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**

For the transition period from to

Commission File Number 001-38114

AVENUE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-4113275**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1140 Avenue of the Americas, Floor 9 New York, NY 10036
(Address of principal executive offices and zip code)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 definition 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 ☒

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of August 1, 2020
Common Stock, $0.0001 par value	16,702,803

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2020

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AVENUE THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
($ in thousands, except share and per share amounts)

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,257	$ 8,745
Prepaid expenses and other current assets	74	170
Total Assets	**$ 5,331**	**$ 8,915**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,193	$ 1,101
Accounts payable and accrued expenses - related party	37	14
Licenses payable	-	1,000
Total current liabilities	1,230	2,115
Total Liabilities	1,230	2,115
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Common shares, 16,702,803 and 16,682,190 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	2	2
Additional paid-in capital	75,346	74,915
Accumulated deficit	(71,247)	(68,117)
Total Stockholders' Equity	4,101	6,800
Total Liabilities and Stockholders' Equity	**$ 5,331**	**$ 8,915**

The accompanying notes are an integral part of these condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
($ in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	**June 30, 2019**	**June 30, 2020**	**June 30, 2019**
Operating expenses:				
Research and development	$ 1,219	$ 6,392	$ 1,916	$ 16,633
General and administrative	684	716	1,261	1,835
Loss from operations	(1,903)	(7,108)	(3,177)	(18,468)
Interest income	(15)	(126)	(47)	(217)
Net Loss	**$ (1,888)**	**$ (6,982)**	**$ (3,130)**	**$ (18,251)**
Net loss per common share outstanding, basic and diluted	$ (0.11)	$ (0.43)	$ (0.19)	$ (1.21)
Weighted average number of common shares outstanding, basic and diluted	16,474,655	16,314,763	16,474,655	15,035,811

The accompanying notes are an integral part of these condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
($ in thousands, except share amounts)
(Unaudited)

Three months ended June 30, 2020

	Class A Preferred Shares		Common Shares		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity
Balance at March 31, 2020	**250,000**	**$ -**	**16,682,803**	**$ 2**	**$ 75,130**	**$ (69,359)**	**$ 5,773**
Share based compensation	-	-	20,000	-	216	-	216
Net loss	-	-	-	-	-	(1,888)	(1,888)
Balance at June 30, 2020	**250,000**	**$ -**	**16,702,803**	**$ 2**	**$ 75,346**	**$ (71,247)**	**$ 4,101**

Six months ended June 30, 2020

	Class A Preferred Shares		Common Shares		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at December 31, 2019	**250,000**	**$ -**	**16,682,190**	**$ 2**	**$ 74,915**	**$ (68,117)**	**$ 6,800**
Share based compensation	-	-	20,000	-	431	-	431
Cashless exercise of warrants under the NSC Note	-	-	613	-	-	-	-
Net loss	-	-	-	-	-	(3,130)	(3,130)
Balance at June 30, 2020	**250,000**	**$ -**	**16,702,803**	**$ 2**	**$ 75,346**	**$ (71,247)**	**$ 4,101**

Three months ended June 30, 2019

	Class A Preferred Shares		Common Shares		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at March 31, 2019	**250,000**	**$ -**	**16,557,122**	**$ 2**	**$ 73,827**	**$ (53,478)**	**$ 20,351**
Share based compensation	-	-	-	-	535	-	535
Cashless exercise of warrants under the NSC Note	-	-	2,625	-	-	-	-
Net loss	-	-	-	-	-	(6,982)	(6,982)
Balance at June 30, 2019	**250,000**	**$ -**	**16,559,747**	**$ 2**	**$ 74,362**	**$ (60,460)**	**$ 13,904**

Six months ended June 30, 2019

	Class A Preferred Shares		Common Shares		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at December 31, 2018	**250,000**	**$ -**	**10,667,714**	**$ 1**	**$ 41,577**	**$ (42,209)**	**$ (631)**
Share based compensation	-	-	-	-	1,286	-	1,286
Issuance of common shares, net of costs	-	-	5,833,333	1	31,499	-	31,500
Cashless exercise of warrants under the NSC Note	-	-	58,700	-	-	-	-
Net loss	-	-	-	-	-	(18,251)	(18,251)
Balance at June 30, 2019	**250,000**	**$ -**	**16,559,747**	**$ 2**	**$ 74,362**	**$ (60,460)**	**$ 13,904**

The accompanying notes are an integral part of these condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
($ in thousands)

	For the Six Months Ended	
	June 30, 2020	**June 30, 2019**
Cash flows from operating activities:		
Net loss	$ (3,130)	$ (18,251)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	431	1,286
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	96	(9)
Accounts payable and accrued expenses	92	(2,133)
Accounts payable and accrued expenses - related party	23	(442)
Net cash used in operating activities	(2,488)	(19,549)
Cash flows from investing activities:		
Purchase of Short-term investments (certificates of deposit)	-	(5,000)
Milestone payment for research and development licenses	(1,000)	-
Net cash used in investing activities	(1,000)	(5,000)
Cash flows from financing activities:		
Issuance of common shares	-	35,000
Offering costs	-	(2,667)
Net cash provided by financing activities	-	32,333
Net change in cash	(3,488)	7,784
Cash and cash equivalents, beginning of period	8,745	2,671
Cash and cash equivalents, end of period	**$ 5,257**	**$ 10,455**
Non-cash financing activities:		
Prior period financing costs	$ -	$ 833

The accompanying notes are an integral part of these condensed financial statements.

Note 1 - Organization, Plan of Business Operations

Avenue Therapeutics, Inc. (the "Company" or "Avenue") was incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress Biotech, Inc. ("Fortress"), to develop and market pharmaceutical products for the acute care setting in the United States. The Company is focused on developing its product candidate, an intravenous ("IV") formulation of tramadol HCI ("IV Tramadol"), for moderate to moderately severe post-operative pain.

Stock Purchase and Merger Agreement

On November 12, 2018, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen"), entered into definitive agreements with two closing stages for a proposed acquisition of the Company for a total aggregate consideration of $215.0 million. The Stock Purchase and Merger Agreement (the "SPMA") was approved by a majority of the Company's stockholders, including a majority of its non-affiliated stockholders, at its special shareholder meeting on February 6, 2019. On February 8, 2019, InvaGen acquired 5,833,333 shares of the Company's common stock at $6.00 per share (the "Stock Purchase Transaction") for net proceeds of $31.5 million after deducting commission fees and other offering costs, representing a 33.3% stake in the Company's capital stock on a fully diluted basis.

