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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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 November 1, 2022
Common Stock, $0.0001 par value	4,773,316

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended September 30, 2022

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

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 217	$ 3,763
Other receivables - related party	—	90
Deferred financing costs	338	—
Prepaid expenses and other current assets	20	107
Total Assets	**$ 575**	**$ 3,960**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 573	$ 451
Accounts payable and accrued expenses - related party	41	58
Total current liabilities	614	509
Total Liabilities	614	509
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 September 30, 2022 and December 31, 2021	—	—
Common Stock ($0.0001 par value), 20,000,000 shares authorized		
Common shares, 1,481,439 and 1,405,934 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	—	2
Additional paid-in capital	81,087	80,448
Accumulated deficit	(81,126)	(76,999)
Total Stockholders' Equity (Deficit)	(39)	3,451
Total Liabilities and Stockholders' Equity (Deficit)	**$ 575**	**$ 3,960**

The accompanying notes are an integral part of these unaudited 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 Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Operating expenses:				
Research and development	$ 194	$ 278	$ 2,153	$ 864
General and administrative	469	594	1,978	1,960
Loss from operations	(663)	(872)	(4,131)	(2,824)
Interest income	(1)	(1)	(4)	(6)
Net Loss	**$ (662)**	**$ (871)**	**$ (4,127)**	**$ (2,818)**
Net loss per common share outstanding, basic and diluted	$ (0.45)	$ (0.79)	$ (2.86)	$ (2.55)
Weighted average number of common shares outstanding, basic and diluted	1,465,691	1,108,495	1,441,542	1,105,352

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

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

Three months ended September 30, 2022

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at June 30, 2022	**250,000**	**$ —**	**1,475,608**	**$ 2**	**$ 81,060**	**$ (80,464)**	**$ 598**
Reverse stock split adjustment	—	—	—	(2)	2	—	—
Share based compensation	—	—	5,831	—	25	—	25
Net loss	—	—	—	—	—	(662)	(662)
Balance at September 30, 2022	**250,000**	**$ —**	**1,481,439**	**$ —**	**$ 81,087**	**$ (81,126)**	**$ (39)**

Nine months ended September 30, 2022

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	**250,000**	**$ —**	**1,405,934**	**$ 2**	**$ 80,448**	**$ (76,999)**	**$ 3,451**
Reverse stock split adjustment	—	—	—	(2)	2	—	—
Share based compensation	—	—	75,505	—	637	—	637
Net loss	—	—	—	—	—	(4,127)	(4,127)
Balance at September 30, 2022	**250,000**	**$ —**	**1,481,439**	**$ —**	**$ 81,087**	**$ (81,126)**	**$ (39)**

Three months ended September 30, 2021

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at June 30, 2021	**250,000**	**$ —**	**1,116,537**	**$ 2**	**$ 75,855**	**$ (75,215)**	**$ 642**
Share based compensation	—	—	3,000	—	69	—	69
Cashless exercise of warrants	—	—	42	—	—	—	—
Net loss	—	—	—	—	—	(871)	(871)
Balance at September 30, 2021	**250,000**	**$ —**	**1,119,579**	**$ 2**	**$ 75,924**	**$ (76,086)**	**$ (160)**

Nine months ended September 30, 2021

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	**250,000**	**$ —**	**1,116,520**	**$ 2**	**$ 75,625**	**$ (73,268)**	**$ 2,359**
Share based compensation	—	—	3,000	—	299	—	299
Cashless exercise of warrants	—	—	59	—	—	—	—
Net loss	—	—	—	—	—	(2,818)	(2,818)
Balance at September 30, 2021	**250,000**	**$ —**	**1,119,579**	**$ 2**	**$ 75,924**	**$ (76,086)**	**$ (160)**

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

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

	For the Nine Months Ended	
	September 30, 2022	September 30, 2021
Cash flows from operating activities:		
Net loss	$ (4,127)	$ (2,818)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	637	299
Changes in operating assets and liabilities:		
Other receivables - related party	90	(74)
Prepaid expenses and other current assets	87	84
Accounts payable and accrued expenses	(97)	(185)
Accounts payable and accrued expenses - related party	(17)	147
Net cash and cash equivalents used in operating activities	(3,427)	(2,547)
Cash flows from financing activity:		
Payment of deferred financing costs	(119)	—
Net cash and cash equivalents used in financing activity	(119)	—
Net change in cash and cash equivalents	(3,546)	(2,547)
Cash and cash equivalents, beginning of period	3,763	3,132
Cash and cash equivalents, end of period	**$ 217**	**$ 585**
Supplemental cash flow information:		
Unpaid deferred financing costs	219	—

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

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM 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 HCl ("IV Tramadol"), for post-operative acute pain, and, to the extent the transactions contemplated by the Contribution Agreement (as defined below) are contemplated, the development of Baergic.

