923	$ 816	$ 78,563,673	$ (39,896,656)	$ 38,667,833
Stock-based compensation expense	—	—	2,356,011	—	2,356,011
Net and comprehensive loss	—	—	—	(6,431,951)	(6,431,951)
Balance, September 30, 2022	8,163,923	$ 816	$ 80,919,684	$ (46,328,607)	$ 34,591,893

See accompanying notes to financial statements.

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (33,990,919)	$ (17,602,400)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,746,022	7,694,716
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,776,212	(4,815,873)
Accounts payable	(2,034,857)	1,157,631
Accrued expenses	(2,098,786)	(137,610)
Net cash used in operating activities	(30,602,328)	(13,703,536)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	8,571,191	—
Proceeds from exercise of stock options	8,386	4,613
Net cash provided by financing activities	8,579,577	4,613
Net (decrease) in cash and cash equivalents	(22,022,751)	(13,698,923)
Cash and cash equivalents, beginning of year	28,377,693	45,686,014
Cash and cash equivalents, end of period	$ 6,354,942	$ 31,987,091

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.

Since its founding, the Company has been engaged in organizational activities, including raising capital, and 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. 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.

The Company's primary source of capital has been the issuance of equity securities. The Company's common stock trades on the New York Stock Exchange under the ticker symbol "ANVS"

At present, the Company lacks sufficient capital on hand to fund its operations for the next 12 months and will need to raise additional capital to ensure its continuity of operations. The Company believes that its current cash and cash equivalents, together with the public offering that closed on November 2, 2023 (see Note 12 – Subsequent Events) will be sufficient to fund its operations into the first quarter of 2024, including its ongoing Phase 2/3 AD Trial and its ongoing Phase 3 PD Trial. The Company plans to raise additional capital to complete the development and commercialization of its 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 the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on the Company's business, results of operations, and financial condition. Accordingly, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern for one year after the date that these financial statements are issued.

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 2022 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 31, 2023. In the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company restated (i) unaudited condensed balance sheets as of March 31, 2022, June 30, 2022 and September 30, 2022, (ii) unaudited condensed statements of operations and comprehensive loss for the three months ended March 31, 2022, three and six months ended June 30, 2022, and three and nine months ended September 30, 2022, and (iii) unaudited condensed statements of cash flows for the three months ended March 31, 2022, six months ended June 30, 2022 and nine months ended September 30, 2022, in each of the Quarterly Reports on Form 10- Q for the quarterly periods ended March 31, 2022, June 30, 2022 and September 30, 2022. The restatement resulted from the Company's prior accounting for payments for research and development expenses and recognition of expenses. Accordingly, certain amounts for the three and nine months ended September 30, 2022 presented herein reflect the restated amounts.

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 September 30, 2023, its results of operations for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine month periods ended September 30, 2023 and 2022. The 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 stock-based compensation expense, and prepaid expenses and accrued liabilities that are measured based on progress toward completion of research and development projects. 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 significant 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.

(f) Fair Value of Financial Instruments

The Company's financial instruments include cash and cash equivalents, accounts payable and accrued expenses. Cash and cash equivalents are reported at fair value. The recorded carrying amounts of accounts payable and accrued expenses reflect their fair value due to their short-term nature.

(g) 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.

(h) Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the fair value of the award and is generally recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company also has options outstanding with a performance-based vesting conditions, for which the Company recognizes expense based on the estimated probability of achievement of the performance metrics over the contractual term of the option. Forfeitures are recognized in compensation expense in the period when they occur.

The Company uses the Black-Scholes option pricing model to value its option awards which requires the use of assumptions, including the expected life of the option and expected share price volatility. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

Upon exercise of stock options, the Company issues shares first from treasury stock, if available, then from authorized but unissued shares.

(i) 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 September 30, 2023 and December 31, 2022, the Company has recorded 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 September 30, 2023 or December 31, 2022.