At the second stage closing, InvaGen will acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity, for up to $180.0 million in the aggregate (the "Merger Transaction"). The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to U.S. Food and Drug Administration approval, labeling, scheduling and the absence of any Risk Evaluation and Mitigation Strategy or similar restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Subject to the terms and conditions described in the SPMA, InvaGen may also provide interim financing to the Company in an amount of up to $7.0 million during the time period between the Stock Purchase Transaction (which occurred on February 8, 2019) and the Merger Transaction. Any amounts drawn on the interim financing will be deducted from the aggregate consideration payable to the Company's stockholders by virtue of the Merger Transaction. There have been no amounts drawn upon this interim financing as of June 30, 2020.

Liquidity and Capital Resources

The Company has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of June 30, 2020, the Company had an accumulated deficit of $71.2 million. The Company believes that its cash and cash equivalents as of June 30, 2020, as well as its access to potential interim financing from InvaGen and pledged financial support from Fortress (see Note 4), will enable the Company to continue to fund operations in the normal course of business for more than a twelve-month period from the date of filing this Quarterly Report on Form 10-Q. However, changing circumstances, some of which may be beyond its control, could cause the Company to consume capital faster than it currently anticipates if certain milestone payments become due, and it may need to seek additional funds sooner than planned. If the amounts made available from InvaGen and Fortress are not sufficient, the Company would be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Note 2 — Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These unaudited interim condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

Therefore, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2019, which were included in the Company's Form 10-K, and filed with the U.S. Securities and Exchange Commission ("SEC") on March 30, 2020. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

The Company has no subsidiaries.

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 and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 in its audited financial statements for the year ended December 31, 2019 included in the Company's Form 10-K. With the exception of those noted below, there have been no material changes to the Company's significant accounting policies.

Net Loss Per Share

Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding, excluding unvested restricted stock and stock options and preferred shares, during the period. Since dividends are declared paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income (loss) per share because to do so would have been anti-dilutive for the periods presented:

	For the Three and Six Months Ended	
	June 30, 2020	**June 30, 2019**
Unvested restricted stock units/awards	1,221,575	1,150,162
Preferred shares	250,000	250,000
Total potential dilutive effect	1,471,575	1,400,162

Recent Accounting Pronouncements to be Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes,* ("ASU 2019-12") which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance 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 the impact of this standard on its financial statements and related disclosures.

Coronavirus Aid, Relief and Economic Security Act ("CARES Act")

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. At this time, the Company does not believe that the CARES Act will have a material impact on the Company's income tax provision for 2020. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

Note 3— Accounts Payable and Accrued Expenses

Accounts payable, accrued expenses and other liabilities consisted of the following (in thousands):

	As of June 30, 2020	As of December 31, 2019
Accounts payable	$ 179	$ 354
Accrued employee compensation	202	477
Accrued contracted services and other	812	270
Accounts payable and accrued expenses	$ 1,193	$ 1,101

Note 4 — Related Party Transactions

On June 12, 2020, the Company, Fortress and InvaGen entered into a Facility Agreement ("Facility Agreement") whereby beginning on October 1, 2020 the Company may borrow up to $2.0 million collectively from Fortress and InvaGen, subject to certain conditions set forth herein. Fortress' commitment amount is $0.8 million, and InvaGen's is $1.2 million, and a 7% per annum interest rate applies (payable on the last day of each fiscal quarter). Repayment of the loan is due upon the earliest of i) the second stage closing ii) April 29, 2021 and iii) the date that is 30 days following the termination of the SPMA. As of June 30, 2020, there have been no amounts drawn on the Facility Agreement.

Note 5 — Stockholders' Equity

Equity Incentive Plan

The Company has in effect the 2015 Incentive Plan ("2015 Incentive Plan"). The 2015 Incentive Plan was adopted in December 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan authorizes grants to issue up to 2,000,000 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes restricted stock unit and award activity for the six months ended June 30, 2020:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2019	1,045,162	$ 5.10
Granted	176,413	$ 10.99
Unvested balance at June 30, 2020	1,221,575	$ 5.95

For the three months ended June 30, 2020 and 2019, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $0.2 million and $0.5 million, respectively. For the six months ended June 30, 2020 and 2019, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $0.4 million and $1.3 million, respectively.

At June 30, 2020, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 0.8 years. This amount does not include, as of June 30, 2020, 487,586 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Warrants

The following table summarizes the warrant activity for the six months ended June 30, 2020:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2019	16,454	$ 0.6079	$ 148
Exercised	(613)	$ 0.0001	-
Outstanding, June 30, 2020	15,841	$ 0.6315	$ 161

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2019 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2020. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company that seeks to develop and commercialize our product principally for use in the acute/intensive care hospital setting. Our current product candidate is intravenous (IV) Tramadol, for the treatment of moderate to moderately severe post-operative pain. In 2016, we completed a pharmacokinetic (PK) study for IV Tramadol in healthy volunteers as well as an end of phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol for the management of post-operative pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. To date, we have not received approval for the sale of our product candidate in any market and, therefore, have not generated any sales revenue from our product candidate.

On June 26, 2017, we completed an initial public offering (IPO) of our common stock, resulting in net proceeds of approximately $34.2 million after deducting underwriting discounts, and other offering costs.

We have used the proceeds from our IPO to initiate our first Phase 3 trial of IV Tramadol in patients with moderate-to-severe pain following bunionectomy, which had its first patient dosed in September 2017. In May 2018, we announced the study met its primary endpoint and all key secondary endpoints.

In December 2018, we initiated the second Phase 3 trial in patients with moderate-to-severe pain following abdominoplasty upon successful completion of the bunionectomy study. In June 2019, we announced the study met its primary endpoint and all key secondary endpoints.

In December 2017, we initiated an open-label safety study, which was completed during the second quarter of 2019. The results showed that IV Tramadol is well-tolerated with a side effect profile consistent with known pharmacology.

In December 2019, we submitted a new drug application (NDA), for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA). In February 2020, the FDA accepted our NDA submission and set a Prescription Drug User Fee Act goal date of October 10, 2020.

On November 12, 2018, we entered into a Stock Purchase and Merger Agreement (SPMA) with InvaGen Pharmaceuticals Inc. (InvaGen), Madison Pharmaceuticals Inc. (Merger Sub), and Fortress Biotech, Inc. (Fortress), pursuant to which InvaGen agreed to purchase, for $35 million, common shares representing 33.3% of the fully diluted capitalization of the Company (the Stock Purchase Transaction) and subsequently acquire the remaining issued and outstanding capital stock of the Company for $180 million, subject to certain reductions, in a reverse subsidiary merger transaction (the Merger Transaction). Pursuant to the terms and subject to the conditions set forth in the SPMA, InvaGen will, at second closing, hold 100% of the issued and outstanding equity interests of the Company. Consummation of the Merger Transaction is conditioned, among other things, upon FDA approval of IV Tramadol, its labeling and scheduling and the absence of any Risk Evaluation and Mitigation Strategy restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The aggregate consideration to be paid by InvaGen under the SPMA is $215 million in cash, subject to certain potential reductions, which InvaGen intends to have sufficient immediately available funds to pay. In addition, we are subject to certain lock-up restrictions and agreed not to (subject to customary exceptions), during the period commencing at the signing of the SPMA until the Merger Transaction, issue, buy, sell, or otherwise subject to a security interest, pledge, hypothecation, mortgage or lien, any securities of the Company.

