ANNOVIS BIO, INC.

FORM 10-Q
(Quarterly Report)

Filed 07/29/20 for the Period Ending 06/30/20

Address	1055 WESTLAKES DRIVE, SUITE 300
	BERWYN, PA, 19312
Telephone	610-727-3913
CIK	0001477845
Symbol	ANVS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2020

OR

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

COMMISSION FILE NUMBER 001-39202

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

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

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

(610) 727-3913
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	ANVS	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	☐	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 July 28, 2020 was: 6,866,608.

ANNOVIS BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2020

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements

Annovis Bio, Inc.
Balance Sheets

	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 9,763,270	$ 1,858
Grant receivable	199,221	735,075
Prepaid expenses and other current assets	238,725	10,579
Total current assets	10,201,216	747,512
Long-term assets:		
Deferred offering costs	—	369,595
Total long-term assets	—	369,595
Total assets	$ 10,201,216	$ 1,117,107
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 124,445	$ 1,233,877
Accrued expenses	578,491	776,871
Total current liabilities	702,936	2,010,748
Long-term liabilities:		
Derivative liability	—	106,000
Convertible promissory notes, net of unamortized deferred financing fees of $7,431 and debt discount of $22,762 at December 31, 2019	—	499,807
Total long-term liabilities	—	605,807
Total liabilities	702,936	2,616,555
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock—$0.0001 par value:		
Series A - 0 and 5,133,159 shares authorized, issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	6,509,303
Series A-1 - 0 and 1,111,111 shares authorized at June 30, 2020 and December 31, 2019, respectively, and 0 and 630,722 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	567,649
Stockholders' equity (deficit):		
Preferred stock - $0.0001 par value, 2,000,000 and 0 shares authorized at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock - $0.0001 par value, 35,000,000 and 10,150,000 shares authorized at June 30, 2020 and December 31, 2019, respectively, and 6,866,608 and 282,614 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	687	28
Additional paid-in capital	21,025,701	200,600
Accumulated deficit	(11,528,108)	(8,777,028)
Total stockholders' equity (deficit)	9,498,280	(8,576,400)
Total liabilities and stockholders' equity (deficit)	$ 10,201,216	$ 1,117,107

See accompanying notes to financial statements.

Annovis Bio, Inc.
Statements of Operations
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 856,478	$ 6,040	$ 922,924	$ 12,061
General and administrative	1,687,151	300,036	2,203,867	480,805
Total operating expenses	2,543,629	306,076	3,126,791	492,866
Operating loss	(2,543,629)	(306,076)	(3,126,791)	(492,866)
Other income (expense):				
Change in fair value of derivative liability	—	(26,500)	(26,500)	(26,500)
Interest income (expense), net	25,878	(12,124)	36,512	(16,237)
Grant income	208,261	—	365,699	—
Total other income (expense)	234,139	(38,624)	375,711	(42,737)
Loss before income taxes	(2,309,490)	(344,700)	(2,751,080)	(535,603)
Income tax expense (benefit)	—	—	—	—
Net loss	$ (2,309,490)	$ (344,700)	$ (2,751,080)	$ (535,603)
Basic and diluted loss per common share	$ (0.34)	$ (1.22)	$ (0.48)	$ (1.90)
Weighted average number of common shares outstanding, basic and diluted	6,860,847	282,614	5,730,158	282,614

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			
Six Months Ended June 30, 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
Exercise of stock options	—	—	—	—	21,149	2	4,609	—	4,611
Share-based compensation expense	—	—	—	—	—	—	1,111,272	—	1,111,272
Net loss	—	—	—	—	—	—	—	(2,309,490)	(2,309,490)
Balance, June 30, 2020	—	$ —	—	$ —	6,866,608	$ 687	$ 21,025,701	$ (11,528,108)	$ 9,498,280
Six Months Ended June 30, 2019									
Balance, December 31, 2018	5,133,159	$ 6,509,303	630,722	$ 567,649	282,614	$ 28	$ 192,117	$ (7,786,048)	$ (7,593,903)
Share-based compensation expense	—	—	—	—	—	—	8,859	—	8,859
Net loss	—	—	—	—	—	—	—	(190,903)	(190,903)
Balance, March 31, 2019	5,133,159	6,509,303	630,722	567,649	282,614	28	200,976	(7,976,951)	(7,775,947)
Net loss	—	—	—	—	—	—	—	(344,700)	(344,700)
Balance, June 30, 2019	5,133,159	$ 6,509,303	630,722	$ 567,649	282,614	$ 28	$ 200,976	$ (8,321,651)	$ (8,120,647)

See accompanying notes to financial statements.