(j) Recent Accounting Pronouncements

There are no recent accounting pronouncements that would have a significant impact on the Company's financial statements.

(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 September 30, 2023 and December 31, 2022:

		Fair Value Measurement at September 30, 2023		
	Carrying Value	Level 1	Level 2	Level 3
Cash equivalents	$ 3,873,159	$ 3,873,159	$ —	$ —

		Fair Value Measurement at December 31, 2022		
	Carrying Value	Level 1	Level 2	Level 3
Cash equivalents	$ 26,001,934	$ 26,001,934	$ —	$ —

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2023	December 31, 2022
Prepaid expenses	$ 66,872	$ 67,532
Prepaid clinical trial expenses	3,719,333	7,528,250
Prepaid insurance	61,340	37,356
Security deposits and other	20,619	11,238
	$ 3,868,164	$ 7,644,376

(5) Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2023	December 31, 2022
Payroll and related benefits	$ 396,384	$ 556,827
Accrued professional and clinical fees	1,242,115	3,180,458
	$ 1,638,499	$ 3,737,285

(6) Commitments and Contingencies

(a) Research & Development

The Company has entered into contracts with contract research organizations (CROs) and contract manufacturers (CMOs) related the Company's clinical trials. The contracts 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 for payments for services rendered through the termination date of the project with the CRO/CMO.

(b) Leases

The Company leases office space which is accounted for as a short term lease. Total rental expense was $23,891 and $16,930 for the three months ended September 30, 2023 and 2022, respectively, and $59,165 and $50,287 for the nine months ended September 30, 2023 and 2022, 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 approximately $1,307,100 at September 30, 2023.

(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.

At September 30, 2023, the Company did not have any pending legal actions.

(7) Stockholders' 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 authorized of two classes of stock 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 shall be common stock and 2,000,000 shall be preferred stock.

On March 31, 2023, the "Company, entered into an ATM Equity Offering Sales Agreement SM (the "Sales Agreement") with BofA Securities, Inc. ("BofA") and ThinkEquity LLC ("ThinkEquity" and, together with BofA, the "Sales Agents"), as sales agents, pursuant to which the Company may offer and sell, from time to time through the Sales Agents, shares of the Company's common stock, par value $0.0001 per share (the "Common Stock"), having an aggregate offering price of up to $50.0 million.

On April 4, 2023, the Company delivered written notice to BofA and ThinkEquity to terminate the Sales Agreement, effective April 9, 2023, pursuant to Section 9(a) of the Sales Agreement. The Company is not subject to any termination penalties related to the termination of the Sales Agreement.

Prior to termination of the Sales Agreement, the Company sold 704,000 shares of Common Stock pursuant to the Sales Agreement at a price of $10.88 per share, for gross proceeds of $7,659,520 before commissions. As a result of the termination of the Sales Agreement, the Company will not offer or sell any additional shares of Common Stock under the Sales Agreement.

In addition, on April 7, 2023, the Company sold 84,453 shares of its common stock in a private placement to individual members of its Board of Directors and management at a price of $12.61 per share, for aggregate proceeds of $ 1.06 million.

(b) Common Stock

1. 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.

2. 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.

3. 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 September 30, 2023 or December 31, 2022.

(d) Warrants

In conjunction with the closing of the Company's IPO, the Company granted the underwriters 100,000 warrants to purchase shares of Company common stock at an exercise price of $7.50 per share, which was 125% of the initial public offering price. The 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 September 30, 2023 and December 31, 2022, 2,400 of the warrants were outstanding. No warrants were exercised during the three or nine months ended September 30, 2023 or 2022.

(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. As of September 30, 2023, 265,991 shares were available for future grants.