The SPMA was approved by a majority of our stockholders, including a majority of our non-affiliated stockholders, at our special shareholder meeting on February 6, 2019. On February 8, 2019, the Company and InvaGen consummated the Stock Purchase Transaction whereby InvaGen acquired 5,833,333 shares of our common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in our capital stock on a fully diluted basis.

Our net loss for the three and six months ended June 30, 2020 was approximately $1.9 million and $3.1 million, respectively. As of June 30, 2020, we had an accumulated deficit of approximately $71.2 million. Substantially all our net losses resulted from costs incurred in connection with our research and development program of IV Tramadol and from general and administrative costs associated with our operations.

We expect to continue to incur research and development costs and increased general and administration related costs and incur operating losses for at least the next several years as we develop and seek regulatory approval and commercialization for IV Tramadol in the U.S.

We may need to obtain additional capital through the sale of debt or equity financings or other arrangements to fund our operations, research and development activity or regulatory approval activity; however, there can be no assurance that we will be able to raise needed capital under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding shares of common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to stockholders. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

We are a majority controlled subsidiary of Fortress.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 1140 Avenue of the Americas, Floor 9, New York, NY 10036. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a global pandemic, which continues to spread throughout the United States and around the world. In the first and second quarters of 2020, the Company did not experience a significant impact on its business resulting from government restrictions on the movement of people, goods, and services. Management believes any disruption, when and if experienced, would be temporary, however, there is uncertainty around when any disruption might occur, the duration and the potential impact.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our unaudited condensed financial statements.

Results of Operations

General

At June 30, 2020, we had an accumulated deficit of $71.2 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate is still in development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Comparison of the Three Months Ended June 30, 2020 and 2019

	For The Three Months Ended		Change	
($ in thousands)	**June 30, 2020**	**June 30, 2019**	**$**	**%**
Operating expenses:				
Research and development	$ 1,219	$ 6,392	$ (5,173)	(81%)
General and administrative	684	716	(32)	(4%)
Loss from operations	(1,903)	(7,108)	5,205	(73%)
Interest income	(15)	(126)	(111)	(88%)
Net Loss	**$ (1,888)**	**$ (6,982)**	**$ 5,094**	(73%)

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings, laboratory costs and other supplies.

For the three months ended June 30, 2020 and 2019, research and development expenses were $1.2 million and $6.4 million, respectively. The decrease of $5.2 million is primarily due to decreases of $4.4 million associated with the completion of our abdominoplasty study, $0.7 million associated with the completion of our safety study, $0.2 million in personnel costs, $0.1 million in stock compensation costs and $0.1 million in NDA related costs partially offset by an increase of $0.3 million for manufacturing activities.

We expect our research and development activities to continue as we develop our existing product candidate, reflecting costs associated with the following:

- employee-related expenses;
- license fees and milestone payments related to in-licensed product and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees for legal and consulting services, market research, personnel-related costs, public reporting company related costs and other general operating expenses not otherwise included in research and development expenses.

For the three months ended June 30, 2020 and 2019, general and administrative expenses were $0.7 million and $0.7 million, respectively. General and administrative expenses remained relatively flat current year quarter over prior year quarter.

Interest Income

Interest income was $15,000 and $0.1 million for the three months ended June 30, 2020 and 2019, respectively. The decrease in interest income was due to the reduction in cash and cash equivalents and short-term investments.

Comparison of the Six Months Ended June 30, 2020 and 2019

($ in thousands)	For The Six Months Ended June 30, 2020	June 30, 2019	Change $	Change %
Operating expenses:				
Research and development	$ 1,916	$ 16,633	$ (14,717)	(88%)
General and administrative	1,261	1,835	(574)	(31%)
Loss from operations	(3,177)	(18,468)	15,291	(83%)
Interest income	(47)	(217)	(170)	(78%)
Net Loss	**$ (3,130)**	**$ (18,251)**	**$ 15,121**	(83%)

Research and Development Expenses

For the six months ended June 30, 2020 and 2019, research and development expenses were $1.9 million and $16.6 million, respectively. The decrease of $14.7 million is primarily due to decreases of $13.2 million associated with the completion of our abdominoplasty study, $1.1 million associated with the completion of our safety study, $0.3 million in personnel costs, $0.2 million in stock compensation costs, and $0.2 million in NDA related costs partially offset by an increase of $0.3 million for manufacturing activities.

General and Administrative Expenses

For the six months ended June 30, 2020 and 2019, general and administrative expenses were $1.2 million and $1.8 million, respectively. General and administrative expenses decreased by $0.6 million primarily due to decreases of $0.7 million in non-cash stock compensation partially offset by an increase of $0.1 million in professional fees.

Interest Income

Interest income was $47,000 and $0.2 million for the six months ended June 30, 2020 and 2019, respectively. The decrease in interest income was due to the reduction in cash and cash equivalents and short-term investments.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2020, we had an accumulated deficit of $71.2 million.

We have used the funds from our IPO and from the InvaGen share purchase to finance our operations and will continue to use the funds primarily for general corporate purposes, which may include financing our growth and developing our product candidate. We currently anticipate that our cash and cash equivalent balances at June 30, 2020 in addition to the SPMA with InvaGen which provides access to potential interim financing of up to $7.0 million up until the second stage closing and additional pledged financial support from Fortress, are sufficient to fund our anticipated operating cash requirements for approximately the next 12 months. If we cannot generate significant cash from our operations, we intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, grants or other arrangements. However, changing circumstances, some of which may be beyond our control, could cause us to consume capital faster than we currently anticipate if certain milestone payments become due, and we may need to seek additional funds sooner than planned. If the amounts made available from InvaGen and Fortress are not sufficient, we would be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources.

In addition to the foregoing, based on our current assessment, we do not expect any material impact on our development timeline and our liquidity due to the worldwide spread of the COVID-19 virus. However, we are continuing to assess the effect on our operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Recently Adopted and Issued Accounting Pronouncements

See Footnote 2.

Cash Flows for the Six Months Ended June 30, 2020 and 2019

	For The Six Months Ended June 30,	
($ in thousands)	**2020**	**2019**
Total cash (used in)/provided by:		
Operating activities	$ (2,488)	$ (19,549)
Investing activities	(1,000)	(5,000)
Financing activities	-	32,333
Net (decrease) increase in cash	$ (3,488)	$ 7,784

Operating Activities

Net cash used in operating activities was $2.5 million for the six months ended June 30, 2020, primarily comprised of our $3.1 million net loss partially offset by increases in operating assets and liabilities of $0.2 million and $0.4 million in share based compensation.

