
**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 MARCH 31, 2022

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
(State or other jurisdiction of
incorporation or organization)

26-2540421
(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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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 May 2, 2022 was: 8,163,923.

ANNOVIS BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2022

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

Annovis Bio, Inc.
Balance Sheets

	<u>March 31,</u> <u>2022</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 42,668,838	\$ 45,686,014
Prepaid expenses and other current assets	627,902	315,464
Total current assets	<u>43,296,740</u>	<u>46,001,478</u>
Total assets	<u>\$ 43,296,740</u>	<u>\$ 46,001,478</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 928,997	\$ 688,074
Accrued expenses	327,435	818,440
Total current liabilities	<u>1,256,432</u>	<u>1,506,514</u>
Total liabilities	<u>1,256,432</u>	<u>1,506,514</u>
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 March 31, 2022 and December 31, 2021, respectively	816	810
Additional paid-in capital	76,659,912	73,220,361
Accumulated deficit	<u>(34,620,420)</u>	<u>(28,726,207)</u>
Total stockholders' equity	<u>42,040,308</u>	<u>44,494,964</u>
Total liabilities and stockholders' equity	<u>\$ 43,296,740</u>	<u>\$ 46,001,478</u>

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 2,809,791	\$ 2,389,583
General and administrative	3,104,071	839,627
Total operating expenses	<u>5,913,862</u>	<u>3,229,210</u>
Operating loss	(5,913,862)	(3,229,210)
Other income:		
Interest income	19,649	197
Grant income	—	29,340
Total other income	<u>19,649</u>	<u>29,537</u>
Loss before income taxes	(5,894,213)	(3,199,673)
Income tax expense (benefit)	—	—
Net loss	<u>\$ (5,894,213)</u>	<u>\$ (3,199,673)</u>
Basic and diluted loss per common share	<u>\$ (0.72)</u>	<u>\$ (0.46)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>8,157,445</u>	<u>6,920,622</u>

See accompanying notes to financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Three Months Ended March 31, 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 loss	—	—	—	(5,894,213)	(5,894,213)
Balance, March 31, 2022	<u>8,163,923</u>	<u>\$ 816</u>	<u>\$ 76,659,912</u>	<u>\$ (34,620,420)</u>	<u>\$ 42,040,308</u>
Three Months Ended March 31, 2021					
Balance, December 31, 2020	6,891,608	\$ 689	\$ 21,779,340	\$ (14,239,075)	\$ 7,540,954
Exercise of stock options	3,868	1	3,016	—	3,017
Cashless exercise of warrants	51,644	5	(5)	—	—
Stock-based compensation expense	—	—	23,977	—	23,977
Net loss	—	—	—	(3,199,673)	(3,199,673)
Balance, March 31, 2021	<u>6,947,120</u>	<u>\$ 695</u>	<u>\$ 21,806,328</u>	<u>\$ (17,438,748)</u>	<u>\$ 4,368,275</u>

See accompanying notes to financial statements.

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

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Cash flows from operating activities:		
Net loss	\$ (5,894,213)	\$ (3,199,673)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,434,944	23,977
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(312,438)	(317,473)
Accounts payable	240,923	482,709
Accrued expenses	(491,005)	535,592
Net cash used in operating activities	<u>(3,021,789)</u>	<u>(2,474,868)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	4,613	3,017
Net cash provided by financing activities	4,613	3,017
Net decrease in cash and cash equivalents	<u>(3,017,176)</u>	<u>(2,471,851)</u>
Cash and cash equivalents, beginning of period	45,686,014	8,074,658
Cash and cash equivalents, end of period	<u>\$ 42,668,838</u>	<u>\$ 5,602,807</u>

See accompanying notes to financial statements.

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

(1) Nature of Business and Liquidity

Annovis Bio, Inc. (the “Company” or “Annovis”) is a clinical-stage drug platform company addressing Alzheimer’s disease (“AD”), Parkinson’s disease (“PD”) and other chronic neurodegenerative diseases, including AD in Down syndrome (“AD-DS”). The Company’s lead compound, buntanetap, is a small, once a day, orally administered, brain penetrant compound. In several clinical and pre-clinical studies, buntanetap inhibited the synthesis of neurotoxic proteins—APP/A β (“APP”), tau/phospho-tau (“tau”) and α -Synuclein (“ α SYN”)—that are the main cause 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. 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. 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 been the issuance of equity securities. On May 26, 2021, the Company closed an underwritten public offering of 1,000,000 shares of its common stock at an offering price of \$50.00 per share, for gross proceeds of \$50.0 million. The net proceeds of the offering were approximately \$46.6 million, after deducting underwriting discounts and issuance costs. The Company’s common stock trades on the New York Stock Exchange under the ticker symbol “ANVS”.