Stock-based compensation expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative	$ 379,364	1,627,820	$ 1,792,819	5,053,502
Research and development	252,827	728,191	1,953,203	2,641,214
	$ 632,191	$ 2,356,011	$ 3,746,022	$ 7,694,716

During the nine months ended September 30, 2023, the Company granted options to purchase 126,883 shares of common stock at a weighted-average exercise price of $13.28 per share to employees and consultants. Under the grant agreements, 35,178 of the options vested immediately and have a 10-year term. The rest of the options have service based vesting conditions and generally vest in substantially equal quarterly installments over two years and have a 10 year term. The options granted during the nine months ended September 30, 2023 were valued using the Black Scholes option pricing model using the following weighted-average assumptions: (i) expected term of 5.56 years; (ii) risk free interest rate of 3.62%; (iii) expected volatility of 127.5%; and (iv) dividend yield of 0.0%. The weighted-average grant date fair value of options issued by the Company during the three months ended September 30, 2023 was $11.29 per share.

No stock options were exercised during the three months ended September 30, 2023 and 2022. Stock options exercised during the nine months ended September 30, 2023 and 2022, were 59,897 and 70,101, respectively. As of September 30, 2023, there were 1,724,328 options outstanding, of which 1,511,289 were vested and exercisable. As of December 31, 2022, there were 1,657,342 options outstanding, of which 1,310,667 were vested and exercisable.

During the nine months ended September 30, 2022, previously issued stock options were modified for an employee who is no longer with the Company. As a result of this modification, $1,219,572 was recognized as stock option modification expense and included in general and administrative expenses on the accompanying statement of operations.

(9) Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator				
Net loss	$ (14,716,616)	$ (6,431,951)	$ (33,990,919)	$ (17,602,400)
Denominator				
Weighted-average common shares outstanding, basic and diluted	9,012,273	8,163,923	8,722,518	8,161,787
Net loss per share, basic and diluted	$ (1.63)	$ (0.79)	$ (3.90)	$ (2.16)

The Company reported a net loss for the three and nine months ended September 30, 2023 and 2022, therefore, the basic and diluted net loss per share were the same in the respective period because the inclusion of potential common shares would have an anti-dilutive effect. Potential shares of common stock that were excluded from the computation of diluted weighted-average shares outstanding were as follows:

	September 30,	
	2023	2022
Stock options	1,724,328	1,657,342
Warrants	2,400	2,400

(10) Income Taxes

The Company's income tax benefit (expense) was $0 for the three and nine months ended September 30, 2023 and 2022. 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 nine months ended September 30, 2023 and 2022 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 September 30, 2023, and December 31, 2022, 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) Restatement of Previously Issued Unaudited Condensed Financial Statements

As disclosed in the Form 10-K filed with the SEC on March 31, 2023, during its preparation of its 2022 audited combined financial statements and notes thereto, the Company concluded that there were material research and development expenses and related balance sheet errors in its previously issued unaudited condensed financial statements for the three and nine months ended September 30, 2022, primarily relating to the timing of payments for research and development expenses and recognition of expenses.

The Company noted the following items were improperly expensed during the three and nine months ended September 30, 2022:

● Payments, in the amount of $1,320,321, were improperly recorded in research and development expenses during the three months ended September 30, 2022. These amounts should have been recorded in prepaid expenses and other current assets as of September 30, 2022. Additionally, $130,826 was expensed during the three months ended September 30, 2022 related to the prior quarter restatements.

These errors, including the errors from the six months ended June 30, 2022, in the accounting for research and development expenses resulted in an understatement of prepaid assets and other current assets of $4,631,390 as of September 30, 2022, and an overstatement of operating expenses and net loss of $1,189,495 and $4,631,390 for the three and nine months ended September 30, 2022, respectively.. See Note 12 – Restatement of Previously Issued Unaudited Condensed Financial Statements, to the Financial Statements in the Form 10-K for additional information related to the restatements.

In connection with the filing of this Quarterly Report on Form 10-Q, the Company has restated the accompanying interim Condensed Financial Statements for the three and nine months ended September 30, 2022 to correct for the impact of the misstatements. The applicable notes to the accompanying financial statements have also been corrected to reflect the impact of the restatement. Below, we have presented a reconciliation from the "As Reported" to the "As Restated" amounts for each of our interim Condensed Financial Statements as of and for the three and nine months ended September 30, 2022. The amounts "As Reported" are from the "As Reported" amounts as disclosed in Note 12 – Restatement of Previously Issued Unaudited Condensed Financial Statements (Unaudited) in the Form 10-K.