Net cash used in operating activities was $19.6 million for the six months ended June 30, 2019, primarily comprised of our $18.3 million net loss and decreases in operating assets and liabilities of $2.6 million partially offset by $1.3 million in share based compensation.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2020 was $1.0 million and consisted of the milestone payment due to our licensor pursuant to our NDA submission.

Net cash used in investing activities for the six months ended June 30, 2019 was $5.0 million. We purchased $5.0 million in short-term investments consisting of six month certificates of deposit in May 2019.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 and 2019 was $0 and $32.3 million, respectively. The source of the net cash provided in the 2019 period was related to our issuance of shares to InvaGen in connection with the SPMA.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments" in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

N/A.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Principal Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2020, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company's Chief Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2020 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations.

Item 1A. Risk Factors

Investing in our common stock is subject to a number of risks and uncertainties. You should carefully consider the risk factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and in other reports we file with the SEC. There have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Item 2. Recent Sales of Unregistered Securities.

N/A.

Item 3. Defaults Upon Senior Securities.

N/A.

Item 4. Mine Safety Disclosures.

N/A.

Item 5. Other Information.

N/A.

Item 6. Financial Statements and Exhibits

Exhibit No.	Description
10.1	Facility Agreement, dated June 12, 2020, by and between Avenue Therapeutics, Inc., InvaGen Pharmaceuticals Inc., and Fortress Biotech, Inc.
31.1	Certification of Chief Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2020.
31.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2020.
32.1	Certification of Chief Executive Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2020.
32.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2020.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) Notes to the Condensed Financial Statements.

SIGNATURES

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

Avenue Therapeutics, Inc.
(Registrant)

Date: August 14, 2020

By: /s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 10.1

FACILITY AGREEMENT

This **FACILITY AGREEMENT**, dated as of June 12, 2020 (as may be amended or modified from time to time, this "**Facility Agreement**"), is entered into by and among **AVENUE THERAPEUTICS, INC.**, a Delaware corporation (the "**Borrower**"), **INVAGEN PHARMACEUTICALS INC.**, a New York corporation ("**Lender 1**") and **FORTRESS BIOTECH, INC.**, a Delaware corporation ("**Lender 2**" and, together with Lender 1, each a "**Lender**" and, collectively, the "**Lenders**").

RECITALS:

A. **WHEREAS**, reference is made to that certain Stock Purchase and Merger Agreement, dated as of November 12, 2018 (as amended, supplemented or otherwise modified from time to time, the "**SPMA**"; capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the SPMA), by and among Lender 1, Madison Pharmaceuticals Inc. and the Borrower, pursuant to which the Borrower has issued, sold, transferred and delivered to Lender 1, free and clear of any Encumbrances, and Lender 1 has purchased and acquired from the Borrower, for $35.00 million, Common Shares equal to 33.3% of the Fully Diluted Capitalization and Lender 1 will, among other things, acquire the remaining issued and outstanding capital stock of the Borrower in a reverse subsidiary merger transaction on the terms and subject to the conditions of the SPMA (the "**Acquisition**");

B. **WHEREAS**, the Borrower has requested that the Lenders jointly provide a delayed term loan facility in the aggregate principal amount not exceeding United States Dollars Two Million ($2,000,000) (the "**Facility**") as set forth herein; and

C. **WHEREAS**, the Lenders are willing to make available their respective Pro Rata Share (*as defined hereinafter*) of the Facility upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the agreements, provisions and covenants herein contained, the parties hereto agree as follows:

1. **Delayed Term Loan.**

(a) Commitment. Subject to the terms and conditions hereof, including satisfaction or waiver of the conditions precedent set forth in Section 4 below, each Lender as part of the Facility hereby agrees to make a delayed term loan to the Borrower (the "**Loan**") on one occasion during the period between October 1, 2020 and the date that is five (5) Business Days prior to the Maturity Date (*as defined below*), in an aggregate principal amount not to exceed such Lender's respective commitment detailed in Schedule A hereto (such commitment of each Lender, its " **Commitment**" and the aggregate of all such commitments, "**Commitments**"). Each Lender's obligation to make the Loan under this Section 1(a) shall terminate immediately and without further action in its entirety five (5) Business Days prior to the Maturity Date. Amounts borrowed under this Section 1(a) and repaid or prepaid may not be reborrowed.

(b) Borrowing Procedures. The Borrower agrees and undertakes that any borrowing of the Loan (not to in any event, in aggregate, exceed each Lender's respective Commitment) shall be made, and any notice in connection with such borrowing shall be issued, only upon the prior written approval of Garrett Ingram as a member of the board of directors of the Borrower. In connection with the borrowing of the Loan, each Lender shall have on the same date received a written borrowing notice from the Borrower no less than five (5) Business Days prior to the date of the borrowing, which notice shall include (a) the date of such borrowing which date shall be (i) a Business Day and (ii) the same for all the Lenders and (b) a description of the intended use of the proceeds of such borrowing that demonstrates that such use is in accordance with Section 1(c) below. Neither Lender shall be obligated to make the Loan in excess of its Pro Rata Share (as defined below). Notwithstanding anything to the contrary contained herein, neither Lender shall be obligated to make its Pro Rata Share of the Loan if the other Lender fails to or is unable to make its Pro Rata Share of the Loan. The term "**Pro Rata Share**" as used in this Facility Agreement means, with respect to any Lender, the percentage obtained by dividing (x) the Commitment of such Lender by (y) the Facility, and as more particularly set out in Schedule A hereto. Each Lender hereby undertakes to honor its Commitment in a timely manner.

(c) Use of Proceeds. The proceeds of the Loan shall solely be intended for and utilized by the Borrower for its working capital requirements or other general corporate purposes, evidenced by documentation supporting each such planned expenditures.

(d) Register. Each Lender is authorized to maintain a register (the "**Register**") to record the date and amount of the Loan made by such Lender, the amount of interest accruing from time to time and the date and amount of each payment or prepayment of principal thereof, and any such recordation shall constitute presumptive evidence of the accuracy of the information so recorded. The Register shall include the name and address of the Lender, and any transfer of the Loan shall not be effective unless recorded by the Lender in its Register.

2. **Interest.**

(a) The outstanding principal amount of the Loan shall bear interest from the date of the borrowing until the Loan is fully repaid at the rate *per annum* of seven percent (7%), compounded quarterly on the last day of each fiscal quarter. Interest shall be calculated on the basis of a year comprised of 360 days for the actual number of days elapsed.

(b) Accrued and unpaid interest on the Loan shall be payable on the last day of each fiscal quarter; provided, that if such date is not a Business Day, interest shall be payable on the next succeeding Business Day.