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (2,751,080)	$ (535,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred financing fees	129	445
Amortization of debt discount	396	1,454
Share-based compensation expense	1,111,272	8,859
Change in fair value of derivative liability	26,500	26,500
Changes in assets and liabilities:		
Grant receivable	535,854	—
Prepaid expenses and other current assets	(228,146)	(29,099)
Accounts payable	(913,071)	(68,425)
Accrued expenses	(64,065)	216,537
Net cash used in operating activities	(2,282,211)	(379,332)
Cash flows from financing activities:		
Proceeds from initial public offering of common stock, net of offering costs	12,034,406	—
Proceeds from issuance of convertible promissory notes	—	530,000
Proceeds from exercise of stock options	9,217	—
Payment of deferred offering costs	—	(73,128)
Payment of deferred financing fees	—	(8,301)
Net cash provided by financing activities	12,043,623	448,571
Net increase in cash	9,761,412	69,239
Cash and cash equivalents, beginning of period	1,858	35,312
Cash and cash equivalents, end of period	$ 9,763,270	$ 104,551
Supplemental disclosure of cash flow information		
Deferred offering costs in accounts payable and accrued expenses	$ —	$ 77,996
Deferred financing fees in accounts payable and accrued expenses	$ —	$ 321
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 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 improving axonal transport.

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 $11,528,108 as of June 30, 2020. 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.

On January 28, 2020, the Company announced the pricing of its initial public offering (the "IPO") of 2,000,000 shares of its common stock at an initial offering price of $6.00 per share. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 300,000 shares of common stock at the public offering price. The Company's common stock commenced trading on the NYSE American on January 29, 2020 under the ticker symbol "ANVS". The IPO closed on January 31, 2020 at which time the underwriters exercised their option to purchase 300,000 additional shares of the Company's common stock bringing the total number of shares of common stock sold by the Company to 2,300,000 shares. The gross proceeds from the IPO, including proceeds from the exercise of the underwriters' option to purchase additional shares, were 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, including offering costs paid in 2019. 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.

As of the date these financial statements are issued, management believes that the current cash and cash equivalents and funding from existing grants are sufficient to fund operations and capital requirements for at least the next 12 months. The Company will need to raise additional capital to complete clinical development of and to commercially develop its product candidates. 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 June 30, 2020, and its results of operations and its cash flows for the three and six

months ended June 30, 2020 and 2019. 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, 2019 and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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 ("FDIC"). Total cash was $9,763,270 and $1,858 as of June 30, 2020 and December 31, 2019, respectively.

(e) Offering Costs Associated with IPO

Included in long-term assets as of June 30, 2020 and December 31, 2019, were deferred offering costs of $0 and $369,595, respectively, incurred in connection with the Company's IPO which primarily consisted of direct incremental legal, printing, listing and accounting fees. Offering costs of $601,635 were offset against proceeds received in the IPO and charged to additional paid-in capital in the six months ended June 30, 2020. Of these offering costs, $78,611 was paid during the year ended December 31, 2019.

(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 external research and development expenses incurred under arrangements with third parties, such as contract research organizations and consultants. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record net prepaid or accrued expenses related to these costs.

(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. Grants 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 the fair value of the Company's common shares, and for 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.

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.

(k) Recent Accounting Pronouncements

In March 2018, the FASB issued ASU 2018-5—Income Taxes (Topic 740): Amendments to SEC Paragraphs pursuant to SEC Staff Accounting Bulletin No. 118. This ASU provided guidance related to Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 118 ("SAB 118"), which addresses the accounting implications of the Tax Cuts and Jobs Act of 2107 (the "Tax Act"). SAB 118 allows a company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date and was effective upon issuance. The Company has analyzed the Tax Act, and in certain areas, has made reasonable estimates of the effects on its financial statements and tax disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820)—Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. The new guidance improves and clarifies the fair value measurement disclosure requirement of ASC 820. The new disclosure requirements include the changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurement held at the end of reporting period and the explicit requirement to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The other provisions of ASU 2018-13 also include eliminated and modified disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019 with early adoption permitted. The adoption of ASU 2018-13 in the first quarter of 2020 did not have a significant impact on the Company's financial statements.

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 standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating ASU 2019-12 but does not believe the adoption of this standard will have a significant impact on its financial statements.