	As of September 30, 2022		
	As Reported	(unaudited) Restatement Impacts	As Restated
Assets			
Current assets:			
Cash and cash equivalents	$ 31,987,091	$	$ 31,987,091
Prepaid expenses and other current assets	499,947	4,631,390	5,131,337
Deferred clinical materials	—	—	—
Total current assets	32,487,038	4,631,390	37,118,428
Total assets	$ 32,487,038	$ 4,631,390	$ 37,118,428
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	$ 1,845,705	$	$ 1,845,705
Accrued expenses	680,830		680,830
Total current liabilities	2,526,535	—	2,526,535
Total liabilities	$ 2,526,535	$ —	$ 2,526,535
Commitments and contingencies (Note 7)			
Stockholders' equity:			
Preferred stock - $0.0001 par value, 2,000,000 shares authorized and 0 shares issued and outstanding	—		—
Common stock - $0.0001 par value, 35,000,000 shares authorized and 8,163,923 and 8,100,570 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	816		816
Additional paid-in capital	80,919,684		80,919,684
Accumulated deficit	(50,959,997)	4,631,390	(46,328,607)
Total stockholders' equity	29,960,503	4,631,390	34,591,893
Total liabilities and stockholders' equity	$ 32,487,038	$ 4,631,390	$ 37,118,428

	Three Months Ended September 30, 2022		
	As Reported	Restatement Impacts	As Restated
Operating expenses:			
Research and development	$ 5,313,033	$ (1,189,495)	$ 4,123,538
General and administrative	2,361,299	—	2,361,299
Total operating expenses	7,674,332	(1,189,495)	6,484,837
Operating loss	(7,674,332)	1,189,495	(6,484,837)
Other income:			
Interest income	52,886	—	52,886
Grant Income			
Total other income	52,886	—	52,886
Loss before income taxes	(7,621,446)	1,189,495	(6,431,951)
Income tax expense (benefit)	—	—	—
Net loss	$ (7,621,446)	$ 1,189,495	$ (6,431,951)
Basic and diluted loss per common share	$ (0.93)	—	$ (0.79)
Weighted average number of common shares outstanding, basic and diluted	8,163,923	—	8,163,923

	Nine Months Ended September 30, 2022		
	As Reported	Restatement Impacts	As Restated
Operating expenses:			
Research and development	$ 14,938,532	$ (4,631,390)	$ 10,307,142
General and administrative	7,403,817	—	7,403,817
Total operating expenses	22,342,349	(4,631,390)	17,710,959
Operating loss	(22,342,349)	4,631,390	(17,710,959)
Other income:			
Interest income	108,559	—	108,559
Grant Income			
Total other income	108,559	—	108,559
Loss before income taxes	(22,233,790)	4,631,390	(17,602,400)
Income tax expense (benefit)	—	—	—
Net loss	$ (22,233,790)	$ 4,631,390	$ (17,602,400)
Basic and diluted loss per common share	$ (2.72)	—	$ (2.16)
Weighted average number of common shares outstanding, basic and diluted	8,161,787	—	8,161,787

	Nine Months Ended September 30, 2022		
	As Reported	Restatement Impacts	As Restated
Cash flows from operating activities:			
Net loss	$ (22,233,790)	4,631,390	$ (17,602,400)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	7,694,716	—	7,694,716
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(184,483)	(4,631,390)	(4,815,873)
Accounts payable	1,157,631	—	1,157,631
Accrued expenses	(137,610)	—	(137,610)
Net cash used in operating activities	(13,703,536)	—	(13,703,536)
Cash flows from financing activities:			
Proceeds from exercise of stock options	4,613	—	4,613
Net cash used in financing activities	4,613	—	4,613
Net (decrease) increase in cash and cash equivalents	(13,698,923)	—	(13,698,923)
Cash and cash equivalents, beginning of period	45,686,014	—	45,686,014
Cash and cash equivalents, end of period	$ 31,987,091	—	$ 31,987,091

