
**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, 2021**

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	NYSE American

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 4, 2021 was: 6,947,269.

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ANNOVIS BIO, INC.
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FOR THE QUARTER ENDED MARCH 31, 2021

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

Annovis Bio, Inc.
Balance Sheets

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,602,807	\$ 8,074,658
Prepaid expenses and other current assets	362,149	44,676
Total current assets	<u>5,964,956</u>	<u>8,119,334</u>
Total assets	<u>\$ 5,964,956</u>	<u>\$ 8,119,334</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 824,565	\$ 341,856
Accrued expenses	772,116	236,524
Total current liabilities	<u>1,596,681</u>	<u>578,380</u>
Total liabilities	<u>1,596,681</u>	<u>578,380</u>
Commitments and contingencies (Note 8)		
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 6,947,120 and 6,891,608 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	695	689
Additional paid-in capital	21,806,328	21,779,340
Accumulated deficit	<u>(17,438,748)</u>	<u>(14,239,075)</u>
Total stockholders' equity	<u>4,368,275</u>	<u>7,540,954</u>
Total liabilities and stockholders' equity	<u>\$ 5,964,956</u>	<u>\$ 8,119,334</u>

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Operations
(unaudited)

	Three Months Ended	
	March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 2,389,583	\$ 66,446
General and administrative	839,627	516,716
Total operating expenses	<u>3,229,210</u>	<u>583,162</u>
Operating loss	(3,229,210)	(583,162)
Other income (expense):		
Change in fair value of derivative liability	—	(26,500)
Interest income (expense), net	197	10,634
Grant income	29,340	157,438
Total other income (expense)	<u>29,537</u>	<u>141,572</u>
Loss before income taxes	(3,199,673)	(441,590)
Income tax expense (benefit)	—	—
Net loss	<u>\$ (3,199,673)</u>	<u>\$ (441,590)</u>
Basic and diluted loss per common share	<u>\$ (0.46)</u>	<u>\$ (0.10)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>6,920,622</u>	<u>4,599,469</u>

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

	Redeemable Convertible Preferred Stock				Stockholders' Equity (Deficit)				
	Series A		Series A-1		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
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
Exercise of warrants	—	—	—	—	51,644	5	(5)	—	—
Share-based compensation expense	—	—	—	—	—	—	23,977	—	23,977
Net loss	—	—	—	—	—	—	—	(3,199,673)	(3,199,673)
Balance, March 31, 2021	—	\$ —	—	\$ —	6,947,120	\$ 695	\$ 21,806,328	\$ (17,438,748)	\$ 4,368,275
Three Months Ended March 31, 2020									
Balance, December 31, 2019	5,133,159	\$ 6,509,303	630,722	\$ 567,649	282,614	\$ 28	\$ 200,600	\$ (8,777,028)	\$ (8,576,400)
Conversion of redeemable convertible preferred stock to common stock upon completion of initial public offering	(5,133,159)	(6,509,303)	(630,722)	(567,649)	4,117,089	412	7,076,540	—	7,076,952
Conversion of convertible promissory notes, including embedded derivative, to common stock upon completion of initial public offering	—	—	—	—	118,470	12	672,512	—	672,524
Issuance of common stock in initial public offering, net of offering costs	—	—	—	—	2,300,000	230	11,955,565	—	11,955,795
Exercise of stock options	—	—	—	—	27,286	3	4,603	—	4,606
Net loss	—	—	—	—	—	—	—	(441,590)	(441,590)
Balance, March 31, 2020	—	\$ —	—	\$ —	6,845,459	\$ 685	\$ 19,909,820	\$ (9,218,618)	\$ 10,691,887

See accompanying notes to financial statements.

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

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (3,199,673)	\$ (441,590)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred financing fees	—	129
Amortization of debt discount	—	396
Share-based compensation expense, including stock issued to consultants and advisors	23,977	—
Change in fair value of derivative liability	—	26,500
Changes in assets and liabilities:		
Grant receivable	—	697,323
Prepaid expenses and other current assets	(317,473)	(272,390)
Accounts payable	482,709	(982,986)
Accrued expenses	535,592	2,213
Net cash used in operating activities	<u>(2,474,868)</u>	<u>(970,405)</u>
Cash flows from financing activities:		
Proceeds from initial public offering of common stock, net of offering costs	—	12,084,406
Proceeds from exercise of stock options	3,017	4,606
Net cash provided by financing activities	<u>3,017</u>	<u>12,089,012</u>
Net (decrease) increase in cash	(2,471,851)	11,118,607
Cash and cash equivalents, beginning of period	8,074,658	1,858
Cash and cash equivalents, end of period	<u>\$ 5,602,807</u>	<u>\$ 11,120,465</u>
Supplemental disclosure of non-cash financing activities:		
Deferred offering costs in accounts payable and accrued expenses	\$ —	\$ 50,000
Conversion of redeemable convertible preferred stock to common stock	\$ —	\$ 7,076,952
Conversion of convertible promissory notes, including embedded derivative, to common stock	\$ —	\$ 672,524

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”) 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”), Parkinson’s disease (“PD”) and Alzheimer’s disease in Down syndrome (“AD-DS”). 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 compound, ANVS401, is a small molecule administered orally that attacks neurodegeneration by entering the brain and inhibiting the translation of multiple neurotoxic proteins thereby impeding the toxic cascade.