(l) Reverse Stock Split

On July 31, 2019, the board of directors (the "Board") and shareholders of the Company approved a reverse stock split of the Company's common stock at a ratio of one share for every 1.4 shares previously held. All common stock share and per-share data included in these financial statements have been retroactively adjusted to reflect the reverse stock split.

(3) Fair Value Measurements

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

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

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

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

The following table provides the carrying value and fair value of certain financial assets and liabilities of the Company measured at fair value on a recurring basis as of June 30, 2020 and December 31, 2019:

		Fair Value Measurement at June 30, 2020		
	Carrying Value	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 9,763,270	$ 9,763,270	$ —	$ —

		Fair Value Measurement at December 31, 2019		
	Carrying Value	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 1,858	$ 1,858	$ —	$ —
Derivative liability	$ 106,000	$ —	$ —	$ 106,000

The derivative liability was associated with the March 2019 issuance of convertible promissory notes (see Note 7). The Company computed the fair value at the date of issuance of $26,500 related to the embedded share settlement feature providing for 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 using a probability weighted approach. Using the same methodology, the Company determined the fair value of the derivative liability immediately prior to the closing of the IPO was $132,500 and at December 31, 2019 was $106,000. The change in the fair value of the derivative liability is reflected in the statements of operations.

(4) Grant Receivable

In September 2019, the Company received a Notice of Award for a $1.7 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 recorded a grant receivable of $199,221 and $735,075 as of June 30, 2020 and December 31, 2019, respectively, to reflect unreimbursed, eligible costs incurred under the grant.

The Company recognized grant income of $208,261 and $365,699 for the three and six months ended June 30, 2020, respectively, in connection with the NIH grant and received payments under the grant of $901,553 during the six months ended June 30, 2020.

(5) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2020	December 31, 2019
Prepaid insurance	$ 193,573	$ —
Prepaid expenses	38,708	4,135
Security deposit	6,444	6,444
Total prepaid expenses and other current assets	$ 238,725	$ 10,579

(6) Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2020	December 31, 2019
Payroll and related benefits	$ 18,279	$ 131,530
Accrued interest expense	—	36,041
Accrued professional fees	31,212	103,300
Accrued license payments	529,000	506,000
	$ 578,491	$ 776,871

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. Interest accrued at 8% compounded annually on all Notes, and the maturity date was defined as the earlier of a Liquidity Event or upon the written demand of the holders of a majority of the outstanding principal amount of the Notes made any time after December 31, 2023. A Liquidity Event was defined as (i) the date of the closing of a merger or reorganization of the Company with another entity; (ii) the sale of substantially all of the assets of the Company in which the Company's stockholders own less than 50% of the equity securities after the event; or (iii) a liquidation of the Company.

The Company incurred costs of $8,622 in connection with the issuance of the Notes. In addition, on issuance, the Company recognized a discount associated with the Notes of $26,500 related to the fair value of an embedded derivative reflecting the share-settlement provision upon the closing of a qualified financing. Unamortized deferred financing fees and debt discount were deducted from the face amount of the Notes on the balance sheets. The Company amortized the 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 during the six months ended June 30, 2020 or 2019.

On January 31, 2020, the Company closed its IPO. In accordance with the terms of the Notes, the outstanding Notes plus accrued interest converted into 118,470 shares of Company common stock at a 20% discount to the initial offering price of shares issued in the IPO.

(8) Commitments and Contingencies

(a) Leases

The Company leases its office facilities under a month-to-month operating lease. Total rental expense was $10,336 and $8,625 for the three months ended June 30, 2020 and 2019, respectively and $20,815 and $14,337 for the six months ended June 30, 2020 and 2019, respectively.

(b) License Agreements

In November 2008, the Company licensed the rights to certain chemical compounds, know-how and intellectual property rights that may be suitable for the development of human therapeutics. Currently, the intellectual property rights are owned by a subsidiary of Horizon Therapeutics, PLC (the "Licensor"). Payments by the Company under the license agreement include a one-time non-refundable fee of $50,000, a minimum annual commitment of $40,000 commencing in 2009, 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 is responsible for the development and commercialization of the licensed products.

In May 2012, such license agreement was amended. The minimum annual commitment was increased to $46,000 and may be deferred by the Company until the Company raises at least $2 million in equity financing, then the aggregate annual payments of all amounts will become payable. The Company is currently in discussions with the Licensor regarding the amounts payable under the license agreement.