(12) Subsequent Events

On October 31, 2023, the Company, entered into an Underwriting Agreement (the "Underwriting Agreement") with Canaccord Genuity LLC relating to the sale of 1,250,000 units consisting of (i) one share of its common stock and (ii) an accompanying warrant (each warrant to purchase one share of common stock). The public offering price was $6.00 per unit.

Each common stock warrant sold with the shares of common stock represents the right to purchase one share of our common stock at an exercise price of $9.00 per share, and 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 (i) the Company's public announcement of Positive Topline Data (as defined in the Warrant Agreement) from its Phase 3 pivotal study in patients with Parkinson's Disease and (ii) 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 will expire on November 2, 2028, five years from the date of issuance. The net proceeds from the offering were approximately $6,766,000, after deducting underwriting discounts and commissions and estimated offering expenses, and excluding the exercise of any warrants.

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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 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;
- our cash needs and financing plans;
- 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, 2022 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 year ended December 31, 2022 which are included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Restatement of Previously Issued Consolidated Financial Statements

As disclosed in our Annual Report on Form 10-K filed with the SEC on March 31, 2023, during our preparation of our 2022 audited combined financial statements and notes thereto, we concluded that there were material research and development expenses and related balance sheet errors in its previously issued unaudited condensed financial statements as of and for each of the quarterly and year to date periods ended March 31, 2022, June 30, 2022 and September 30, 2022, primarily relating to the timing of payments for research and development expenses and recognition of expenses.

See Note 12 – Restatement of Previously Issued Unaudited Condensed Financial Statements, to the Financial Statements in the Form 10-K for additional information related to the restatements.

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 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 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 a MMSE score between 19 and 28. All three clinical trials were double-blind, placebo-controlled studies. We designed the studies by applying our understanding of the underlying neurodegenerative disease states, and measured efficacy as well as both target and pathway engagement in the spinal fluid of patients to determine whether patients improvement following treatment correlated with the CSF biomarkers. In addition to meeting their primary endpoints of safety and tolerability and secondary endpoint of pharmacokinetics, 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 a MMSE score between 14 and 24. 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.

Our Phase 3 PD Study and Phase 2/3 AD Study each have 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. As the interim analysis was conducted at two months of the six- month endpoint and only on 132 patients, it may not be indicative of the results at six months for the full patient population because as the trial progresses, clinical outcomes may materially change as patient enrollment continues. 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 data safety monitoring board (DSMB) also conducted an interim safety analysis and reported that buntanetap was generally well-tolerated and the study should proceed as planned. We remain blinded to the Phase 3 PD Study and we do not have safety or efficacy data from the trial.

The pre-planned interim analysis for the Phase 2/3 AD Study was based on 107 patients having completed six weeks of treatment. Based on the results of the interim analysis, which we disclosed on October 12, 2023, we are proceeding with the Phase 2/3 AD study as planned without the need to add additional patients. The data safety monitoring board (DSMB) also conducted an interim safety analysis and reported that buntanetap was generally well-tolerated and the study should proceed as planned.

We plan to consult with the FDA following completion of both studies, to obtain feedback on our additional AD and PD studies, including conducting an open label extension study following the completion of the initial trials. Using the data from the Phase 3 PD Study, we intend to design an 18-month long disease-modifying Phase 3 study in the same early PD patients. In addition, we intend to conduct a short 6-month study in advanced PD patients during the second half of the 18-month disease modifying Phase 3 study, at which time we will define the advanced PD patient population for the purposes of such study. Similarly, using the data from the Phase 2/3 AD Study interim analysis, we intend to design an 18-month disease modifying Phase 3 study in the same early AD patient population. In addition, we intend to conduct a short 6-month study in advanced AD patients during the second half of the 18-month disease modifying Phase 3 study, at which time we will define the advanced AD patient population for the purposes of such study. We expect both the ongoing Phase 3 PD Study and the Phase 2/3 AD Study to be completed by the end of 2023, and we intend to announce the data from the final analyses in the first quarter of 2024.