Baergic

On May 11, 2022, the Company entered into a stock contribution agreement (the "Contribution Agreement") with Fortress, pursuant to which Fortress agreed to transfer ownership of 100% of its shares (common and preferred) (the "Contributed Shares") in a private subsidiary company of Fortress, Baergic Bio, Inc. ("Baergic"), to the Company. Under the Contribution Agreement, Fortress also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement, by and between Fortress and Baergic, dated as of March 9, 2017, and Management Services Agreement, by and between Fortress and Baergic, dated as of March 9, 2017. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by the Company resulting in gross proceeds of at least $7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen Pharmaceuticals Inc. ("InvaGen") to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements into which it entered with the Company and/or Fortress in connection with InvaGen's 2019 equity investment in the Company, which would eliminate certain negative consent rights of InvaGen over the Company and restore certain rights and privileges of Fortress in the Company (all upon terms to be agreed upon with InvaGen); and (iii) the sustained listing of Avenue's common stock on The Nasdaq Capital Market.

The transaction is expected to expand Avenue's development portfolio within neuroscience. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies' boards. See Note 6 below.

Reverse Stock Split

On July 25, 2022, the holders of a majority of the voting power of the capital stock of the Company executed a written consent approving a grant of discretionary authority to the board of directors of the Company (the "Board") to, without further stockholder approval, (i) effect a reverse stock split of the Company's issued and outstanding common stock within a range of between 10-for-1 and 20-for-1 (with the Board being authorized to determinate the exact ratio) (the "Reverse Stock Split") and (ii) reduce the number of the Company's authorized shares of common stock from 50,000,000 to 20,000,000 (the "Authorized Share Reduction") by filing an amendment (the "Amendment") to the Company's Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The written consent was signed by the holders of 9,423,429 shares of the Company's common stock and 250,000 shares of the Company's Class A Preferred Stock. Each share of common stock entitles the holder thereof to one vote on all matters submitted to stockholders and each share of Class A Preferred Stock has the voting power of 1.1 times (A) the number of outstanding shares of common stock plus (B) the whole shares of Company common stock into which the outstanding shares of Class A Preferred Stock are convertible, divided by the number of outstanding shares of Class A Preferred Stock, or 99 votes per share as of July 25, 2022. Accordingly, the holders of approximately 73% of the voting power of the Company's capital stock as of July 25, 2022 signed the written consent approving the Reverse Stock Split, the Authorized Share Reduction and the Amendment. The Board also approved the Reverse Stock Split, the Authorized Share Reduction and the Amendment.

The Reverse Stock Split was effective on September 23, 2022 upon filing of the Amendment with the Secretary of State of Delaware, which date was at least twenty (20) days from the mailing of the information statement. Under the Amendment, the number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") was simultaneously reduced from 50,000,000 to 20,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

As a result of the Reverse Stock Split, every 15 shares of Common Stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of New Common Stock without any change in the par value per share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to a fraction of one share of New Common Stock as a result of the Reverse Stock Split instead received an amount in cash equal to such fraction multiplied by the closing sale price of Common Stock on The Nasdaq Capital Market on September 22, 2022, as adjusted for the Reverse Stock Split.

Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at September 23, 2022, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

Liquidity and Capital Resources

The Company is not yet generating revenue, 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 September 30, 2022, the Company had an accumulated deficit of $81.1 million. Due to uncertainties regarding future operations of the Company for a study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol, and the expansion of the Company's development portfolio within neuroscience with the consummation of the transaction with Baergic, the Company will need to secure additional funds through equity or debt offerings, or other potential sources, the timing of which is unknown at this time. The Company cannot be certain that additional funding will be available to it on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing this Quarterly Report on Form 10-Q. The unaudited interim condensed financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainty.