At June 30, 2020 and December 31, 2019, the Company had accrued $529,000 and $506,000, respectively, in license payments under the term of this license, included in accrued liabilities, of which no amounts have been paid to date. Expenses related to the license agreement are recognized in general and administrative expense in the statements of operations.

In further consideration for the licenses granted, the Company shall make the following milestone payments to the Licensor based upon the attainment of each milestone event indicated below.

Milestone Event	Amount
Commencement of Phase II	$ 230,000
Commencement of Phase III	$ 575,000
Filing of an NDA for Regulatory Approval (or equivalent in Europe or Japan)	$ 1,150,000
Receipt of Regulatory Approval in the United States	$ 5,750,000
Receipt of Regulatory Approval outside the United States	$ 5,750,000

No milestones have been achieved as of June 30, 2020.

Royalties shall be paid to the Licensor assessed on net sales of licensed products on a country-by-country basis in an amount equal to 5.75%. Should the Company be required to obtain a license from a third party in order to sell a licensed product, the Company may deduct 50% of the royalties on such licensed product paid to the third party subject to certain minimums.

In addition to the royalties the Company shall pay the Licensor 9.2% of all sublicense income attributable to licensed products.

The Licensor also granted the Company a buy-out option which may be exercised at any time during the term of the agreement. The option price will be as follows: $500,000 if exercised prior to the commencement of the first Phase II clinical trial; $1,000,000 if exercised on or after the commencement of the first Phase II clinical trial and prior to the commencement of the first Phase III clinical trial; $5,000,000 if exercised on or after the commencement of the first Phase III clinical trial and prior to the filing of a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (the “FDA”) for the first licensed product; and $8,000,000 if exercised on or after the filing of an NDA for the first licensed product.

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. If the Company does not terminate the agreement or exercise the buy-out option, the term of the agreement shall continue until the expiration of the Company’s obligation to make royalty payments. Such royalty payments continue for each product in each country until the later of the expiration of the related patent or 10 years after the initial sale of the product in the respective country. The agreement may also be terminated for cause by either party upon the breach of the material obligations of the other party or the bankruptcy or liquidation of the other party.

(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 June 30, 2020 and December 31, 2019, the Company did not have any pending legal actions.

(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. Each share of redeemable convertible preferred stock was converted into the number of shares of common stock determined by dividing the original issue price by the applicable conversion price. The Series A-1 conversion price was $1.26, and the Series A conversion price was $0.70, as adjusted for the reverse stock split discussed in Note 2.

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.

(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 is 125% of the initial public offering price. The warrants have a five-year term and are not exercisable prior to January 29, 2021. All of the warrants were outstanding at June 30, 2020, and 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). Under the 2019 Plan, 1,000,000 shares are authorized to be issued, and 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. As of June 30, 2020, 401,283 stock options were available for future grants.

During the three and six months ended June 30, 2020, the Company granted options to purchase 600,000 shares of common stock at an exercise price of $3.13 per share to the executive officers of the Company. Under the grant agreements, 550,000 of the options were vested and exercisable upon grant and 50,000 of the options vest after one year, provided the executive officer is employed by the Company at such time. These options have a 10-year term. There were no options issued during the three and six months ended June 30, 2019.

The options granted during the three and six months ended June 30, 2020 were valued using the Black Scholes option pricing model using the following weighted average assumptions: expected term of 5.0 years; risk free interest rate of 0.4%; expected volatility of 80.0%; and dividend yield of 0.0%. The weighted-average grant date fair value of options issued by the Company during the three months ended June 30, 2020 was $1.99 per share.

Share-based compensation expense for the three months ended June 30, 2020 and 2019 was $1,111,272 and $0, respectively, and for the six months ended June 30, 2020 and 2019 was $1,111,272 and $8,859, respectively.

As of June 30, 2020, there were 903,847 options outstanding, of which 853,847 were vested and exercisable. As of December 31, 2019, there were 352,282 options outstanding, all of which 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator				
Net loss	$ (2,309,490)	$ (344,700)	$ (2,751,080)	$ (535,603)
Denominator				
Weighted-average common shares outstanding, basic and diluted	6,860,847	282,614	5,730,158	282,614
Net loss per share, basic and diluted	$ (0.34)	$ (1.22)	$ (0.48)	$ (1.90)

The Company reported a net loss for the three and six months ended June 30, 2020 and 2019, therefore, the basic and diluted net loss per share are the same for all periods 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:

	June 30,	
	2020	2019
Redeemable convertible preferred stock, as converted	—	4,117,089
Stock options	903,847	353,565
Warrants	100,000	—

In addition, common shares issuable upon the conversion of the $530,000 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 and six months ended June 30, 2020 and 2019. The Company has recorded a valuation allowance to reduce its net deferred tax asset to an amount that is more likely than not to be realized in future years. Accordingly, the benefit of the net operating loss ("NOL") that would have been recognized in the three and six months ended June 30, 2020 and 2019 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 January 31, 2020 IPO, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code or could result in a change in control in the future.