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 had an accumulated deficit of \$17,438,748 as of March 31, 2021. The Company 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.

The Company closed its initial public offering (the “IPO”) on January 31, 2020, pursuant to which it sold a total of 2,300,000 shares of common stock at an initial offering price of \$6.00 per share for total gross proceeds of approximately \$13.8 million. The net proceeds of the IPO were approximately \$12.0 million after deducting underwriting discounts, commissions and offering expenses payable by the Company. In conjunction with the 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 is 125% of the initial public offering price. Upon the closing of the IPO, outstanding redeemable convertible preferred stock and convertible promissory notes converted into shares of Company common stock totaling 4,117,089 and 118,470, respectively. The Company’s common stock trades on the NYSE American 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 the completion of its Phase 2a clinical trial in AD and PD (the “AD/PD Trial”) in mid-2021. In order to fund its planned 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 only of normal, recurring adjustments, necessary for a fair presentation of the financial position of Annovis at March 31, 2021, and its results of operations and its cash flows for the three months ended March 31, 2021 and 2020. 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, 2020 and notes thereto contained in the Company’s Annual Report

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on Form 10-K for the year ended December 31, 2020. 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 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 share-based compensation expense, the valuation of the derivative liability 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 redeemable convertible preferred stock, convertible promissory notes, 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) Offering Costs Associated with IPO

Offering costs of \$601,635 incurred in connection with the Company’s IPO, which primarily consisted of direct incremental legal, printing, listing and accounting fees, were offset against proceeds received in the IPO and charged to additional paid-in capital in the three months ended March 31, 2020.

(f) Fair Value of Financial Instruments

The Company’s financial instruments include cash and cash equivalents, accounts payable, accrued expenses, a derivative liability and debt. Cash and cash equivalents and the derivative liability are reported at fair value. The recorded carrying amount of accounts payable and accrued expenses reflect their fair value due to their short-term nature. The carrying value of the interest-bearing debt approximates fair value based upon the borrowing rates currently available to the Company for loans with similar terms and maturities.

(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

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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.

(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) Share-Based Compensation

Share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which is generally the vesting period. Forfeitures are recognized in compensation expense in the period when they occur.

Determining the appropriate fair value of share-based awards requires the use of subjective assumptions including, in the case of stock options, the expected life of the option and expected share price volatility. The expected life of options was estimated using the simplified method, as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment.

The Company uses the Black-Scholes option pricing model to value its option awards. The assumptions used in calculating the fair value of share-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, share-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, 2021 and December 31, 2020, 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, 2021 or December 31, 2020.

(k) Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and clarifying and amending existing guidance. The new

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standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The adoption of this standard did not have an 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, 2021 and December 31, 2020:

	Carrying Value	Fair Value Measurement at March 31, 2021		
		Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 5,602,807	\$ 5,602,807	\$ —	\$ —

	Carrying Value	Fair Value Measurement at December 31, 2020		
		Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 8,074,658	\$ 8,074,658	\$ —	\$ —

(4) Grant Receivable

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 ANVS401 in rats and dogs. The Company began the long-term chronic toxicology studies in November 2019. The Company recognized grant income of \$29,340 and \$157,438 for the three months ended March 31, 2021, and 2020, respectively, in connection with the NIH grant and received payments under the grant of \$29,340 and \$854,761 during the three months ended March 31, 2021 and 2020, respectively. The Company recorded a grant receivable of \$0 as of March 31, 2021 and December 31, 2020, and had no unreimbursed, eligible costs incurred under the grant. As of March 31, 2021, remaining funds available under the grant were \$7,414.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Prepaid insurance	\$ 297,220	\$ 26,542
Prepaid expenses	58,485	11,690
Security deposit	6,444	6,444
Total prepaid expenses and other current assets	<u>\$ 362,149</u>	<u>\$ 44,676</u>

(6) Accrued Expenses

Accrued expenses consisted of the following:

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Payroll and related benefits	\$ 392,885	\$ 16,493
Accrued professional and clinical fees	363,898	216,198
Accrued license payments	15,333	3,833
	<u>\$ 772,116</u>	<u>\$ 236,524</u>

See Note 8 for further detail on the accrued license payments.

(7) Convertible Promissory Notes

In March 2019, the Company issued convertible promissory notes (the “Notes”) to various investors in the aggregate principal amount of \$530,000 with a stated interest rate of 8% compounded annually. On issuance, the Company recognized a discount associated with the Notes related to the fair value of an embedded derivative liability reflecting the share-settlement feature providing for the conversion of the Notes at a 20% discount to the price of the shares issued in a qualified financing. The Company estimated the fair value of the derivative liability using a probability-weighted approach at issuance, as of the end of each reporting period and immediately prior to the closing of the IPO. The change in the fair value of the derivative liability was reflected in the statements of operations. The Company amortized deferred financing fees and debt discount over the term of the Notes as additional interest expense using the effective interest method. The effective interest rate on the Notes was 9.8%. The Company made no cash payments for interest on the Notes. On January 31, 2020, the Company closed its IPO and in accordance with the terms of the Notes, the outstanding Notes plus accrued interest converted into 118,470 shares of Company common stock.