3. **Repayment of Loan.**

(a) The Borrower hereby unconditionally promises to pay to each Lender, in lawful money of the United States of America and in immediately available funds, the full outstanding principal amount of the Loan, together with accrued and unpaid interest thereon, no later than the earliest of (i) the Second Stage Closing Date, (ii) April 29, 2021, and (iii) date that is 30 days following the termination of the SPMA for any reason provided in the SPMA (such earliest date, the " **Maturity Date**").

(b) Voluntary prepayments of the outstanding principal amount of the Loan, and/or interest accruing thereon, in full but not in part, shall be permitted at any time, on not less than three (3) Business Days' prior written notice to the Lenders, and from time to time without premium or penalty.

(c) The Borrower shall pay all taxes or similar impositions or tariffs (other than United States Federal and applicable state income taxes payable by the Lenders) owed or owing or asserted to be owed to any Governmental Authority in respect of any payment of principal or interest or other amounts due under this Facility Agreement or any related agreement, document or writing. If required by such a Governmental Authority, the Borrower shall pay any such taxes, impositions or tariffs directly to such Governmental Authority and at the request of the Lenders, shall provide satisfactory proof to the Lenders of such payment. The Borrower shall indemnify the Lenders for and hold them harmless against the full amount of taxes or similar impositions of tariffs, other than United States Federal and applicable state income taxes payable by the Lenders, imposed on or paid by the Lenders or any affiliate of the Lenders in respect of any liability (including, without limitation, any taxes or tariffs imposed or asserted by any Governmental Authority on amounts payable under this Section 3(c), and penalties, interest and expenses) arising therefrom or with respect thereto. This indemnification shall be made within ten (10) Business Days from the date the Lenders make written demand therefor.

4. **Conditions Precedent.**

(a) At the time of the execution and delivery of this Facility Agreement, each Lender shall have received (i) a counterpart of this Facility Agreement signed on behalf of each party hereto, (ii) evidence that the Borrower has obtained all necessary consents and approvals to execute, deliver and perform this Facility Agreement and to obtain the Loan from the Lenders, including but not limited to its board of directors' and/or members' resolutions authorizing the execution of this Facility Agreement and the availing of the Loan proposed under it and (iii) such other certifications, opinions, financial or other information, approvals and documents as the Lenders may have reasonably requested, all in form and substance reasonably satisfactory to the Lenders.

(b) The obligation of the Lenders to make the Loan hereunder in accordance with the terms hereof is subject to the following conditions precedent having been complied with to the reasonable satisfaction of, or waived in writing by, each Lender: (i) no Event of Default (as defined below) shall have occurred and be continuing on and as of the date of making of the Loan; (ii) the representations and warranties contained in Section 5 below shall be true and correct on and as of the date of making of the Loan, unless such representations and warranties refer to an earlier date, in which case such representations and warranties shall be true and correct as of such earlier date; (iii) no applicable law or regulation or interpretation thereof by any Governmental Authority shall be in effect which, in the reasonable opinion of each Lender or its counsel, would materially restrict, prohibit or make it illegal for such Lender to make available its Pro Rata Share of the Loan; (iv) no action or proceeding shall have been instituted nor shall government action be threatened before any court or Governmental Authority, nor shall any order, judgment or decree have been issued or proposed to be issued by any court or Governmental Authority at the time of the making of the Loan to set aside, restrain, enjoin or prevent the completion and consummation of this Facility Agreement or the transactions contemplated hereby; and (v) the Borrower shall have paid to the Lenders the expenses referred to in Section 10(b) below, or, alternatively, the Lenders shall have received instructions from the Borrower to pay such expenses from the proceeds of the disbursement of the Loan, in each case, to the extent invoices with respect to expenses have been delivered to the Borrower.

5. **Representations and Warranties.** The Borrower hereby represents and warrants to the Lenders that on and as of the date hereof and as of the date of making of the Loan:

(a) the Borrower is a corporation duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, and having full corporate power and authority to enter into this Facility Agreement and to carry out the transactions contemplated hereby;

(b) the execution and delivery by the Borrower of this Facility Agreement and the consummation by the Borrower of the transactions contemplated hereby have been duly authorized by all necessary corporate action of the Borrower. This Facility Agreement has been duly executed and delivered by the Borrower and constitutes the legal, valid and binding obligation of the Borrower enforceable against the Borrower in accordance with its terms, subject to the effect of bankruptcy, insolvency, reorganization, moratorium or similar laws at the time in effect affecting the rights of creditors generally and subject to the effects of general principles of equity (regardless of whether considered in a proceeding in law or equity);

(c) the execution and delivery of this Facility Agreement and the consummation by the Borrower of the transactions contemplated hereby do not (i) contravene or result in a default under the Borrower's certificate of incorporation or bylaws, (ii) contravene or result in a default under any contractual restriction or Legal Requirements binding on the Borrower, (iii) require any filings, approvals, consents or authorizations which have not been duly obtained or (iv) result in the creation or imposition of any lien on the Borrower's properties;

(d) the Borrower is not an "investment company," or an "affiliated Person" of, or "promoter" or "principal underwriter" for, an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended;

(e) no judgments, orders, writs or decrees are outstanding against the Borrower, nor is there any pending or, to the best of the Borrower's knowledge, threatened litigation, contested claim, investigation, arbitration, or governmental proceeding by or against the Borrower that (i) individually or in the aggregate would reasonably be expected to have a Material Adverse Effect or (ii) purports to affect the legality, validity or enforceability of this Facility Agreement or the consummation of the transactions contemplated hereby;

(f) none of the written financial or other information relating to the Borrower and provided by the Borrower to the Lenders contain any material misstatement of fact or omits to state any material fact necessary to make the statements contained therein not misleading in light of the circumstances under which they were made;

(g) the Borrower has filed all tax returns (Federal, state and local) required to be filed and paid all taxes shown thereon to be due, including interest and penalties, or, to the extent the Borrower is contesting in good faith an assertion of liability based on such returns, has provided adequate reserves for payment thereof in accordance with GAAP;

(h) there are no conditions precedent to the effectiveness of this Facility Agreement that have not been satisfied or waived; and

(i) the Borrower has, independently and without reliance upon any of the Lenders and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Facility Agreement.

The parties acknowledge that the representations and warranties contained in this Facility Agreement shall survive the execution and delivery of this Facility Agreement.

6. **Affirmative Covenants.** The Borrower covenants and agrees that, until the date of the indefeasible payment in full in cash of all obligations hereunder (other than (i) the obligations that are intended to survive the termination of this Facility Agreement and (ii) contingent indemnification obligations for which no claim has been asserted) and the termination of the Commitments of the Lenders under this Facility Agreement (such date, the "**Termination Date**"), the Borrower will, unless each Lender shall otherwise consent in writing:

(a) Corporate Existence. (i) Maintain its corporate existence, (ii) qualify to transact business as a foreign corporation where the nature or extent of its business or the ownership of its property requires it to be so qualified and (iii) maintain in full force and effect all licenses, permits, approvals, bonds, franchises, leases and qualifications to do business, and all patents, trademarks, copyrights, intellectual property, contracts and other rights and privileges necessary to the conduct of its businesses or the performance of its obligations under this Facility Agreement.