As of June 30, 2020, and December 31, 2019, 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.

(14) Subsequent Events and Impact of COVID-19 Pandemic

The clinical trial sites participating in the Company's Phase 2a trial in AD patients in collaboration with the Alzheimer's Disease Cooperative Study have 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. 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.

On July 1, 2020, the Company granted options to purchase an aggregate of 210,000 shares of common stock at an exercise price of $4.39 per share to members of the board of directors of the Company, members of the Company's scientific advisory board and other consultants to the Company. Under the grant agreements, all of the options were vested and exercisable upon grant, and these options have a 10-year term. The estimated grant date fair value of these options was $2.77 per share.

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, 2019 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Those factors are updated, as applicable, in "Factors that May Affect Future Results" below. As a result of the risks, uncertainties and assumptions described above and elsewhere, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the

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

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with: (i) the interim financial statements and related notes thereto which are included in this Quarterly Report on Form 10-Q; and (ii) our annual financial statements for the year ended December 31, 2019 which are included in our Annual Report on Form 10-K for the year ended December 31, 2019.

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"). 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/Aβ ("APP"), tau/phospho-tau ("tau") and α-Synuclein ("αSYN")—thereby improving axonal transport. 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 a Phase 2a study in AD patients in collaboration with the Alzheimer's Disease Cooperative Study ("ADCS") and began recruitment of patients in a second Phase 2a proof-of-concept study of ANVS401 in July 2020 with 54 PD patients and 14 AD patients. We have designed the Phase 2a study with Parexel by applying our understanding of the underlying disease states in neurodegeneration and by measuring not just target, but also pathway validation in the spinal fluid of these patients. If we are able to show 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.

The clinical trial sites participating in our Phase 2a trial in AD patients in collaboration with the ADCS have 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. 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 our 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 have never been profitable and have incurred net losses since inception. Our accumulated deficit at June 30, 2020 was $11,528.1 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Operating expenses:				
Research and development	$ 856.5	$ 6.1	$ 922.9	$ 12.1
General and administrative	1,687.2	300.0	2,203.9	480.8
Other income (expense):				
Change in fair value of derivative liability	—	(26.5)	(26.5)	(26.5)
Interest income (expense), net	25.9	(12.1)	36.5	(16.2)
Grant income	208.3	—	365.7	—

Three and Six Months Ended June 30, 2020 and 2019

Research and Development Expenses

Research and development expenses increased by $850.4 thousand and $910.8 thousand for the three and six months ended June 30, 2020, respectively, compared to the prior year periods. The increases were primarily the result of contract research costs associated with our long-term toxicology studies in rats and dogs which began in November of 2019 and initial costs of our Phase 2a clinical trial in PD and AD patients. We expect research and development expenses in 2020 will be higher as compared to 2019 due to the start of our Phase 2a clinical trial and the continuation of our long-term toxicology studies.

General and Administrative Expenses

General and administrative expenses increased by $1,387.2 thousand and $1,723.1 thousand for the three and six months ended June 30, 2020, respectively, compared to the prior year periods. The increase for the three months ended June 30, 2020 was primarily the result of increases of $1,111.3 thousand in share-based compensation expense, $162.7 thousand in other personnel expenses and $82.8 thousand in insurance expense. The increase for the six months ended June 30, 2020 was primarily the result of increases of $1,111.3 thousand in share-based compensation expense, $332.8 thousand in other personnel expenses, $140.5 thousand in insurance expense and $80.0 thousand in stock listing fees and other financial printing and filing fees. We expect general and administrative expenses in 2020 will be higher as compared to 2019 due to additional costs associated with being a public company.

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 increased $38.0 thousand and $52.7 thousand for the three and six months ended June 30, 2020, respectively, compared to the prior year periods. The increases were primarily the result of interest income generated on cash and cash equivalents from the proceeds of our IPO which closed on January 31, 2020. We expect interest income (expense), net will be higher in 2020 as compared to 2019 due to higher expected cash balances and the conversion to common stock of our convertible promissory notes upon the closing of the IPO.