As of the date these financial statements are issued, management believes that the current cash and cash equivalents are sufficient to fund operations and capital requirements for at least the next 12 months including one planned six-month clinical trial in early PD patients and one potential short-term trial in early AD patients. To fund additional expected Phase 3 trials, however, the Company will need to raise additional capital. There is no assurance that such financing will be available when needed or on acceptable terms.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation of Interim Unaudited Financial Statements

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 March 31, 2022, and its results of operations and its cash flows for the three months ended March 31, 2022 and 2021. The interim results of operations are not necessarily indicative of the results to be expected for a full year. These interim unaudited financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2021 and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021. 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 Securities and Exchange Commission (“SEC”). Any reference in these notes to applicable guidance is meant to refer to

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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, progress toward completion of research and development projects, grant income and contingent liabilities. 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 Income (Loss) per Share

Basic net income (loss) per share is determined using the weighted average number of shares of common stock outstanding during each period. Diluted net income (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 income (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. At times, the Company’s cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation.

(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 expensed as incurred 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

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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.

(h) Grant Income

Grants received are recognized as grant income in the statements of operations as and when they are earned for the specific research and development projects for which these grants are designated. Grant payments received in excess of grant income earned are recognized as deferred grant on the balance sheets, and grant income earned in excess of grant payments received is recognized as grant receivable on the balance sheets.

(i) Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. 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 subjective 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.

(j) 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 March 31, 2022 and December 31, 2021, 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 March 31, 2022 or December 31, 2021.

(k) Recent Accounting Pronouncements

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance. The amendments in ASU 2021-10 require annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The new disclosure requirements include information about the nature of the transactions and the related accounting policy used to account for the transactions; the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item; and significant terms and conditions of the transactions, including commitments and contingencies. The guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted, and may be adopted prospectively or retrospectively. The adoption of this standard did not 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 March 31, 2022 and December 31, 2021:

	Carrying Value	Fair Value Measurement at March 31, 2022		
		Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 42,668,838	\$ 42,668,838	\$ —	\$ —

	Carrying Value	Fair Value Measurement at December 31, 2021		
		Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 45,686,014	\$ 45,686,014	\$ —	\$ —

(4) Grant Income

In September 2019, as modified in September 2020, the Company received a Notice of Award for a \$1.9 million grant from the National Institute on Aging of the National Institutes of Health (the “NIH”) to cover costs of long-term chronic toxicology studies of buntanetap in rats and dogs. The Company began the long-term chronic toxicology studies in November 2019. The Company recognized grant income of \$0 and \$29,340 for the three months ended March 31, 2022 and 2021, respectively, in connection with the NIH grant. The Company received payments under the grant of \$0 and \$29,340 during the three months ended March 31, 2022 and 2021, respectively. The Company recorded a grant receivable of \$0 as of March 31, 2022 and December 31, 2021, and had no unreimbursed, eligible costs incurred under the grant. As of March 31, 2022, there were no remaining funds available under the grant.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Prepaid clinical trial expenses	\$ 258,361	\$ 232,752
Prepaid insurance	313,119	29,111
Prepaid expenses	46,557	43,736
Security deposits	9,865	9,865
	<u>\$ 627,902</u>	<u>\$ 315,464</u>

(6) Accrued Expenses

Accrued expenses consisted of the following:

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Payroll and related benefits	\$ 168,515	\$ 712,768
Accrued professional and clinical fees	158,920	105,672
	<u>\$ 327,435</u>	<u>\$ 818,440</u>

(7) Commitments and Contingencies

(a) Leases

The Company leases its office facilities under a month-to-month operating lease. Total rental expense was \$17,276 and \$10,615 for the three months ended March 31, 2022 and 2021, respectively.

(b) License Agreement

The Company previously licensed the rights to certain chemical compounds, know-how and intellectual property rights that may be suitable for the development of human therapeutics from a subsidiary of Horizon Therapeutics, PLC (the "Licensor"). Under the license agreement, the Company paid a minimum annual fee of \$46,000 and was required to make milestone payments upon attainment of certain milestone events, royalties based on net sales of products covered by the patent-related rights and a portion of any sublicense income received by the Company. The Licensor also granted the Company a buy-out option which was exercisable at any time during the term of the agreement at increasing amounts based on the achievement of certain milestones. The Company had the right to terminate the agreement at any time by giving 90 days advance notice subject to the payment of any amounts due under the agreement at that time. Expenses related to the license agreement were recognized in general and administrative expense in the statements of operations.

In July 2021, the Company gave notice to the Licensor of its termination of the license agreement and the license agreement was terminated effective October 14, 2021. The Company has paid to the Licensor the prorated annual fees through the termination date. No milestones had been achieved as of the termination date.

