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, 2019

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.)

2 Gansevoort Street, 9th Floor, New York NY 10014
(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, 2019**
Common Stock, $0.0001 par value	16,560,122

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2019

Table of Contents

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

	June 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,455	$ 2,671
Short-term investments	5,000	-
Deferred financing costs	61	1,702
Prepaid expenses and other current assets	161	152
Total Assets	**$ 15,677**	**$ 4,525**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,728	$ 4,669
Accounts payable and accrued expenses - related party	45	487
Total current liabilities	1,773	5,156
Total Liabilities	1,773	5,156
Commitments and Contingencies		
Stockholders' Equity (Deficit)		
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, 2019 and December 31, 2018	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Common shares; 16,559,747 and 10,667,714 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	2	1
Additional paid-in capital	74,362	41,577
Accumulated deficit	(60,460)	(42,209)
Total Stockholders' Equity (Deficit)	13,904	(631)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 15,677**	**$ 4,525**

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, 2019	**June 30, 2018**	**June 30, 2019**	**June 30, 2018**
Operating expenses:				
Research and development	$ 6,392	$ 3,754	$ 16,633	$ 13,193
General and administrative	716	927	1,835	1,913
Loss from operations	(7,108)	(4,681)	(18,468)	(15,106)
Interest income	(126)	(24)	(217)	(72)
Net Loss	**$ (6,982)**	**$ (4,657)**	**$ (18,251)**	**$ (15,034)**
Net loss per common share outstanding, basic and diluted	$ (0.43)	$ (0.45)	$ (1.21)	$ (1.48)
Weighted average number of common shares outstanding, basic and diluted	16,314,763	10,251,950	15,035,811	10,176,062

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, 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**

Three months ended June 30, 2018

	Class A Preferred Shares		Common Shares		Common Shares Issuable		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at March 31, 2018	**250,000**	**$ -**	**10,552,045**	**$ 1**	**-**	**$ -**	**$ 40,390**	**$ (31,038)**	**$ 9,353**
Share based compensation	-	-	-	-	-	-	321	-	321
Cashless exercise of warrants under the NSC Note	-	-	2,125	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	(4,657)	(4,657)
Balance at June 30, 2018	**250,000**	**$ -**	**10,554,170**	**$ 1**	**-**	**$ -**	**$ 40,711**	**(35,695)**	**$ 5,017**

Six months ended June 30, 2018

	Class A Preferred Shares		Common Shares		Common Shares Issuable		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at December 31, 2017	**250,000**	**$ -**	**10,265,083**	**$ 1**	**273,837**	**$ 1,103**	**$ 38,937**	**$ (20,661)**	**$ 19,380**
Share based compensation	-	-	-	-	-	-	671	-	671
Issuance of common shares - Founder Agreement	-	-	273,837	-	(273,837)	(1,103)	1,103	-	-
Cashless exercise of warrants under the NSC Note	-	-	15,250	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	(15,034)	(15,034)
Balance at June 30, 2018	**250,000**	**$ -**	**10,554,170**	**$ 1**	**-**	**$ -**	**$ 40,711**	**$ (35,695)**	**$ 5,017**

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, 2019	**June 30, 2018**
Cash flows from operating activities:		
Net loss	$ (18,251)	$ (15,034)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	1,286	671
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(9)	(108)
Accounts payable and accrued expenses	(2,133)	1,497
Accounts payable and accrued expenses - related party	(442)	132
Net cash used in operating activities	(19,549)	(12,842)
Cash flows from investing activities:		
Purchase of Short-term investments (certificates of deposit)	(5,000)	-
Maturity of Short-term investments (certificates of deposit)	-	10,000
Net cash (used in) provided by investing activities	(5,000)	10,000
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	7,784	(2,842)
Cash and cash equivalents, beginning of period	2,671	11,782
Cash and cash equivalents, end of period	**$ 10,455**	**$ 8,940**
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, 2019.

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, 2019, the Company had an accumulated deficit of $60.5 million. The Company believes that its cash and cash equivalents and short-term investments as of June 30, 2019, as well as its ability for interim financing of $7.0 million from InvaGen, 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.

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, 2018, which were included in the Company's Form 10-K, and filed with the U.S. Securities and Exchange Commission ("SEC") on March 12, 2019. 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, 2018 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.