Grant Income

Grant income increased $208.3 thousand and $365.7 thousand for the three and six months ended June 30, 2020, respectively, compared to the prior year period. The increases were the result of income recognized related to a grant from the NIH to reimburse the costs of our long-term toxicology studies in rats and dogs, which studies began in November 2019.

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. 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 June 30, 2020, our principal source of liquidity was our cash, which totaled $9,763.3 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 six months ended June 30, 2020.

Debt Financings

At June 30, 2020 and December 31, 2019, we had outstanding $0 and $530.0 thousand principal amount of convertible promissory notes, which were issued in March 2019. 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.

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Statement of Cash Flows Data:		
Total net cash provided by (used in):		
Operating activities	$ (2,282.2)	$ (379.3)
Financing activities	12,043.6	448.5
Increase (decrease) in cash and cash equivalents	$ 9,761.4	$ 69.2

Operating Activities

For the six months ended June 30, 2020, cash used in operations was $2,282.2 thousand compared to $379.3 thousand for the same period in the prior year. The increase in cash used in operations was primarily the result of the payment of accounts payable, accrued expenses and prepaid insurance and the initial costs of our Phase 2a study in PD and AD in the six months ended June 30, 2020.

We expect cash used in operating activities to increase in 2020 as compared to 2019 due to an expected increase in our operating losses associated with ongoing development of our product candidates, including our Phase 2a study in PD and AD patients, and additional costs associated with being a public company.

Financing Activities

Cash provided by financing activities was $12,043.6 thousand during the six months ended June 30, 2020, attributable to net proceeds from our IPO of $12,034.4 thousand, after deducting underwriting discounts and commissions and offering expenses, and $9.2 thousand proceeds from the exercise of stock options.

Cash provided by financing activities was $448.6 thousand during the six months ended June 30, 2019, attributable to $530.0 thousand proceeds from the sale of convertible promissory notes partially offset by the payment of $73.1 thousand of deferred offering costs and $8.3 thousand of fees on the issuance of the convertible promissory notes.

Funding Requirements

We expect that the net proceeds from our IPO 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 our Phase 3 study in AD-DS 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, 2019 for a discussion of important factors that may affect our future results. The following factors are new or updated risk factors as compared to our 10-K based on recent developments.

Disruptions associated with widespread health emergencies could harm our ability to complete or could materially delay our clinical trials.

The emergence of widespread health emergencies or pandemics, such as COVID-19, could lead to quarantines, business shutdowns, labor shortages, disruptions to the healthcare system, and overall economic instability. If the suppliers, CROs, hospitals, clinical trial sites, regulators, consultants and other third parties with whom we conduct business were to experience shutdowns or other business disruptions, our ability to enroll patients and conduct our clinical trials in the manner and on the timelines presently planned could be materially and negatively impacted. The clinical trial sites participating in our Phase 2a trial in AD patients have 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. 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 our clinical trials is dependent on the spread of the disease and government and healthcare system responses to such spread, which are presently highly uncertain.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

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 net operating loss (“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 us due to our tax losses generated during all prior years.

U.S. tax legislation enacted in 2017 significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. The legislation could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of our Phase 2a trials of ANVS401;
- if we are required to conduct more than one Phase 3 trial in any one indication;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize ANVS401 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to ANVS401 or any other product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for ANVS401 or any other product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;

- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our shareholders in the future;
- trading volume of our common stock; and
- general economic, industry and market conditions, including, but not limited to, the impact of the COVID-19 pandemic.

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 and six months ended June 30, 2020, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2019, which we included in our Annual Report on Form 10-K for the year ended December 31, 2019.

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.

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
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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Signature	Title	Date
/s/ MARIA MACCECCHINI Maria Maccecchini	President and Chief Executive Officer (principal executive officer)	July 29, 2020
/s/ JEFFREY MCGROARTY Jeffrey McGroarty	Chief Financial Officer (principal financial and accounting officer)	July 29, 2020

Exhibit 31.1

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

I, Maria Maccecchini, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

   (c) 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: July 29, 2020

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

Exhibit 31.2

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

I, 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)) 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) 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

   (c) 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: July 29, 2020

/s/ Jeffrey McGroarty
Jeffrey McGroarty
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Annovis Bio, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Maria Maccecchini, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2020

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

Exhibit 32.2

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

In connection with the Quarterly Report of Annovis Bio, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020 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: July 29, 2020

/s/ Jeffrey McGroarty
Jeffrey McGroarty
Chief Financial Officer