(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 \$986,000 at March 31, 2022.

(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 March 31, 2022, the Company did not have any pending legal actions.

(e) Risks and Uncertainties

The extent to which the COVID-19 pandemic could have a material impact on the Company's current or future clinical trials is dependent on the spread of the disease and government and healthcare system responses to such spread, which are presently highly uncertain. Management continues to evaluate the potential impact. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

(8) 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"), to authorize the issuance of two classes of stock to be designated, respectively, common stock and preferred stock. The total number of shares which the Company is authorized to issue is 37,000,000, each with a par value of \$0.0001 per share. Of these shares, 35,000,000 shall be common stock and 2,000,000 shall be preferred stock.

(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 March 31, 2022 or December 31, 2021.

(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

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public offering price. The warrants have a five-year term and were exercisable as of January 29, 2021. During the year ended December 31, 2021, 97,600 of the warrants were tendered to the Company by the holders pursuant to cashless exercises. As of March 31, 2022 and December 31, 2021, 2,400 of the warrants were outstanding. The Company accounts for the warrants as a component of stockholders' equity.

(9) 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 March 31, 2022, 442,275 shares were available for future grants.

Stock-based compensation expense was as follows:

	Three Months Ended March 31,	
	2022	2021
General and administrative	\$ 2,245,043	\$ 23,977
Research and development	1,189,901	—
	<u>\$ 3,434,944</u>	<u>\$ 23,977</u>

During the three months ended March 31, 2022, the Company granted options to purchase 188,294 shares of common stock at an exercise price of \$19.78 per share to employees, members of its board of directors and consultants. Under the grant agreements, the options generally vest in substantially equal quarterly installments over two years and have a 10-year term. The options granted during the three months ended March 31, 2022 were valued using the Black Scholes option pricing model using the following assumptions: (i) expected term of 5.5 years; (ii) risk free interest rate of 1.42%; (iii) expected volatility of 114.0%; 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 March 31, 2022 was \$16.36 per share.

Stock options exercised during the three months ended March 31, 2022 and 2021, were 70,101 and 3,868, respectively. As of March 31, 2022, there were 1,607,941 options outstanding, of which 1,211,193 were vested and exercisable. As of December 31, 2021, there were 1,489,748 options outstanding, of which 1,105,568 were vested and exercisable.

(10) Net Loss Per Share

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

	Three Months Ended March 31,	
	2022	2021
Numerator		
Net loss	\$ (5,894,213)	\$ (3,199,673)
Denominator		
Weighted-average common shares outstanding, basic and diluted	8,157,445	6,920,622
Net loss per share, basic and diluted	\$ (0.72)	\$ (0.46)

The Company reported a net loss for the three months ended March 31, 2022 and 2021, therefore, the basic and diluted net loss per share were the same in the respective period because the inclusion of potential common shares would

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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:

	<u>March 31,</u>	
	<u>2022</u>	<u>2021</u>
Stock options	1,607,941	1,107,598
Warrants	2,400	5,000

(11) Income Taxes

The Company's income tax benefit (expense) was \$0 for the three months ended March 31, 2022 and 2021. 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 months ended March 31, 2022 and 2021 was offset by changes in the valuation allowance.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. Previously, NOLs generated after December 31, 2017 were limited to 80% of taxable income in future years. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The NOL carryback provision of the CARES Act had no impact on the Company due to its tax losses generated during all prior years.

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 March 31, 2022, and December 31, 2021, 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.

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, 2021 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

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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, 2021 which are included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Company Overview

We are a clinical stage, drug platform company addressing Alzheimer's disease ("AD"), Parkinson's disease ("PD") and other chronic neurodegenerative diseases, including AD in Down Syndrome ("AD-DS"). Our lead compound, buntanetap is a small, once a day, orally administered, brain penetrant compound. In several clinical and pre-clinical studies, buntanetap inhibited the synthesis of neurotoxic proteins—amyloid precursor protein APP/A β ("APP"), tau/phospho-tau ("tau") and α -Synuclein (" α SYN")— 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 shown in our 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.

We recently completed two Phase 2a clinical trials. In 2021 we completed a Phase 2a clinical trial in 14 AD and 54 PD patients (the "AD/PD Trial") which began treating patients in August 2020. In collaboration with the Alzheimer's Disease Cooperative Study ("ADCS") we conducted a trial in 16 early AD patients (the "ADCS Trial"). Both clinical trials were double-blind, placebo-controlled studies. We designed the two Phase 2a studies by applying our understanding of the underlying disease states in neurodegeneration and measured not just target, but also pathway validation in the spinal fluid of these patients. We measured as many factors as possible associated with the toxic cascade which begins with high levels of neurotoxic proteins which lead to impaired axonal transport, inflammation, the death of nerve cells and loss of cognition and motor function. By showing both target and pathway validation in two patient populations, we believe that our opportunity for successful Phase 3 studies is better than if we merely demonstrated target validation in one patient population.