(8) Commitments and Contingencies

(a) Leases

The Company leases its office facilities under a month-to-month operating lease. Total rental expense was \$10,615 and \$10,479 for the three months ended March 31, 2021 and 2020, respectively.

(b) License Agreement

The Company licenses 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 pays a minimum annual commitment of \$46,000 and is 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 Company has paid to the Licensor all annual fees through November 2020. At March 31, 2021 and December 31, 2020, the Company

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had accrued \$15,333 and \$3,833, respectively, in license payments under the term of this license, included in accrued liabilities. No milestones have been achieved as of March 31, 2021. The Licensor also granted the Company a buy-out option which may be exercised at any time during the term of the agreement at increasing amounts based on the achievement of certain milestones. The Company has 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 are recognized in general and administrative expense in the statements of operations.

(c) Employment Agreements

In March 2020, the Company entered into employment agreements with its executive officers. The maximum aggregate severance payments under the agreements are approximately \$720,000.

(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, 2021 and December 31, 2020, the Company did not have any pending legal actions.

(e) Risks and Uncertainties

In March 2020, the clinical trial sites participating in the Company's Phase 2a trial in AD patients in collaboration with the Alzheimer's Disease Cooperative Study temporarily suspended enrollment of new patients because of the ongoing COVID-19 pandemic. Prior to suspension of enrollment, 14 patients had been enrolled and completed treatment, out of a total trial size of 24 patients. The trial sites have reopened, and patient recruitment and treatment have resumed. In addition, due to restrictions related to COVID-19 during 2020, the Company experienced delays in opening clinical trial sites for its AD/PD Trial. In early 2021, the remaining sites which are participating in the AD/PD Trial opened for recruitment and treatment of patients. Although the Company currently believes its clinical trials will be completed on time, the extent to which the COVID-19 pandemic could have a material impact on the 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.

(9) Redeemable Convertible Preferred Stock and Stockholders' Equity

(a) Overview

The Company closed its IPO on January 31, 2020, issuing 2,300,000 shares of common stock. In connection with the closing of the Company's IPO, the then-outstanding 5,133,159 shares of Series A and 630,722 shares of Series A-1 redeemable convertible preferred stock converted into an aggregate of 4,117,089 shares of Company common stock.

The Company's Amended and Restated Certificate of Incorporation was adopted on January 31, 2020 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 is no preferred stock issued or outstanding as of March 31, 2021.

(d) Warrants

In conjunction with the 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 are exercisable commencing January 29, 2021. During the three months ended March 31, 2021, the Company issued 51,644 shares of common stock pursuant to cashless exercise of 95,000 of the warrants. As of March 31, 2021, 5,000 of the warrants were outstanding. The Company accounts for the warrants as a component of stockholders' equity.

(10) Share-Based Compensation

Effective upon the closing of the Company's IPO on January 31, 2020, the Company's 2019 Equity Incentive Plan (the "2019 Plan") became effective, succeeding the Company's previous plan (see Note 1). The previous plan had 352,282 options outstanding as of the effective date of the 2019 Plan. Under the 2019 Plan, 1,000,000 additional shares are authorized to be issued, and no new awards 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. As of March 31, 2021, 168,664 shares were available for future grants.

There were no options or stock awards issued during the three months ended March 31, 2021 and 2020. Share-based compensation expense for the three months ended March 31, 2021 and 2020 was \$23,977 and \$0, respectively. As of March 31, 2021, there were 1,107,598 options outstanding, of which 1,057,598 were vested and exercisable. As of December 31, 2020, there were 1,111,466 options outstanding, of which 1,061,466 were vested and exercisable.

(11) Net Loss Per Share

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

	Three Months Ended	
	March 31,	
	2021	2020
Numerator		
Net loss	\$ (3,199,673)	\$ (441,590)
Denominator		
Weighted-average common shares outstanding, basic and diluted	6,920,622	4,599,469
Net loss per share, basic and diluted	\$ (0.46)	\$ (0.10)

The Company reported a net loss for the three months ended March 31, 2021 and 2020, therefore, the basic and diluted net loss per share are 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 are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	March 31,	
	2021	2020
Stock options	1,107,598	324,996
Warrants	5,000	100,000

In addition, common shares issuable upon the conversion of the Notes were excluded for all periods in which the Notes were outstanding.

(12) Income Taxes

The Company's income tax benefit (expense) was \$0.0 million for the three months ended March 31, 2021 and 2020. 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, 2021 and 2020 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, including its IPO which closed on January 31, 2020, 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, 2021, and December 31, 2020, 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.

(13) Related-Party Transactions

As discussed in Note 7, in March 2019 the Company issued Notes in the aggregate principal amount of \$530,000. Three of the Company's directors purchased an aggregate of \$305,000 of the Notes. On January 31, 2020, the Company closed its IPO, and the outstanding Notes plus accrued interest held by directors converted into 71,429 shares of Company common stock.