Short-term Investments

The Company classifies certain of its certificates of deposit as short-term investments in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 320, *Investments - Debt and Equity Securities*. The Company considers all short-term investments with an original maturity in excess of three months but less than a year when purchased to be short-term investments. In May 2019, the Company purchased $5.0 million of certificates of deposit with an original maturity of six months. There were no investments as of December 31, 2018. The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period. The Company has determined that its certificates of deposit with an original maturity of six months should be classified as short-term investments as of June 30, 2019. This classification was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as its investments mature within one year and the underlying cash invested in these securities is not required for current operations.

Investments consist of short-term FDIC insured certificates of deposit carried at amortized cost using the effective interest method. The cost of the Company's certificates of deposit approximated fair value.

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, 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 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, 2019	**June 30, 2018**
Restricted stock units/awards	1,150,162	673,332
Preferred shares	250,000	250,000
Options	-	20,000
Total potential dilutive effect	1,400,162	943,332

Recently Adopted Accounting Standards

In June 2018, the FASB issued Accounting Standard Updated ("ASU") No. 2018-07,*Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU 2018-07 in the first quarter of 2019 and its adoption did not have a material impact on the Company's unaudited condensed financial statements.

Note 3 — Related Party Agreements

Management Services Agreement with Fortress

Effective as of February 17, 2015, Fortress entered into a Management Services Agreement (the "MSA") with Avenue to provide advisory and consulting services to Avenue for a period of five (5) years. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Avenue's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Avenue with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Avenue is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Avenue is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of Avenue's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Avenue's Board of Directors, have been contractually exempt from fiduciary duties to Avenue relating to corporate opportunities. In consideration for the Services, Avenue will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Avenue has net assets in excess of $100.0 million at the beginning of the calendar year. Concurrently with the execution and delivery of the SPMA, the Company, InvaGen and Fortress entered into a Waiver Agreement, pursuant to which, among other things, Fortress irrevocably waived its right to receive dividends of the Company's common shares under the terms of the Class A Preferred Stock and any fees, payments, reimbursements or other distributions under the MSA, until the termination of certain rights of InvaGen, pursuant to the Stockholders Agreement. For the three months ended June 30, 2019 and 2018, the Company had expenses related to the MSA of $0 and approximately $0.1 million, respectively. For the six months ended June 30, 2019 and 2018, the Company had expenses related to the MSA of $0 and approximately $0.3 million, respectively.

Note 4— Accounts Payable and Accrued Expenses

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

	As of June 30, 2019	As of December 31, 2018
Accounts payable	$ 851	$ 3,089
Accrued employee compensation	233	463
Accrued contracted services and other	644	1,117
Accounts payable and accrued expenses	$ 1,728	$ 4,669

Note 5 — Stockholders' Equity

Stock Purchase Transaction

On February 8, 2019, InvaGen acquired 5,833,333 shares of the Company's common stock at $6.00 per share 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.

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, 2019:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2018	1,104,643	$ 4.45
Granted	241,173	$ 5.93
Vested	(195,654)	$ 4.32
Unvested balance at June 30, 2019	1,150,162	$ 4.74

For the three months ended June 30, 2019 and 2018, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $0.5 million and $0.3 million, respectively. For the six months ended June 30, 2019 and 2018, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $1.3 million and $0.7 million, respectively.

At June 30, 2019, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $1.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.5 years. This amount does not include, as of June 30, 2019, 341,173 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 Options

The following table summarizes stock option award activity for the six months ended June 30, 2019:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding, December 31, 2018	20,000	$ 6.29	3.63
Cancelled/forfeited	(20,000)	6.29	-
Outstanding, June 30, 2019	-	$ -	-

Stock Warrants

The following table summarizes the warrant activity for the six months ended June 30, 2019:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2018	102,597	$ 0.0976	$ 544
Exercised	(58,700)	$ 0.0001	-
Outstanding, June 30, 2019	43,897	$ 0.2279	$ 267

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, 2018 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2019. 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.

We plan to submit 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) by the end of 2019.

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, 2019 was approximately $7.0 million and $18.3 million, respectively. As of June 30, 2019, we had an accumulated deficit of approximately $60.5 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 general and administration related costs and incur operating losses for at least the next several years as we develop and seek regulatory approval 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 and research and development 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. For related party transactions, see Note 3.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

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, 2019, we had an accumulated deficit of $60.5 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, 2019 and 2018

	For The Three Months Ended		Change	
($ in thousands)	**June 30, 2019**	**June 30, 2018**	**$**	**%**
Operating expenses:				
Research and development	$ 6,392	$ 3,754	$ 2,638	70%
General and administrative	716	927	(211)	(23)%
Loss from operations	(7,108)	(4,681)	(2,427)	52%
Interest income	(126)	(24)	(102)	425%
Net Loss	**$ (6,982)**	**$ (4,657)**	**$ (2,325)**	50%