We have never been profitable and have incurred net losses since inception. Our accumulated deficit at March 31, 2022 was \$34,620.4 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.

Results of Operations

Operating expenses and other income were comprised of the following:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Operating expenses:		
Research and development	\$ 2,809.8	\$ 2,389.6
General and administrative	\$ 3,104.1	\$ 839.6
Other income:		
Interest income	\$ 19.6	\$ 0.2
Grant income	\$ —	\$ 29.3

Three Months Ended March 31, 2022 and 2021

Research and Development Expenses

Research and development expenses increased by \$420.2 thousand for the three months ended March 31, 2022 compared to the prior year period. The increase was primarily the result of an increase of \$1,189.9 thousand in stock-based compensation expense, partially offset by a decrease of \$740.8 thousand in expenses related to our clinical trials as we completed the AD/PD Trial in 2021. We expect research and development expenses in 2022 will be higher than the prior year as we begin a Phase 3 study in early PD patients.

General and Administrative Expenses

General and administrative expenses increased by \$2,264.5 thousand for the three months ended March 31, 2022 compared to the prior year period. The increase was primarily the result of increases of \$2,221.1 thousand in stock-based compensation expense and \$105.4 thousand in professional fees. We expect general and administrative expenses in 2022 will be higher as compared to 2021 due to increased personnel expenses.

Interest Income

Interest income increased \$19.4 thousand for the three months ended March 31, 2022 compared to the prior year period. The increase was primarily the result of higher average cash and cash equivalents balances and higher interest rates compared to the prior year period.

Grant Income

Grant income decreased \$29.3 thousand for the three months ended March 31, 2022 compared to the prior year period. The income relates to a grant from the NIH to reimburse the costs of our long-term toxicology studies in rats and dogs, which was completed in 2021.

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 March 31, 2022, our principal source of liquidity was our cash, which totaled \$42,668.8 thousand.

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Equity Financings

We closed an equity offering on May 26, 2021, raising gross proceeds of \$50,000.0 thousand and net proceeds of \$46,648.4 thousand, after deducting underwriting discounts and issuance costs.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Statement of Cash Flows Data:		
Total net cash provided by (used in):		
Operating activities	\$ (3,021.8)	\$ (2,474.9)
Financing activities	4.6	3.0
Net decrease in cash and cash equivalents	<u>\$ (3,017.2)</u>	<u>\$ (2,471.9)</u>

Operating Activities

For the three months ended March 31, 2022, cash used in operations increased \$546.9 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 payments to satisfy accrued expenses.

We expect cash used in operating activities to increase in 2022 as compared to 2021 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 was \$4.6 thousand during the three months ended March 31, 2022, attributable to proceeds from the exercise of stock options.

Cash provided by financing activities was \$3.0 thousand during the three months ended March 31, 2021, attributable to proceeds from the exercise of stock options.

Funding Requirements

We expect that current cash and cash equivalents will be sufficient to fund our operations and capital requirements for at least the next 12 months. We believe that these available funds will be sufficient to complete a six-month Phase 3 clinical trial for buntanetap in early PD patients and conduct a second study in early AD patients for this product candidate. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need 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, 2021 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 three months ended March 31, 2022, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2021, which we included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

This item is not required for smaller reporting companies.

Item 4. Controls and Procedures

(a) 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 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 Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

(b) 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 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.

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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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ MARIA MACCECCHINI</u> Maria Maccicchini	President and Chief Executive Officer (principal executive officer)	May 4, 2022
<u>/s/ JEFFREY MCGROARTY</u> Jeffrey McGroarty	Chief Financial Officer (principal financial and accounting officer)	May 4, 2022

**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 Maccicchini, 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: May 4, 2022

/s/ Maria Maccicchini

Maria Maccicchini
President and Chief Executive Officer

**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, Jeffrey McGroarty, 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: May 4, 2022

/s/ Jeffrey McGroarty

Jeffrey McGroarty
Chief Financial Officer

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

In connection with the Quarterly Report of Annovis Bio, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Maria Maccicchini, 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: May 4, 2022

/s/ Maria Maccicchini

Maria Maccicchini
President and Chief Executive Officer

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

In connection with the Quarterly Report of Annovis Bio, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey McGroarty, 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: May 4, 2022

/s/ Jeffrey McGroarty

Jeffrey McGroarty
Chief Financial Officer