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, 2020 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, 2020 which are included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Company Overview

We are a clinical stage, drug platform company addressing neurodegeneration such as Alzheimer's disease ("AD"), Parkinson's disease ("PD") and Alzheimer's disease in Down Syndrome ("AD-DS"). 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. Our lead compound, ANVS401, is a small molecule administered orally that attacks neurodegeneration by entering the brain and inhibiting the translation of neurotoxic proteins—amyloid precursor protein APP/A β ("APP"), tau/phospho-tau ("tau") and α -Synuclein (" α SYN")—thereby impeding the toxic cascade. Human studies in four mildly cognitive impaired patients have shown that ANVS401 lowered the levels of neurotoxic proteins and inflammatory factors. In preclinical studies, lower neurotoxic protein levels led to improved axonal transport, reduced inflammation, lower nerve cell death and improved function.

We are presently conducting two Phase 2a clinical trials. In collaboration with the Alzheimer's Disease Cooperative Study ("ADCS") we are conducting a trial in 24 early AD patients (the "ADCS Trial"). Under an agreement with UC San Diego, where ADCS is located, we have contracted to provide study supplies at our cost but the remaining costs of the ADCS Trial are paid for by the National Institutes of Health ("NIH"). We are also conducting a Phase 2a clinical trial in 14 AD and 54 PD patients (the "AD/PD Trial") which began treating patients in August 2020. Both clinical trials are double-blind, placebo-controlled studies.

In March 2020, the clinical trial sites participating in the ADCS Trial suspended enrollment of new patients because of the ongoing COVID-19 pandemic. Prior to suspension of enrollment, 14 patients had been enrolled and completed treatment, out of a total trial size of 24 patients. The trial sites have reopened, and patient recruitment and treatment have resumed. In addition, due to restrictions related to COVID-19 during 2020, we experienced delays in opening clinical trial sites for the AD/PD Trial. In early 2021, the remaining sites which are participating in the AD/PD Trial opened for recruitment and treatment of patients. Although we currently believe our clinical trials will be completed on time, the extent to which the COVID-19 pandemic could have a material impact on the clinical trials is dependent on the spread of the disease and government and healthcare system responses to such spread, which are presently highly uncertain. We continue to evaluate the potential impact.

We have never been profitable and have incurred net losses since inception. Our accumulated deficit at March 31, 2021 was \$17,438.7 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 (expense) were comprised of the following:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Operating expenses:		
Research and development	\$ 2,389.6	\$ 66.4
General and administrative	839.6	516.7
Other income (expense):		
Change in fair value of derivative liability	—	(26.5)
Interest income (expense), net	0.2	10.6
Grant income	29.3	157.4

Three Months Ended March 31, 2021 and 2020

Research and Development Expenses

Research and development expenses increased by \$2,323.2 thousand for the three months ended March 31, 2021 compared to the prior year period. The increase was primarily the result of an increase of \$1,851.1 thousand in expenses related to our AD/PD Trial which began treating patients in August 2020, an increase of \$253.3 thousand in costs for the manufacture of clinical materials, and an increase of \$194.7 thousand in personnel expenses. For the year ending December 31, 2021, we expect research and development expenses to be higher than the prior year as we complete our AD/PD Trial and commence the planning of a Phase 3 study. The expenses for the AD/PD Trial were higher in the quarter ended March 31, 2021, due in part to the achievement of several milestones in the trial during the period. We expect quarterly expenses for the AD/PD Trial as compared to the quarter ended March 31, 2021 will decrease over the remainder of 2021 as the trial is completed.

General and Administrative Expenses

General and administrative expenses increased by \$322.9 thousand for the three months ended March 31, 2021 compared to the prior year period. The increase was primarily the result of increases of \$360.0 thousand in accrued incentive compensation expense, partially offset by a reduction in other compensation expense related to general and administrative activities. We expect general and administrative expenses in 2021 will be higher as compared to 2020 due to increased personnel expenses.

Change in Fair Value of Derivative Liability

The derivative liability represents an embedded derivative in our convertible promissory notes which were issued in March 2019. At each balance sheet date, we estimated the fair value of the derivative liability and recognized any change in our statements of operations. The fair value of the derivative liability was adjusted to \$132.5 thousand immediately prior to the closing of the IPO on January 31, 2020. Effective upon the closing of the IPO, the derivative liability was eliminated, and the amount was reclassified to additional paid-in capital on the balance sheet.

Interest Income (Expense), Net

Interest income (expense), net decreased \$10.4 thousand for the three months ended March 31, 2021 compared to the prior year period. The decrease was primarily the result of lower interest rates and lower average cash balance compared to the prior year period.

Grant Income

Grant income decreased \$128.1 thousand for the three months ended March 31, 2021 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 substantially completed in 2020.

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 revenues from the sale of products, and we do not anticipate generating any revenues from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of March 31, 2021, our principal source of liquidity was our cash, which totaled \$5,602.8 thousand.

Equity Financings

We closed our IPO on January 31, 2020, raising gross proceeds of \$13,800.0 thousand and net proceeds of \$12,034.4 thousand, after deducting underwriting discounts and commissions and offering expenses, in the three months ended March 31, 2020.