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, 2019 and 2018, research and development expenses were $6.4 million and $3.8 million, respectively. The increase of $2.6 million is primarily due to increases of $4.4 million associated with the completion of our abdominoplasty study, $0.4 million in personnel costs and $0.4 million in consulting costs associated with our NDA preparation. These increases were partially offset by decreases of $2.2 million associated with the completion of our bunionectomy study, $0.3 million associated with the completion of our safety study and $0.1 million associated with the waiver of our Management Services Agreement (MSA) with Fortress.

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, 2019 and 2018, general and administrative expenses were $0.7 million and $0.9 million, respectively. General and administrative expenses decreased by $0.2 million primarily due to decreases in marketing costs of $0.1 million, investor relations costs of $0.1 million and $0.1 million in Board of Directors fees. These decreases were partially offset by an increase of $0.1 million in non-cash stock compensation.

Interest Income

Interest income was $0.1 million and $24,000 for the three months ended June 30, 2019 and 2018, respectively. The increase in interest income was from the interest on our cash and cash equivalents and short-term investments derived from our share issuance to InvaGen.

Comparison of the Six Months Ended June 30, 2019 and 2018

	For The Six Months Ended		Change	
($ in thousands)	**June 30, 2019**	**June 30, 2018**	**$**	**%**
Operating expenses:				
Research and development	$ 16,633	$ 13,193	$ 3,440	26%
General and administrative	1,835	1,913	(78)	(4)%
Loss from operations	18,468	15,106	3,362	22%
Interest income	(217)	(72)	(145)	201%
Net Loss	**$ (18,251)**	**$ (15,034)**	**$ (3,217)**	21%

Research and Development Expenses

For the six months ended June 30, 2019 and 2018, research and development expenses were $16.6 million and $13.2 million, respectively. The increase of $3.4 million is primarily due to increases of $13.2 million associated with the completion of our abdominoplasty study, $0.6 million in personnel costs and $0.7 million in consulting costs associated with our NDA preparation. These increases were partially offset by decreases of $7.5 million associated with the completion of our bunionectomy study and $3.6 million associated with the completion of our safety study.

General and Administrative Expenses

For the six months ended June 30, 2019 and 2018, general and administrative expenses were $1.8 million and $1.9 million, respectively. General and administrative expenses decreased by $0.1 million primarily due to decreases in investor relations spending of $0.2 million, market research costs of $0.2 million and $0.2 million in other general and administrative costs. These decreases were partially offset by an increase in non-cash stock compensation of $0.5 million.

Interest Income

Interest income was $0.2 million and $72,000 for the six months ended June 30, 2019 and 2018, respectively. The increase in interest income was from the interest on our cash and cash equivalents and short-term investments derived from our share issuance to InvaGen.

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, 2019, we had an accumulated deficit of $60.5 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, 2019 in addition to the SPMA with InvaGen which provides interim financing of up to $7.0 million up until the second stage closing, 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.

Recently Adopted and Issued Accounting Pronouncements

See Footnote 2.

Cash Flows for the Six Months Ended June 30, 2019 and 2018

($ in thousands)	**For The Six Months Ended June 30, 2019**	**2018**
Total cash (used in)/provided by:		
Operating activities	$ (19,549)	$ (12,842)
Investing activities	(5,000)	10,000
Financing activities	32,333	-
Net increase in cash	$ 7,784	$ (2,842)

Operating Activities

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.

Net cash used in operating activities was $12.8 million for the six months ended June 30, 2018, primarily comprised of our $15.0 million net loss, partially offset by increases of: $1.5 million in operating assets and liabilities and $0.7 million in share based compensation.

Investing Activities

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.

Net cash provided by investing activities for the six months ended June 30, 2018 was $10.0 million. Our $10.0 million short-term investments consisting of certificates of deposit matured during the six months ended June 30, 2018.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2019 and 2018 was $32.3 million and $0, 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, 2018.

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, 2019, 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, 2019 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, 2018, 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, 2018.

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
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, 2019.
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, 2019.
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, 2019.
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, 2019.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, 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, 2019

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

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 and Chief Executive Officer
(Principal Executive Officer)
August 14, 2019

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, 2019

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, 2019 (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 and Chief Executive Officer
(Principal Executive Officer)
August 14, 2019

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, 2019 (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, 2019