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 fiscal year ended December 31, 2021, which were included in the Company's Annual Report on Form 10-K and filed with the U.S. Securities and Exchange Commission ("SEC") on March 25, 2022. 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.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 in its audited financial statements for the fiscal year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2022. 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 net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the Three and Nine Months Ended September 30,	
	2022	2021
Unvested restricted stock units/awards	13,145	67,617
Preferred shares	16,666	16,666
Total potential dilutive effect	29,811	84,283

Note 3 - Accounts Payable and Accrued Expenses

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

	As of September 30, 2022	As of December 31, 2021
Accounts payable	$ 364	$ 304
Accrued employee compensation	90	24
Accrued contracted services and other	119	123
Total accounts payable and accrued expenses	$ 573	$ 451

Note 4 - Related Party Transactions

On May 11, 2022, the Company entered into the Contribution Agreement with Fortress related to the Company's acquisition of Baergic, on the terms and subject to the satisfaction of conditions described above in Note 1 – Organization, Plan of Business Operations. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies' boards. The Company believes that the terms of the Contribution Agreement is at least as favorable as the terms that the Company would have been able to obtain with a disinterested party.

Note 5 - Stockholders' Equity

Equity Incentive Plan

The Company has in effect the Amended 2015 Equity Incentive Plan ("2015 Incentive Plan" or "Plan"). The 2015 Incentive Plan was adopted in December 2015 by the Company's stockholders and an amendment to the Plan to increase the number of authorized shares issuable to 266,667 shares was approved by the Company's stockholders in December 2021. Under the 2015 Incentive Plan, the compensation committee of the Board is authorized to grant stock-based awards to directors, officers, employees and consultants. The Plan authorizes grants to issue up to 266,667 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. As of September 30, 2022, there are 122,489 shares available to be issued under the Plan.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes restricted stock unit and award activity for the nine months ended September 30, 2022:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2021	94,423	$ 56.25
Forfeited	(666)	$ 13.95
Vested	(80,612)	$ 40.80
Unvested balance at September 30, 2022	13,145	$ 12.07

For the three months ended September 30, 2022 and 2021, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $26,000 and $69,000, respectively. For the nine months ended September 30, 2022 and 2021, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $0.6 million and $0.3 million, respectively.

At September 30, 2022, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.2 years. This amount does not include, as of September 30, 2022, 3,333 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. 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

There was no warrant activity for the nine months ended September 30, 2022.

Note 6 – Subsequent Events

October 2022 Public Offering

On October 6, 2022, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Aegis Capital Corp., as underwriter (the "Underwriter"), related to the Company's underwritten public offering (the "Offering") of 2,652,065 units ("Units") and 984,300 pre-funded units ("Pre-funded Units"). Each Unit consisted of one share (a "Share") of the Company's common stock, par value $0.0001 per share ("Common Stock"), and one warrant to purchase one share of Common Stock (each, a "Warrant" and, collectively, the "Warrants"), and each Pre-funded Unit consisted of one pre-funded warrant to purchase one share of Common Stock (each, a "Pre-funded Warrant" and collectively, the "Pre-funded Warrants") and one Warrant. The Units were sold at a price of $3.30 per Unit, and the Pre-Funded Units were sold at a price of $3.2999 ($3.30 less $0.0001, the exercise price of the Pre-funded Warrants).

The Warrants are immediately exercisable upon issuance and are exercisable for a period of five years after the issuance date. The Shares, the Pre-funded Warrants and the Warrants were immediately separable upon issuance and were issued separately. The Underwriter was granted a 45-day option to purchase up to an aggregate of (i) 545,454 additional Shares and/or Pre-funded Units, representing 15% of the Shares and Pre-funded Warrants sold in the Offering, and/or (ii) Warrants to purchase 545,454 additional Shares, representing 15% of the Warrants sold in the Offering, which it initially exercised, in part, electing to purchase 545,454 Warrants at a purchase price of $0.01 per Warrant. The Company consummated the transactions contemplated by the Offering and the Underwriting Agreement, including the partial exercise of the Underwriter's option, on October 11, 2022. Prior to the closing date of the Offering, investors in certain of the Pre-funded Warrants, pursuant to the terms thereof, elected to exercise 949,900 Pre-funded Warrants. Accordingly, at the closing, the Company issued 949,900 fewer Pre-funded Warrants and, in lieu thereof, the corresponding 949,900 shares of Common Stock.