Debt Financings

In March 2019 we issued \$530.0 thousand principal amount of convertible promissory notes. Upon the closing of our IPO on January 31, 2020, the outstanding convertible promissory notes plus accrued interest converted into 118,470 shares of our common stock at a 20% discount to the public offering price.

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities.

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Statement of Cash Flows Data:		
Total net cash provided by (used in):		
Operating activities	\$ (2,474.9)	\$ (970.4)
Financing activities	3.0	12,089.0
Increase (decrease) in cash and cash equivalents	<u>\$ (2,471.9)</u>	<u>\$ 11,118.6</u>

Operating Activities

For the three months ended March 31, 2021, cash used in operations increased \$1,504.5 thousand compared to the same period in the prior year. The increase in cash used in operations was primarily the result of the ongoing costs of our AD/PD Trial in the three months ended March 31, 2021.

We expect cash used in operating activities to increase in 2021 as compared to 2020 due to an expected increase in our operating losses associated with ongoing development of our product candidates, including our AD/PD Trial.

Financing Activities

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.

Cash provided by financing activities was \$12,089.0 thousand during the three months ended March 31, 2020, attributable to net proceeds from our IPO of \$12,084.4 thousand, after deducting underwriting discounts and commissions and offering expenses, and \$4.6 thousand 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 our Phase 2a clinical trials for ANVS401 and commence the planning of a Phase 3 study 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, 2020 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, 2021, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2020, which we included in our Annual Report on Form 10-K for the year ended December 31, 2020.

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.)
10.1*#	Manufacturing Agreement, dated March 9, 2021, by and between the Registrant and Wilmington PharmaTech Company, LLC .
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
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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 Maccocchi	President and Chief Executive Officer (principal executive officer)	May 6, 2021
<u>/s/ JEFFREY MCGROARTY</u> Jeffrey McGroarty	Chief Financial Officer (principal financial and accounting officer)	May 6, 2021

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.



Wilmington PharmaTech Company LLC

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Web: www.WilmingtonPharmaTech.com

Wilmington PharmaTech PROPOSAL #: WPT-210203-06R5

- 1. Preparation Date: March 9, 2021
- 2. Client: Maria Maccicchini, Ph. D.
President and CEO
Annovis Bio, Inc.
1055 Westlakes Drive
Berwyn, PA 19312
Tel: [***]
E-mail: [***]
- 3. Project Name: Process research, non-GMP and GMP Synthesis and reference standard of Posiphen Tartrate
- 4. Contract: The project scope, budget summary, standard terms and conditions for pharmaceutical development services in this proposal, when accepted by the client, shall become a contract binding on both parties.
- 5. Description of Service: See Part A: Project Scope
- 6. Payment: See Part B: Project Pricing & Invoice Schedule
- 7. Effective Date: Beginning when this proposal is approved by both parties.
- 8. Term: From the effective date until completion by Wilmington PharmaTech of this project.
- 9. Confidentiality: The confidentiality agreement entered into between the parties shall apply to all confidential information about the parties and the services to be conducted under this contract and such a confidentiality agreement is deemed to be incorporated herein by reference.

Wilmington PharmaTech

Annovis Bio, Inc.

By: /s/ Hui-Yin Li
 Name: Hui-Yin (Harry) Li
 Title: President
 Date: March 9, 2021

By: /s/ Maria Maccicchini
 Name: Maria Maccicchini
 Title: President & Chief Executive Officer
 Date: March 9, 2021



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Part A: Project Scope

Upon request from Annovis Bio (Annovis), Wilmington PharmaTech Company (WPT) will perform process research and non-GMP manufacturing of (+)-phenserine D-(-)- tartrate salt (also known as posiphen tartrate) starting with (+)-eserethole as starting material. The current synthetic scheme of posiphen tartrate is presented below as illustrated in Scheme I.



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Scope of Work

The following items are included in the scope of this project:

Sourcing of GMP starting material (+)-Eserethole

- Purchase [***] kg of (+)-etherethole in a purity of [***] by HPLC, with a “+”-optical rotation. The tentative specification of (+)-eserethole is listed in Appendix I.
- Test the material to prepare (+)-Posiphen D-tartrate to make sure it can generate the product to meet the specifications.

Lab Familiarization and Process Research

- Perform process research to repeat the existing synthesis of (+)-Posiphen D- tartrate (lab familiarization) starting from (+)-eserethole and perform minor process R&D to attempt to improve and/or optimize the process if necessary and adapt the process to the existing equipment.

Non-GMP Demo Batch of (+)-Posiphen D-Tartrate (up to [***] g) and Ref Std

- Production of a non-GMP demo batch of (+)-Posiphen D-Tartrate (up to [***] g).
- Designate about [***] g of the API as the reference standard. Perform repurification if necessary.
- Perform analysis and generate a COA to certificate it as a reference standard.
- The tentative specification of (+)-Posiphen D-Tartrate is listed in Appendix II.

cGMP production of [***] kg (+)-Posiphen D-Tartrate

- Production of [***] kg GMP batch of (+)-Posiphen D-Tartrate.
- Perform GMP release tests and generate a COA.
- Prepare a campaign summary for the GMP batch.
- The tentative specification of (+)-Posiphen D-Tartrate is listed in Appendix II.