By the end of 2026, our goal is to have conducted the required pivotal studies for buntanetap 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 is designed to inhibit 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 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 three 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.

We have never been profitable and have incurred net losses since inception. Our accumulated deficit at September 30, 2023 was $88,046 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.

Results of Operations

Operating expenses and other income were comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Operating expenses:				
Research and development	$ 13,837.7	$ 4,123.5	$ 29,885.9	$ 10,307.1
General and administrative	$ 1,025.6	$ 2,361.3	$ 4,706.8	$ 7,403.8
Other income:				
Interest income	$ 146.7	$ 52.9	$ 601.8	$ 108.6

Three Months Ended September 30, 2023 and 2022

Research and Development Expenses

Research and development expenses increased by $9,714.2 thousand for the three months ended September 30, 2023 compared to the prior year period. The increase was primarily the result of an increase of $10,006.8 thousand in clinical expenses related to our Phase 3 study in early PD patients, Phase 2/3 in AD patients, an increase of $291.3 thousand in contract research expenses, partially offset by a decrease of $475.4 thousand in stock-based compensation expense. We expect research and development expenses in 2023 will be higher than the prior year as we continue our Phase 3 study in early PD patients and our Phase 2/3 study in moderate AD patients.

General and Administrative Expenses

General and administrative expenses decreased by $1,335.7 thousand for the three months ended September 30, 2023 compared to the prior year period. The decrease was primarily the result of a decrease of $1,248.5 thousand in stock-based compensation expense, a decrease of $81.4 in administrative expenses and a decrease of $58.0 in insurance expense, partially offset by an increase of $45.5 in salary expense.

Other Income

Other income increased $93.8 thousand for the three months ended September 30, 2023 compared to the prior year period. The increase was primarily the result of higher return on investment compared to the prior year period.

Nine Months Ended September 30, 2023 and 2022

Research and Development Expenses

Research and development expenses increased by $19,578.7 thousand for the nine months ended September 30, 2023 compared to the prior year period. The increase was primarily the result of an increase of $20,305.1 thousand in clinical expenses related to our Phase 3 study in early PD patients, Phase 2/3 in AD patients, and an increase in salary expense of 384.6, partially offset by decrease of $482.7 thousand for the cost of materials and a decrease of $688.0 thousand in stock-based compensation expense. We expect research and development expenses in 2023 will be higher than the prior year as we continue our Phase 3 study in early PD patients and our Phase 2/3 study in moderate AD patients.

General and Administrative Expenses

General and administrative expenses decreased by $2,697.0 thousand for the nine months ended September 30, 2023 compared to the prior year period. The decrease was primarily the result of a decrease of $3,260.7 thousand in stock-based compensation expense, partially offset by an increase of $552.3 thousand in professional fees.

Other Income

Other income increased $493.2 thousand for the nine months ended September 30, 2023 compared to the prior year period. The increase was primarily the result of higher return on invested funds 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, redeemable convertible preferred stock, and convertible promissory notes and funding from research grants. 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 September 30, 2023, our principal source of liquidity was our cash and cash equivalents, which totaled $6,354.9 thousand.

Cash Flows

The following table summarizes our cash flows for the respective period:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Statement of Cash Flows Data:		
Total net cash provided by (used in):		
Operating activities	$ (30,602.3)	$ (13,703.5)
Financing activities	8,579.6	4.6
Net (decrease) in cash and cash equivalents	$ (22,022.8)	$ (13,698.9)

Operating Activities

For the nine months ended September 30, 2023, cash used in operations increased $16,898.8 thousand compared to the same period in the prior year. The increase in cash used in operations was primarily the result of an increase in cash paid for clinical trial expenses.