The Company estimates the net proceeds from the Offering to be $10.4 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

InvaGen Share Repurchase

In connection with the closing of the Offering, on October 11, 2022, the Company consummated the transactions contemplated by the Share Repurchase Agreement with InvaGen, pursuant to which the Company repurchased 100% of the shares in the Company held by InvaGen (the "InvaGen Shares") for a purchase price of $3 million. In addition, under the Share Repurchase Agreement the Company agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4 million. In connection with the closing of the Share Repurchase Agreement, which occurred on October 31, 2022, all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among the Company, InvaGen and Fortress on November 12, 2018, were terminated.

Acquisition of Baergic Bio

The transaction contemplated by the Contribution Agreement was closed on November 8, 2022, following the satisfaction of the closing conditions of the Contribution Agreement. In exchange for the Contributed Shares, the Company assumed and became solely liable for all obligations, duties, covenants and liabilities arising from, based upon, related to or associated with the Contributed Shares, Fortress' obligations under the contracts being assumed and Fortress' ownership in Baergic. As a result of the closing of the Contribution Agreement, Baergic is now a majority owned subsidiary of the Company. Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of central nervous system disorders. Baergic's pipeline currently consists of a single compound, BAER-101, a selective GABA-A positive allosteric modulator ("BAER-101"). BAER-101 (formally known as AZD7325) is Baergic's principal asset and was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

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 fiscal year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2022 (the "2021 Form 10-K"). 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 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 focused on the development and commercialization of therapies for the treatment of central nervous system diseases. Our lead product candidate is intravenous (IV) Tramadol ("IV Tramadol"), for the treatment of post-operative acute pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. In 2016, we completed a pharmacokinetic study for IV Tramadol in healthy volunteers as well as an end of phase 2 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. In December 2019, we submitted a New Drug Application ("NDA") for IV Tramadol and received a Complete Response Letter (the "First CRL") from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV Tramadol. The FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received a second Complete Response Letter (the "Second CRL") from the FDA regarding our NDA for IV tramadol. We submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, we received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the OND in response to the FDRR. On August 31, 2022, the Company disclosed that, on June 17, 2022, following the receipt of the Letter, the Company submitted a Type A Meeting Request and related briefing documents to the FDA. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") on June 27, 2022, and scheduled for August 9, 2022. The Company submitted a briefing document presenting a study design that the Company believed has the potential to address the comments and deficiencies noted in the Letter and sought the DAAAP's guidance to refine the study design that would support a resubmission of a New Drug Application for the Company's current lead product candidate, intravenous Tramadol. The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. We intend to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol. We continue to evaluate next steps with regard to IV Tramadol.

We have recently expanded our business with the acquisition of Baergic Bio, Inc. ("Baergic") and its asset BAER-101, which would strategically align with Avenue's goals of building a CNS pipeline. On May 11, 2022, we entered into a stock contribution agreement (the "Contribution Agreement") with Fortress, pursuant to which Fortress agreed to transfer ownership of 100% of its shares (common and preferred) in a private subsidiary company of Fortress, Baergic Bio, Inc. ("Baergic"), to us. The acquisition was completed on November 8, 2022 and Baergic is currently a private subsidiary company of Avenue.

Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of CNS disorders. Baergic's pipeline currently consists of a single compound, BAER-101, a selective GABA-A positive allosteric modulator ("BAER-101"). BAER-101 (formally known as AZD7325) was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

Under the Contribution Agreement, Fortress also agreed to assign to us certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement was subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than $7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen Pharmaceuticals Inc. ("InvaGen") to (A) have 100% of its shares in us repurchased by us and (B) terminate certain of the agreements into which it entered with us and/or Fortress in connection with InvaGen's 2019 equity investment in us, which will eliminate certain negative consent rights of InvaGen over us and restore certain rights and privileges of Fortress in us (all upon terms to be agreed upon with InvaGen); and (iii) the sustained listing of our common stock on Nasdaq.

The Baergic transaction expands our development portfolio within neuroscience. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies' boards.

Our net loss for the nine months ended September 30, 2022 and 2021 was approximately $4.1 million and $2.8 million, respectively. As of September 30, 2022, we had an accumulated deficit of approximately $81.1 million. Substantially all of 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 to incur operating losses for at least the next several years as we develop and seek regulatory approval for IV Tramadol in the United States and pursue the continued development of BAER-101.