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Deliverables

- Purchase of about [***] kg of (+)-eserethole in China.
- Lab familiarization and process research in US with updates and report.
- Non-GMP demo batch (up to [***] g) of Posiphen tartrate prepared in US.
- [***] kg cGMP batch of Posiphen tartrate with COA.
- Release and certify a batch of [***] g from the demo batch as reference standard and issue a COA.
- Analytical method setup and qualification for an achiral HPLC method, a chiral HPLC method and one GC method.

Note: Annovis will receive [***] kg of GMP Posiphen by [***]. Annovis will contract up to additional [***] kg of Posiphen. If the new batch is ordered by [***], the additional [***] kg of Posiphen will be delivered by [***].

Note: Annovis will own the intellectual property (IP) that is generated by Wilmington PharmaTech Company LLC for the Posiphen related work starting from (+)-eserethole as a starting material. A diagram to make (+)-eserethole will be provided.

Required from the Customer

- Any available intermediates as HPLC marker
- Achiral HPLC method
- Chiral HPLC method

Project Schedule

Wilmington PharmaTech will initiate work promptly upon acceptance of this proposal by both parties and upon receipt of all necessary starting materials and reagents. WPT estimates that the timeline for completing the scope of work is about [***] weeks from the receipt of the PO.

This schedule is our best estimation based on the technical package provided by the client and/or the best knowledge we can find from public sources. It is assumed that all customer and/or literature procedures will work as described and will provide comparable yield and purity with only relatively minor conventional changes and improvements to allow for scale-up. The cost and schedule could be affected if the technical package and/or literature procedures are not reproducible. Rush service to provide an accelerated delivery date is available upon request at additional cost, provided that the technical package and/or the literature procedures are reproducible.

The cost, lead time, and schedule are based on the best knowledge of starting materials and commercially available intermediates that we can find from public sources. The project may be delayed and/or the cost may vary depending upon cost and timely availability of starting materials and commercially available intermediates.



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Project Staffing and Communications

1. [***] will be the Wilmington PharmaTech project manager and serve as the technical liaison for process chemistry with the Client. For Analytical, Dawn Chen will be the Wilmington PharmaTech technical liaison with the Client.
2. Periodic project progress updates will be provided by e-mail at a frequency agreed to by the Client and Wilmington PharmaTech project managers. Conference calls will be arranged to discuss project results and adjust the project plan on an as needed basis. Meetings between the Client and Wilmington PharmaTech will be scheduled as needed. Additional discussion of the results and adjustment of the project scope or plan will be communicated on an "as needed" basis.
3. The Client's personnel will have access to the Wilmington PharmaTech facilities used on the project for the purposes of observing key runs and providing technical input and direction. The Client's personnel will follow the Wilmington PharmaTech safety practices while on-site.



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Contact information

[***]



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Part B. Project Pricing & Invoice Schedule

1. The Wilmington PharmaTech Fee for complete execution of the scope of work shown below:

Item #	Service Description	Cost	Notes
	Part 1: Synthesis		
1a	<p>Sourcing of (+)-eserethole (starting material)</p> <p>WPT will purchase about [***] kg of (+)-eserethole from China. This will be the starting material for lab familiarization and both the [***] g demo batch and the [***] kg GMP batch.</p> <p>This amount can be reduced if the overall yield of preparing posiphen can be improved and the leftover of (+)-eserethole can be used for a later campaign.</p>	[***]	<p><i>Note: This material will be purchased from a vendor. The lead time is about [***] weeks after receiving a PO.</i></p>
1b	<p>Lab Familiarization (to support up to [***] g demo)</p> <p><i>Perform lab familiarization to repeat the existing synthesis of (+)-Posiphen D-tartrate from (+)- eserethole and perform minimal process R&D as needed if necessary to adapt the process to the existing equipment.</i></p>	[***]	<p><i>This is for [***] weeks of time based research. Additional research can be performed at additional cost upon mutual agreement.</i></p> <p><i>The required (+)-eserethole starting material is covered by Item 1a.</i></p>
1c	<p>Demo Batch of (+)-Posiphen D-Tartrate (about [***] g)</p> <p><i>Upon successful completion of the lab familiarization, a non-GMP demo batch of up to [***] will be synthesized.</i></p>	[***]	<p><i>The lead time is about [***] weeks after completion of 1a and 1b.</i></p> <p><i>The required (+)-eserethole starting material (about [***] kg) is covered by Item 1a.</i></p> <p><i>[***]g will be retrieved and used as reference standard.</i></p>
1d	<p>Project summary for Lab familiarization and Demo Batch</p>	[***]	