(b) Maintenance of Property. Keep all property useful, necessary and material to its business in good working order and condition (ordinary wear and tear excepted) as may be required or appropriate.

(c) Taxes and other Claims. Pay and discharge when due all federal, state and local tax assessments and other governmental charges, and levies imposed against the Borrower or any of its property; *provided*, *however*, that any such tax assessment, charge or levy need not be paid if it is being contested, in good faith, by appropriate proceedings diligently conducted and if an adequate reserve or other appropriate provision shall have been made therefor to the extent required in accordance with GAAP.

(d) Legal Requirements. Comply with all applicable Legal Requirements, including, without limitation, those relating to environmental matters, employee matters (including the collection, payment and deposit of employees' income, unemployment and social security taxes) and with respect to pension liabilities.

(e) Books and Records. Maintain adequate books and records (including, without limitation, computer printouts and programs) in accordance with GAAP.

(f) Inspection Rights. At any reasonable time and from time to time upon reasonable notice, (i) permit or arrange for each Lender and its agents and representatives to examine and make copies of and abstracts from the records and books of account of, and the properties of, the Borrower, and (ii) permit or arrange for each Lender and its agents and representatives to discuss the affairs, finances and accounts of the Borrower with the Borrower and its officers, directors and accountants.

(g) Notice of Event of Default, Violations, etc. Furnish to each Lender as soon as possible, and in any event within five (5) Business Days after the Borrower (i) becomes aware that an Event of Default or any event or condition that, with the passage of time and/or the giving of notice, would become an Event of Default has occurred, written notice specifying the nature and extent thereof and the corrective action (if any) taken or proposed to be taken with respect thereto; or (ii) receives or produces any (A) financial statement, budget or other financial report or information pursuant to its bylaws or (B) other notice of any event, occurrence or other act that has or would reasonably result in a Material Adverse Effect.

(h) Further Assurances. Upon the request of the Lenders, duly execute and deliver, or cause to be duly executed and delivered, to each Lenders such further instruments and do and cause to be done such further acts as may be necessary or advisable in the reasonable opinion of the Lenders to carry out the intent and purpose of the express provisions of this Facility Agreement.

7. **Negative Covenants**. The Borrower covenants and agrees that, until the Termination Date, the Borrower will not, without the prior written consent of each Lender:

(a) Consolidation and Merger. Wind up, liquidate or dissolve its affairs or enter into any transaction of merger or consolidation (other than pursuant to the SPMA), or agree to do any of the foregoing at any future time.

(b) Corporate Changes, etc. Other than in accordance with the SPMA, amend, alter or modify its certification of incorporation or bylaws or its corporate or capital structure or status in a manner adverse to the Lenders.

(c) Change of Business. Make any change in the nature of its business as carried on at the date hereof or enter into any new type of business outside the pharmaceutical industry.

(d) Sales, etc. of Assets. Except to the extent expressly permitted under this Facility Agreement or the SPMA, directly or indirectly sell, lease, transfer, assign or otherwise dispose of all or substantially all of its assets.

(e) Indebtedness. Create, assume, guaranty, incur or otherwise become or remain directly or indirectly liable with respect to any indebtedness for borrowed money other than the obligations due to the Lenders under this Facility Agreement.

(f) Liens. (i) Create or suffer to exist any lien on any ownership interest in the Borrower or (ii) enter into any agreement prohibiting the creation or assumption of any lien upon any of its properties or assets, whether now owned or hereafter acquired.

8. **Events of Default**. The occurrence of any of the following events shall constitute an "**Event of Default**":

(a) failure of the Borrower to pay any principal, interest or other amount due under this Facility Agreement when due, whether at stated maturity, by declaration, acceleration, demand or otherwise;

(b) any representation, warranty or statement made by the Borrower to the Lenders herein shall (i) fail to be true and correct in all respects or (ii) is misleading, when made;

(c) failure of the Borrower to perform or observe any other term, covenant or agreement to be performed or observed by it pursuant to this Facility Agreement, and such failure shall continue unremedied for thirty (30) days after written notice thereof from any of the Lenders;

(d) (i) the Borrower institutes or consents to the institution of any proceeding under Title 11 of the United States Code entitled "Bankruptcy" (as now and hereinafter in effect, or any successor thereto, the "**Bankruptcy Code**") or any other applicable bankruptcy, insolvency or other similar law now or hereafter in effect, whether in the United States or any other applicable jurisdiction (collectively, the "**Debtor Relief Laws**"), or makes an assignment for the benefit of creditors; or applies for or consents to the appointment of any receiver, trustee, custodian, conservator, liquidator, administrator or similar officer for the Borrower or for all or substantially all of its property; (ii) any receiver, trustee, custodian, conservator, liquidator, administrator or similar officer is appointed without the application or consent of the Borrower and the appointment continues undischarged or unstayed for thirty (30) calendar days; (iii) any proceeding under any Debtor Relief Law relating to the Borrower or to all or substantially all of its property is instituted without the consent of the Borrower and continues undismissed or unstayed for thirty (30) calendar days, or an order for relief is entered in any such proceeding; or (iv) the Borrower becomes insolvent or shall generally be unable to pay its debts as they fall due; or

(e) the Borrower shall challenge, or institute any proceedings to challenge, the validity, binding effect or enforceability of this Facility Agreement or any endorsement of this Facility Agreement or any other obligation to any of the Lenders.

9 . **Remedies.** Upon the occurrence of any Event of Default specified in Section 8(d) above, the outstanding principal amount of the Loan and any accrued and unpaid interest thereon shall be automatically accelerated and become immediately due and payable, without presentment, demand, notice, protest or other requirements of any kind (all of which are hereby expressly waived by the Borrower). Upon the occurrence and during the continuance of any other Event of Default, the Lenders may, by written notice to the Borrower, terminate the Commitments and declare the outstanding principal amount of the Loan and any accrued and unpaid interest thereon to be due and payable, and the outstanding principal amount of the Loan and any accrued and unpaid interest thereon shall thereupon immediately become due and payable without presentment, further notice, protest or other requirements of any kind (all of which are hereby expressly waived by the Borrower).

10. **Miscellaneous.**

(a) Entire Agreement. This Facility Agreement, together with the Schedules and all other documents referred to herein, constitute the entire agreement between the parties with respect to the subject matter of this Facility Agreement and supersede any and all prior agreements, negotiations, correspondence, undertakings, understandings and communications of the parties with respect to the subject matter of this Facility Agreement. Nothing contained in this Facility Agreement shall be deemed or construed as creating a joint venture or partnership between any of the parties hereto.