We intend 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 the necessary 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 our common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to our stockholders. If we are unable to obtain such additional financing, future operations may 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 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

Recent Developments

Chief Executive Officer

On August 1, 2022, the Board approved the appointment of Dr. Alexandra MacLean as Chief Executive Officer of the Company. With the appointment of Dr. MacLean as the new Chief Executive Officer, Mr. David Jin ended his term as interim Chief Executive Officer and will continue his responsibilities as Interim Chief Financial Officer and Chief Operating Officer of the Company.

Baergic

The transaction contemplated by the Contribution Agreement was closed on November 8, 2022, following the satisfaction of the closing conditions of the Contribution Agreement. In exchange for the Contributed Shares, the Company assumed and became solely liable for all obligations, duties, covenants and liabilities arising from, based upon, related to or associated with the Contributed Shares, Fortress' obligations under the contracts being assumed and Fortress' ownership in Baergic. As a result of the closing of the Contribution Agreement, Baergic is now a majority owned subsidiary of the Company. Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of central nervous system disorders. Baergic's pipeline currently consists of a single compound, BAER-101, a selective GABA-A positive allosteric modulator ("BAER-101"). BAER-101 (formally known as AZD7325) is Baergic's principal asset and was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

NASDAQ Deficiency Letter

On May 24, 2022, we received a deficiency letter (the "Nasdaq Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq"), notifying us that we are not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires us to maintain a minimum of $2,500,000 in stockholders' equity for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"), nor in compliance with either of the alternative listing standards, market value of listed securities of at least $35 million or net income of $500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. Our failure to comply with the Stockholders' Equity Requirement was based on the filing of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders' equity of $1,159,000. Pursuant to the Nasdaq Letter, we had 45 calendar days from the date of the Nasdaq Letter to submit a plan to regain compliance. On July 8, 2022, we submitted a compliance plan (the "Compliance Plan") to Nasdaq.

On August 9, 2022, we received written notice (the "Notice") from Nasdaq, stating that the Nasdaq has determined that we have not complied with the Nasdaq Listing Rule 5550(a)(2), which requires us to maintain a minimum bid price of our common stock be at least $1.00 per share (the "Minimum-Bid Price Requirement"), or the Stockholders' Equity Requirement. The Notice indicated that our common stock would be suspended from trading on Nasdaq unless we request a hearing before an independent hearings panel (the "Panel") by August 16, 2022.

Additionally, as previously disclosed on February 8, 2022, we received a letter from the Regulations Department of The Nasdaq Stock Market LLC indicating that the closing bid price of our common stock has been below $1.00 per share for 30 consecutive business days, and that, therefore, we are not in compliance with the Minimum-Bid Price Requirement for continued listing on The Nasdaq Capital Market.

We timely requested a hearing before the Panel, which took place on September 22, 2022. On September 29, 2022, the Panel issued a decision granting our request for continued listing on Nasdaq, through October 31, 2022, to demonstrate compliance with the Stockholders' Equity Requirement, and through October 6, 2022 to satisfy the Minimum Bid Price Requirement.

On October 18, 2022, we were formally notified by Nasdaq that we have evidenced compliance with the Minimum-Bid Price Requirement the Stockholders' Equity Requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rules 5550(a)(2) and 5550(b)(1), respectively. Accordingly, the listing matter has been closed.

Reverse Stock Split

On July 25, 2022, the holders of a majority of the voting power of the capital stock of the Company executed a written consent approving a grant of discretionary authority to the board of directors of the Company (the "Board") to, without further stockholder approval, (i) effect a reverse stock split of the Company's issued and outstanding common stock within a range of between 10-for-1 and 20-for-1 (with the Board being authorized to determinate the exact ratio) (the "Reverse Stock Split") and (ii) reduce the number of the Company's authorized shares of common stock from 50,000,000 to 20,000,000 (the "Authorized Share Reduction") by filing an amendment (the "Amendment") to the Company's Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The written consent was signed by the holders of 9,423,429 shares of the Company's common stock and 250,000 shares of the Company's Class A Preferred Stock. Each share of common stock entitles the holder thereof to one vote on all matters submitted to stockholders and each share of Class A Preferred Stock has the voting power of 1.1 times (A) the number of outstanding shares of common stock plus (B) the whole shares of Company common stock into which the outstanding shares of Class A Preferred Stock are convertible, divided by the number of outstanding shares of Class A Preferred Stock, or 99 votes per share as of July 25, 2022. Accordingly, the holders of approximately 73% of the voting power of the Company's capital stock as of July 25, 2022 signed the written consent approving the Reverse Stock Split, the Authorized Share Reduction and the Amendment. The Board also approved the Reverse Stock Split, the Authorized Share Reduction and the Amendment.