Wilmington PharmaTech Company LLC

229A Lake Drive
 Newark, DE 19702, USA
 Phone: (302) 737-9916 Fax: (302) 261-7000
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Item #	Service Description	Cost	Notes
1e	Manufacture of GMP Batch of (+)-Posiphen D- Tartrate ([***] kg)	[***]	<i>The lead time is about [***] weeks after receiving of (+)-eserethole, and completion of the lab familiarization and the demo batch. The overall estimated timeline for [***] kg of API is about [***] weeks after receiving the PO.</i> <i>The required (+)-eserethole starting material (about [***] kg) is covered by Item 1a.</i>
1f	Campaign summary for [***] kg GMP batch	[***]	
	Subtotal cost for Part 1	[***]	
	Part B: Analytical development		
2a	Achiral HPLC Method Set-up and qualification This work includes method set-up for achiral HPLC method set-up for starting materials, reaction monitoring, and final API release. Method qualification work will include the following tasks: <ul style="list-style-type: none"> • System suitability • Linearity • Repeatability • LOD and LOQ Note: Forced degradation (stress studies) are not included.	[***]for one (1) method set-up. [***]for method qualification.	<i>The customer will provide the current HPLC method and samples of all available intermediates and related products and the final product as HPLC markers.</i> <i>A written method and qualification report will be provided. A protocol is not required for method qualification.</i> <i>Note: HPLC method development is <u>not</u> included but may be available by separate proposal.</i>



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Item #	Service Description	Cost	Notes
2b	<p>Chiral HPLC Method Set-up and qualification</p> <p>This work includes method set-up for achiral HPLC method set-up for starting materials, reaction monitoring, and final API release.</p> <p>Method qualification work will include the following tasks:</p> <ul style="list-style-type: none"> • System suitability • Linearity • Repeatability • LOD and LOQ 	<p>[***] for one (1) method set-up.</p> <p>[***] for method qualification.</p> <p>Note: Timeline is about [***] week for setup and [***] weeks for method qualification.</p>	<p><i>The customer will provide the current chiral HPLC method and enantiomer (-)-phenserine as HPLC marker.</i></p> <p><i>A written method and qualification report will be provided. A protocol is not required for method qualification.</i></p> <p><i>Note: HPLC method development is <u>not</u> included but may be available by separate proposal.</i></p> <p><i>Note: Annovis can choose to have WPT synthesize the enantiomer (-)-phenserine with an additional fee (optional item 10).</i></p>
2c	<p>GC Residual Solvent Method Setup and Qualification</p> <p>GC method qualification will include the following tasks:</p> <ul style="list-style-type: none"> • System suitability • Linearity • Specificity • Accuracy • Repeatability • LOD and LOQ 	<p>[***] for one (1) method setup</p> <p>[***] for one (1) method qualification</p> <p>Note: Timeline is about [***] week for setup and [***] weeks for</p>	<p><i>Lead time is about [***] weeks.</i></p> <p><i>A written method and qualification report will be provided. A protocol is not required for method qualification.</i></p> <p><i>Note: Assuming one GC method can be used for all solvents. An additional charge will apply if more than one method is required.</i></p>
2d	<p>Analytical HPLC columns</p>	<p>[***]</p>	<p><i>To purchase [***].</i></p>
	<p>Subtotal for Part 2</p>	<p>[***]</p>	
	<p>Part 3: Reference standard and release</p>		
3a	<p>Release Testing with COA for the [***] g reference standard</p> <p>Perform GLP release testing and generate a COA.</p> <p>COA tests include appearance, IR, ¹H NMR, elemental analysis, HPLC area%, ee by chiral HPLC, tartaric acid, residual solvents by GC, elemental impurities, ROI and KF.</p>	<p>[***]</p> <p>Note: cost is per batch and the timeline is about [***] weeks.</p>	<p><i>Other tests can be requested at additional cost.</i></p>



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Item #	Service Description	Cost	Notes
3b	<p>GMP Release Testing with COA for the GMP lot of (+)-Posiphen D-Tartrate</p> <p>Perform GMP release testing and generate a COA.</p> <p>COA tests include appearance, IR, ¹H NMR, elemental analysis, HPLC area%, assay (HPLC area), ee by chiral HPLC, tartaric acid, residual solvents by GC, elemental impurities, ROI and KF.</p>	<p>[***]</p> <p>Note: cost is per batch and the timeline is about [***] weeks.</p>	<p><i>Other tests can be requested at additional cost.</i></p>
	Subtotal for Part 3	[***]	
4	<p>Shipping and Handling</p> <p>Ship the product to a designated recipient(s)</p>	[***]	
5	<p>Weekly progress update</p> <p>Progress updates and reports will be provided approximately weekly.</p>	[***]	
6	<p>Special Materials</p> <p>Any special items (e.g. special reagents, starting materials, solvents, HPLC columns, etc.) required for the project will be charged at cost with written pre-approval from the customer.</p>	[***]	<p><i>Will be billed when occurred. Must be pre-approved by the client in writing.</i></p>
7	<p>Out of scope Work</p>	[***]	<p><i>The cost will be [***]/hour with additional approval/instruction from the client.</i></p>
	Total production cost (Part 1-3)	[***]	<p><i>By using vendor 2 for (+)- eserethole.</i></p>
	Part 4: Stability		
8	<p>Setup ICH stability for the GMP batch of (+)- Posiphen D-Tartrate for up to 3 years</p> <p>Setup ICH stability at two conditions [***]</p>	<p>[***]</p> <p>Note: cost will be billed per pulling</p>	[***]
	Subtotal for Part 4	[***]	
9	<p>Preparation of (-)-phenserine (optional) as reference material for chiral method setup and qualification</p>	[***]	<p><i>Optional, can be executed upon mutual agreement.</i></p>