We expect cash used in operating activities to increase in 2023 as compared to 2022 due to an expected increase in our operating losses associated with ongoing development of our product candidates, including clinical trial expenses for our planned Phase 3 trial in early PD patients and a second clinical trial in early AD patients.

Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2023 was due to $8,571.2 thousand in proceeds from the sale of common stock and $8.4 thousand in proceeds from the exercise of stock options.

On October 31, 2023, the Company, entered into an Underwriting Agreement (the "Underwriting Agreement") with Canaccord Genuity LLC relating to the sale of 1,250,000 units consisting of (i) one share of its common stock and (ii) an accompanying warrant (each warrant to purchase one share of common stock). The public offering price was $6.00 per unit. Each common stock warrant sold with the shares of common stock represents the right to purchase one share of our common stock at an exercise price of $9.00 per share, and 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 (i) the Company's public announcement of Positive Topline Data (as defined in the Warrant Agreement) from its Phase 3 pivotal study in patients with Parkinson's Disease and (ii) 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 will expire on November 2, 2028, five years from the date of issuance. The net proceeds from the offering were approximately $6,766,000, after deducting underwriting discounts and commissions and estimated offering expenses, and excluding the exercise of any warrants.

Funding Requirements

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 current cash and cash equivalents and funding from existing grants will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2024, including our ongoing Phase 2/3 AD Trial and our ongoing Phase 3 PD Trial. 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. We have no committed external sources of funds. 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. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

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, 2022 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.

Discussion of 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 nine month period ended September 30, 2023, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2022, which we included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective, due to the material weakness in our internal control over financial reporting described below, 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 Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Identified Material Weakness

In connection with the audit of our financial statements as of December 31, 2022 and 2021 and for the years ended December 31, 2022 and 2021, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to the proper classification of research and development expenses, which impacted our previously issued condensed financial statements as of and for the three months ended March 31, 2022, three and six months ended June 30, 2022 and three and nine months ended September 30, 2022.

Remediation Plan

Our management, with the oversight of the Audit Committee of the Board of Directors, has updated our internal processes and controls to strengthen their effectiveness and developed a remediation plan which includes the following actions:

- Enhance our review procedures over significant contracts with contract manufacturing organizations and contract research organizations;
- Augment existing staff; and
- Strengthen the review process.

We will not be able to conclude whether the actions we are taking will fully remediate the material weakness in our internal control over financial reporting until the updated controls have operated for a sufficient period of time and management has concluded, through testing, that such controls are operating effectively. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate further action.

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. except for the initiation of our remediation efforts with respect to the material weakness relating to our internal control over financial reporting described above. We have taken actions to remediate the material weakness, which has resulted and may continue to result in changes in our internal control over financial reporting in periods subsequent to March 31, 2023 as we continue to address this material weakness.

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 material legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

This item is not required for smaller reporting companies.

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.)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification Pursuant to Section 906 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.

Signature	Title	Date
/s/ Maria Maccecchini Maria Maccecchini	President and Chief Executive Officer (principal executive officer)	November 8, 2023
/s/ Henry Hagopian III Henry Hagopian III	Chief Financial Officer (principal financial and accounting officer)	November 8, 2023

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. 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 (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. 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: November 8, 2023

/s/ Maria Maccecchini
Maria Maccecchini
President and Chief Executive Officer

Exhibit 31.2

**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, Henry Hagopian III, 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. 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 (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. 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: November 8, 2023

/s/ Henry Hagopian III

Henry Hagopian III
Chief 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 period ended September 30, 2023 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 operations of the Company.

Date: November 8, 2023

/s/ Maria Maccecchini
Maria Maccecchini
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of Annovis Bio, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Henry Hagopian III, 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 operations of the Company.

Date: November 8, 2023

/s/ Henry Hagopian III
Henry Hagopian III
Chief Financial Officer