The Reverse Stock Split was effective on September 23, 2022 upon filing of the Amendment with the Secretary of State of Delaware, which date was at least twenty (20) days from the mailing of the information statement. Under the Amendment, the number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") was simultaneously reduced from 50,000,000 to 20,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

As a result of the Reverse Stock Split, every 15 shares of Common Stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of New Common Stock without any change in the par value per share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to a fraction of one share of New Common Stock as a result of the Reverse Stock Split instead received an amount in cash equal to such fraction multiplied by the closing sale price of Common Stock on the Nasdaq Capital Market on September 22, 2022, as adjusted for the Reverse Stock Split.

October 2022 Public Offering

On October 6, 2022, we entered into an Underwriting Agreement (the "Underwriting Agreement") with Aegis Capital Corp., as underwriter (the "Underwriter"), related to our underwritten public offering (the "Offering") of 2,652,065 units ("Units") and 984,300 pre-funded units ("Pre-funded Units"). Each Unit consisted of one share (a "Share") of our common stock, par value $0.0001 per share ("Common Stock"), and one warrant to purchase one share of Common Stock (each, a "Warrant" and, collectively, the "Warrants"), and each Pre-funded Unit consisted of one pre-funded warrant to purchase one share of Common Stock (each, a "Pre-funded Warrant" and collectively, the "Pre-funded Warrants") and one Warrant. The Units were sold at a price of $3.30 per Unit, and the Pre-Funded Units were sold at a price of $3.2999 ($3.30 less $0.0001, the exercise price of the Pre-funded Warrants).

The Warrants are immediately exercisable upon issuance and are exercisable for a period of five years after the issuance date. The Shares, the Pre-funded Warrants and the Warrants were immediately separable upon issuance and were issued separately. The Underwriter was granted a 45-day option to purchase up to an aggregate of (i) 545,454 additional Shares and/or Pre-funded Units, representing 15% of the Shares and Pre-funded Warrants sold in the Offering, and/or (ii) Warrants to purchase 545,454 additional Shares, representing 15% of the Warrants sold in the Offering, which it initially exercised, in part, electing to purchase 545,454 Warrants at a purchase price of $0.01 per Warrant. We consummated the transactions contemplated by the Offering and the Underwriting Agreement on October 11, 2022. Prior to the closing date of the Offering, investors in certain of the Pre-funded Warrants, pursuant to the terms thereof, elected to exercise 949,900 Pre-funded Warrants. Accordingly, at the closing, we issued 949,900 fewer Pre-funded Warrants and, in lieu thereof, the corresponding 949,900 shares of Common Stock.

We estimate the net proceeds from the Offering to be $10.4 million, after deducting underwriting discounts and commissions and estimated offering expenses payable us.

InvaGen Share Repurchase

In connection with the closing of the Offering, on October 11, 2022, the Company consummated the transactions contemplated by the Share Repurchase Agreement with InvaGen, pursuant to which the Company repurchased 100% of the shares in the Company held by InvaGen (the "InvaGen Shares") for a purchase price of $3 million. In addition, under the Share Repurchase Agreement the Company agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4 million. In connection with the closing of the Share Repurchase Agreement, which occurred on October 31, 2022, all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among the Company, InvaGen and Fortress on November 12, 2018, were terminated.

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.

For a discussion of our critical accounting estimates, see the Management's Discussion and Analysis of the Results of Operations in the 2021 Form 10-K.

There were no material changes in our critical accounting estimates or accounting policies from December 31, 2021.

Results of Operations

General

At September 30, 2022, we had an accumulated deficit of $81.1 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 are 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 September 30, 2022 and 2021

($ in thousands)	For The Three Months Ended September 30, 2022	2021	Change $	Change %
Operating expenses:				
Research and development	$ 194	$ 278	$ (84)	(30)%
General and administrative	469	594	(125)	(21)%
Loss from operations	(663)	(872)	209	(24)%
Interest income	(1)	(1)	—	— %
Net Loss	$ (662)	$ (871)	$ 209	(24)%

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 pre-commercialization validation manufacturing, costs associated with regulatory filings, laboratory costs and other supplies.