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Item #	Service Description	Cost	Notes
10	IC method setup and qualification	[[***/method setup [[***/ for method qualification	<i>Optional, can be executed upon mutual agreement. A written method and a qualification report will be provide. Qualification no included.</i>
11	API hydrate study (e.g. DVS experiment)	N/A	<i>Not included, but can be performed at additional cost.</i>
12	API salt screening	N/A	<i>Not included, but can be performed at additional cost.</i>
13	API polymorph screening and control	N/A	<i>Not included, but can be performed at additional cost.</i>
14	Crystal size control	N/A	<i>Not included, but can be performed at additional cost.</i>
15	API unknown impurity ID, isolation, preparation, certification and control; additional analytical method investigations	N/A	<i>Not included, but can be performed at additional cost.</i>
16	Final API residual solvent control It is assumed that all organic solvents can be removed under normal vacuum drying condition. If not, additional work and cost might be needed upon client's approval.	N/A	<i>Not included, but can be performed at additional cost. It is assumed that all organic solvents can be removed to acceptable levels under normal vacuum drying condition. If not, additional work and cost might be needed upon client's approval.</i>
17	API sample management	N/A	<i>Not included, but can be performed at additional cost.</i>
18	Genotoxic impurity analysis	N/A	<i>Not included, but can be performed at additional cost.</i>
19	Stability and Photostability (ICH)	N/A	<i>Not included, but can be performed at additional cost.</i>
20	Final API heavy metal control	N/A	<i>Not included, but can be performed at additional cost.</i>

Note: Unless a service is specifically identified as included in the "Service Description", the service is not included in this proposal, but may be available by a separate proposal with additional cost.

Note: In the event that unanticipated circumstances or technical difficulties arise that interfere with or preclude completion of the scope of work as quoted, WPT will notify Customer to discuss the best alternative path forward. Pre-approval is required if there is additional cost.

Note: WPT reserves the right to adjust the pricing and timelines, as mutually agreed upon in consultation with customer, or to cancel the order in part or in its entirety if no satisfactory resolution of the issues can be achieved. In the event of cancellation by



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WPT, only work performed up to the point of cancellation will be invoiced. Any prepayment made in excess will be refunded to customer.

Note: Deviations from the initial assumptions may have an impact on the scope of the work. Should this occur, both parties will enter into good faith negotiations to redefine the scope of the project.

2. Payment schedule:

Cost of Item 1a (50%), Item 1b	Upon receiving PO or signed proposal
Cost of Item 1a (remaining 50%)	Upon completion
Cost of Part 1c-1d	Upon completion
Cost of Part 2	Upon completion
Cost of Part 3	Upon completion
Part 4 (Stability)	Billed by pulling schedule

3. Early termination: In case the project is terminated by the Client for any reason, the project will be charged at actual cost. The cost calculation is based on [***] per Ph. D. per day, [***] per associate chemist per day, [***] per hour per Senior manager and other actual costs listed in Part B, 5 below.

4. Failure to deliver: In case Wilmington PharmaTech fails to deliver satisfactory results due to natural properties of this compound, the project will be charged at actual cost. The cost calculation is based on [***] per Ph. D. per day, [***] per associate chemist per day, [***] per hour per Senior manager and other actual costs listed in Part B, 5 below. However, the total amount will not exceed [***] of the original quote price.

5. Special requirements such as operating supplies, analytical columns, containers, shipping and handling, and waste disposal may be billed to the Client at actual cost plus [***] as incurred with advance notice. Direct expense allocations have been included where appropriate.

6. Sample storage. WPT will provide [***] months of storage free of charge for samples produced under this proposal. After [***] months, WPT can provide extended storage service under a separate proposal if there is a need.

7. WPT will provide GMP documentation storage free of charge for [***] years from the date of completion of the project for GMP documentation produced under this proposal. After [***], WPT can provide extended storage service under a separate proposal if there is a need.



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8. All payment should be sent to:

Payment method: Check

Accounts Receivable
Wilmington PharmaTech
229A Lake Drive
Newark, DE 19702

9. This proposal is valid for 21 days and is subject to final acceptance by Wilmington PharmaTech.

AUTHORIZATION

The proposed project may be authorized by returning or faxing Proposal to:

[***]
Wilmington PharmaTech
229A Lake Drive Newark, DE 19702, USA
Phone: [***]
Fax: [***]
Email: [***]



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Appendix I: Tentative specifications for (+)-eserethole

Specification FOR (+)-ESERETHOLE

[***]

Appendix II: Tentative specifications for (+)-Posiphen D-Tartrate

Specification FOR (+)-POSIPHEN D-TARTRATE API

[***]

**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 6, 2021

/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 6, 2021

/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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Maria Maccacchini, 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 6, 2021

/s/ Maria Maccacchini

Maria Maccacchini
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, 2021 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 6, 2021

/s/ Jeffrey McGroarty

Jeffrey McGroarty
Chief Financial Officer