(b) Indemnity; Transaction Costs. The Borrower agrees to indemnify the Lenders and their respective successors and assigns, and their respective directors, officers, employees, consultants, attorneys, agents and affiliates (each an "**Indemnified Party**") from and against any losses, taxes, claims, actions, suits, damages, demand, fines, interest, penalties and liabilities and related expenses (including expenses incurred in relation to any proceedings, judgements, orders, awards), including reasonable and documented attorneys' fees and expenses ("**Losses**"), incurred by such Indemnified Part(ies) arising out of or in connection with or as a result of (i) any inaccuracy or breach by the Borrower of the representations and warranties hereunder, (ii) any breach, non-compliance, non-fulfilment or failure to perform by the Borrower of any provision, covenant, obligation, Facility Agreement or undertaking of the Borrower contained in this Facility Agreement or (iii) the transactions contemplated by this Facility Agreement, except to the extent that any such Losses results from the gross negligence or willful misconduct of the Indemnified Party. In particular, the Borrower promises to pay all costs and expenses, including reasonable attorneys' fees and expenses, incurred in connection with the collection and enforcement of this Facility Agreement.

(c) Modifications, Etc. Any amendment or modification to this Facility Agreement, including this undertaking itself, any waiver of any provision of this Facility Agreement and any consent to any departure by the Borrower therefrom shall only be valid if effected by an instrument or instruments in writing signed by the Lenders and, in only in the case of any such amendment or modification, the Borrower as well, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given. Without limiting the generality of the foregoing, the making of the Loan hereunder shall not be construed as a waiver of any Event of Default, regardless of whether any of the Lenders may have had notice or knowledge of such Event of Default at the time. The parties agree that they jointly negotiated and prepared this Facility Agreement and this Facility Agreement will not be construed against any party on the grounds that such party prepared or drafted the same.

(d) Notices. Notices will be deemed to have been received (a) upon receipt of a registered letter, (b) three (3) Business Days following proper deposit with an internationally recognized express overnight delivery service, (c) in the case of transmission by email, as of the date so transmitted (or if so transmitted after normal business hours at the place of the recipient, on the Business Day following such transmission), or (d) in the case of transmission by email, upon confirmation of a facsimile transmission (or if so transmitted after normal business hours at the place of the recipient, on the Business Day following such confirmation):

If to the Borrower:

Avenue Therapeutics, Inc.
1140 Avenue of the Americas, Floor 9
New York, NY 10036
Attn: Dr. Lucy Lu, M.D.
Email: llu@avenuetx.com

with a copy (which shall not constitute notice) to:

Alston & Bird LLP
90 Park Avenue, 12th Floor
New York, NY 10016
Attn: Mark F. McElreath, Esq.
Email: mark.mcelreath@alston.com

If to Lender 1:

InvaGen Pharmaceuticals Inc.
Site B, 7 Oser Ave.
Hauppauge, NY 11788
c/o
A.S. Kumar, Esq.
Global General Counsel
Cipla House, Peninsula Business Park,
Ganapatrao Kadam Marg, Lower Parel West,
Mumbai, Maharashtra 400013, India
Email: as.kumar@cipla.com and cosecretary@cipla.com

with a copy (which shall not constitute notice) to:

InvaGen Pharmaceuticals Inc.
Site B, 7 Oser Ave.
Hauppauge, NY 11788
c/o
Jasdeep Singh
Chief Strategy Officer
Cipla Limited
Cipla House, Peninsula Business Park,
Ganapatrao Kadam Marg, Lower Parel West,
Mumbai, Maharashtra 400013, India
Email: jasdeeop.singh@cipla.com

with a copy (which shall not constitute notice) to:

Hughes Hubbard & Reed LLP
One Battery Park Plaza
New York, NY 10004-1482
Attn: Kenneth A. Lefkowitz
Email: ken.lefkowitz@hugheshubbard.com

If to Lender 2:

Fortress Biotech, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Attn: Dr. Lindsay Rosenwald, M.D.
Email: lrosenwald@fortressbiotech.com

with a copy (which shall not constitute notice) to:

Fortress Biotech, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Attn: Samuel W. Berry, Esq.
Email: sberry@fortressbiotech.com

or to such other address as may be hereafter communicated in writing by the parties in a notice given in accordance with this Section 10(d).

(e) Severability. Each provision of this Facility Agreement will be interpreted in such manner as to be effective and valid under applicable Legal Requirements, but if any provision of this Facility Agreement is found to be unenforceable or invalid under applicable Legal Requirements, such provision will be ineffective only to the extent of such unenforceability or invalidity, and the parties will negotiate in good faith to modify this Facility Agreement so that the unenforceable or invalid provision is replaced by such valid and enforceable provision which the parties consider, in good faith, to match as closely as possible the invalid or unenforceable provision and to achieve the same or a similar economic effect and to give effect to the parties' original intent. The remaining provisions of this Facility Agreement will continue to be binding and in full force and effect.

(f) Binding on Successors, Transferees and Assigns; Assignment. This Facility Agreement shall be binding upon the Borrower and its successors, transferees and assigns and shall inure to the benefit of and be enforceable by the Lenders and its successors, transferees and assigns; *provided*, *however*, that neither the Borrower nor Lender 2 may assign any of its obligations hereunder without the prior written consent of Lender 1 (and any such assignment without such consent shall be null and void *ab initio*). Lender 1 may assign its rights and obligations hereunder to any other Person upon written notice to, but without the consent of, the Borrower and Lender 2.

(g) Right to Set-Off. Upon the occurrence and during the continuance of any Event of Default, each Lender is hereby authorized at any time and from time to time, to the fullest extent permitted by law, to setoff and apply any and all deposits (general or special, time or demand, provisional or final) at any time held and other indebtedness at any time owing by that Lender to or for the credit or the account of the Borrower against any and all of the obligations of the Borrower now or hereafter existing under this Facility Agreement, irrespective of whether that Lender shall have made any demand under this Facility Agreement. Each Lender agrees promptly to notify the Borrower after any such set-off and application made by that Lender; *provided*, that the failure to give such notice shall not affect the validity of such set-off and application. The rights of each Lender under this Section 10(f) are in addition to other rights and remedies (including, without limitation, other rights of set-off) which that Lender may have.

(h) Governing Law. This Facility Agreement and any claims or causes of action pursuant to it shall be governed by and construed in accordance with the laws of the State of Delaware, without regard for its principles of conflict of laws. The Borrower acknowledges and agrees that it has received full and sufficient consideration for this provision (and each other provision of each other credit document to which it is a party) and that this provision is a material inducement for the Lenders entering into this Facility Agreement.

(i) Submission to jurisdiction. Each of the parties hereto irrevocably agrees that any Proceeding with respect to this Facility Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Facility Agreement and the rights and obligations arising hereunder brought by any other party hereto or its successors or assigns, shall be brought and determined exclusively in the Court of Chancery of the State of Delaware, or in the event (but only in the event) that such court does not have subject matter jurisdiction over such action or proceeding, in the federal courts sitting in the State of Delaware. Each of the parties hereto agrees that mailing of process or other papers in connection with any such action or proceeding in the manner provided in Section 10(d) or in such other manner as may be permitted by applicable Legal Requirements, will be valid and sufficient service thereof. Each of the parties hereto hereby irrevocably submits with regard to any such action or proceeding for itself and in respect of its property, generally and unconditionally, to the personal jurisdiction of the aforesaid courts and agrees that it will not bring any action relating to this Facility Agreement or any of the transactions contemplated by this Facility Agreement in any court or tribunal other than the aforesaid courts. Each of the parties hereto hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim, or otherwise, in any action or proceeding with respect to this Facility Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Facility Agreement and the rights and obligations arising hereunder: (a) any claim that it is not personally subject to the jurisdiction of the above named courts for any reason other than the failure to serve process in accordance with this Section 10 (j); (b) any claim that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise); and (c) to the fullest extent permitted by the applicable Legal Requirements, any claim that (i) the suit, action or proceeding in such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper, or (iii) this Facility Agreement, or the subject matter hereof, may not be enforced in or by such courts.

(j) Counterparts; Facsimile Signature. This Facility Agreement and any amendments, waivers, consents or supplements hereto or in connection herewith may be executed in one (1) or more counterparts, by original or facsimile (or other such electronically transmitted) signature, each of which will be deemed an original, but all of which will constitute one and the same instrument.

(k) Rights Cumulative. All rights and remedies of each of the parties under this Facility Agreement will be cumulative, and the exercise of one or more rights or remedies will not preclude the exercise of any other right or remedy available under this Facility Agreement or applicable Legal Requirements.

(l) Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS FACILITY AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS FACILITY AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS FACILITY AGREEMENT. EACH PARTY TO THIS FACILITY AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT: (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION; (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER; (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY; AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS FACILITY AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10 (m).

(m) No Waiver. No failure on the part of any Lender to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right hereunder preclude any other or further exercise thereof or the exercise of any other right. The Lenders shall have all remedies available at law or equity, including without limitation, the remedy of specific performance for any breach of any provision hereof. No notice to or demand on the Borrower in any case shall entitle the Borrower to any other or further notice or demand in similar or other circumstances or constitute a waiver of the right of the Lenders to any other or further action in any circumstances without notice or demand.

(n) Waiver of Certain Claims. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE BORROWER SHALL NOT ASSERT, AND HEREBY WAIVES, ANY CLAIM AGAINST THE LENDERS ON ANY THEORY OF LIABILITY FOR SPECIAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES (AS OPPOSED TO DIRECT OR ACTUAL DAMAGES) ARISING OUT OF, IN CONNECTION WITH, OR AS A RESULT OF, THIS FACILITY AGREEMENT OR ANY INSTRUMENT CONTEMPLATED HEREBY.

(o) No Third-Party Beneficiaries. This Facility Agreement is entered into for the sole benefit of the Borrower and the Lenders; no other Person shall be entitled to enforce any provision hereof or otherwise be a third-party beneficiary hereunder.

(p) Setoff; Reinstatement. All payments to be made hereunder by the Borrower shall be made without offset, setoff or deduction of any kind. To the extent that the Borrower makes a payment or payments to any Lender and such payment or payments or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside and/or required to be repaid to a trustee, receiver or any other party under any Debtor Relief Law, state or Federal law, common law or equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made.

(q) Headings. Section headings used herein are for convenience of reference only, are not part of this Facility Agreement and shall not affect the construction of, or be taken into consideration in interpreting, this Facility Agreement.

(r) Effectiveness; Time**.** This Facility Agreement shall become effective when it shall have been executed by the parties hereto and the Lenders shall have received counterparts hereof which, when taken together, bear the signatures of each of the parties hereto, and thereafter shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. Time is of the essence with respect to the Borrower's payment and other obligations under this Facility Agreement.

(s) Interpretation. (a) The words "hereof", "herein", and "hereunder" and words of similar import, when used in this Facility Agreement, shall refer to this Facility Agreement as a whole and not to any particular provision of this Facility Agreement; (b) the words "date hereof," when used in this Facility Agreement, shall refer to the date set forth in the Preamble; (c) the terms defined in the singular have a comparable meaning when used in the plural, and vice versa; (d) the terms defined in the present tense have a comparable meaning when used in the past tense, and vice versa; (e) any references herein to a specific Section or Article shall refer, respectively, to Sections or Articles of this Facility Agreement; (f) wherever the word "include", "includes", or "including" is used in this Facility Agreement, it shall be deemed to be followed by the words "without limitation"; (g) references herein to any gender include each other gender; (h) the word "or" shall not be exclusive; (i) the headings herein are for convenience of reference only, do not constitute part of this Facility Agreement and shall not be deemed to limit or otherwise affect any of the provisions hereof; (j) any references herein to any Governmental Authority shall be deemed to also be a reference to any successor Governmental Authority thereto; and (k) the parties hereto have participated jointly in the negotiation and drafting of this Facility Agreement and, in the event that an ambiguity or question of intent or interpretation arises, this Facility Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Facility Agreement.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this Facility Agreement to be duly executed and delivered as of the date first above written.

BORROWER:

AVENUE THERAPEUTICS, INC.

By: /s/ Joseph Vazzano
Name: Joseph Vazzano
Title: Chief Financial Officer
Date: 6/12/2020

LENDER 1:

INVAGEN PHARMACEUTICALS INC.

By: /s/ Deepak Agarwal
Name: Deepak Agarwal
Title: Director
Date: 6/12/2020

LENDER 2:

FORTRESS BIOTECH, INC.

By: /s/ Lindsay Rosenwald
Name: Lindsay Rosenwald
Title: Chairman, President and Chief Executive Officer
Date: 6/16/2020

SCHEDULE A

COMMITMENTS

Name of Lender	Commitment of such Lender	Pro Rata Share
Lender 1 - Invagen Pharmaceuticals Inc.	$1,200,000	60%
Lender 2 - Fortress Biotech, Inc.	$800,000	40%
TOTAL	**$2,000,000**	**100%**

Exhibit 31.1

Certification of
Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Lucy Lu, M.D., certify that:

1. I have reviewed this report on Form 10-Q of Avenue Therapeutics, 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, 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 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.

/s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)
August 14, 2020

Exhibit 31.2

Certification of
Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q of Avenue Therapeutics, 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, 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 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.

/s/ Joseph Vazzano
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)
August 14, 2020

Exhibit 32.1

Certification of
Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Lucy Lu, M.D., Chief Executive Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)
August 14, 2020

Exhibit 32.2

Certification of
Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Joseph Vazzano, Principal Financial Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020 (the "Report") filed with the Securities and Exchange Commission:

· Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Joseph Vazzano
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)
August 14, 2020