For the three months ended September 30, 2022 and 2021, research and development expenses were $0.2 million and $0.3 million, respectively. The decrease of $0.1 million is primarily associated with a decrease in consulting costs.

We expect our research and development activities to continue as we attempt to gain regulatory approval for 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. We expect our general and administrative costs to continue as we seek potential regulatory approval and potential commercialization of our product candidates.

For the three months ended September 30, 2022 and 2021, general and administrative expenses were $0.5 million and $0.6 million, respectively. The decrease of $0.1 million is primarily associated with a decrease of $0.1 million in personnel expenses.

Interest Income

Interest income was $1,000 for both the three months ended September 30, 2022 and 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

	For The Nine Months Ended September 30,		Change	
($in thousands)	2022	2021	$	%
Operating expenses:				
Research and development	$ 2,153	$ 864	$ 1,289	149 %
General and administrative	1,978	1,960	18	1 %
Loss from operations	(4,131)	(2,824)	(1,307)	46 %
Interest income	(4)	(6)	(2)	(33)%
Net Loss	$ (4,127)	$ (2,818)	$ (1,309)	46 %

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 pre-commercialization validation manufacturing, costs associated with regulatory filings, laboratory costs and other supplies.

For the nine months ended September 30, 2022 and 2021, research and development expenses were $2.2 million and $0.9 million, respectively. The increase of $1.3 million is primarily associated with increases of: $1.0 million due to advisory committee preparation and costs, $0.1 million in bonus costs, and $0.2 million in non-cash stock compensation costs.

We expect our research and development activities to continue as we attempt to gain regulatory approval for 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. We expect our general and administrative costs to continue as we seek potential regulatory approval and potential commercialization of our product candidates.

For the nine months ended September 30, 2022 and 2021, general and administrative expenses were $2.0 million and $2.0 million, respectively. There were increases of $0.2 million in non-cash stock compensation offset by decreases of $0.1 million in personnel costs and $0.1 million in professional fees.

Interest Income

Interest income was $4,000 and $6,000 for the nine months ended September 30, 2022 and 2021, respectively. The decrease in interest income was due to the reduction in cash and cash equivalents.

Liquidity and Capital Resources

Going Concern

The Company is not yet generating revenue, 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 September 30, 2022, the Company had an accumulated deficit of $81.1 million.

On October 12, 2020, the Company announced that it had received a Complete Response Letter (the "First CRL") from the FDA regarding the Company's NDA for IV Tramadol. The First CRL cited deficiencies related to the terminal sterilization validation and stated that IV Tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. On February 12, 2021, the Company resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of official minutes from a Type A meeting with the FDA. The resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On June 14, 2021, the Company announced that it had received a second Complete Response Letter (the "Second CRL") from the FDA regarding the Company's NDA for IV Tramadol. The Second CRL stated that the delayed and unpredictable onset of analgesia with IV Tramadol does not support its benefit as a monotherapy to treat patients in acute pain and that there is insufficient information to support that IV Tramadol in combination with other analgesics is safe and effective for the intended patient population. In particular, the Second CRL stated that, while the primary endpoint was met in two efficacy studies, meaningful pain relief was delayed (accounting for the use of rescue medication, e.g., ibuprofen), and some patients never achieved pain relief. The Company continues to pursue regulatory approval for IV Tramadol and had a Type A meeting with the FDA in July 2021. The FDA did not deviate from any of the positions the FDA previously took in the First CRL and the Second CRL. The Company submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, the Company received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, the Company submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, the Company received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, the Company had its Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. On March 18, 2022, the Company received an Appeal Denied Letter from the OND in response to the FDRR. On August 31, 2022, the Company disclosed that, on June 17, 2022, following the receipt of the Letter, the Company submitted a Type A Meeting Request and related briefing documents to the FDA. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") on June 27, 2022, and took place on August 9, 2022. The Company intends to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol. The Company is continuing to evaluate next steps with regard to IV Tramadol.

As further disclosed in Note 6, on October 6, 2022, the Company entered into an Underwriting Agreement with Aegis Capital Corp. and on October 11, 2022 received net proceeds from the sale of equity in the Company of approximately $10.4 million (the "Offering"). In connection with the closing of the Offering, the Company repurchased 100% of the shares in the Company held by InvaGen for a purchase price of $3.0 million.

Due to uncertainties regarding future operations of the Company for a study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol, and the expansion of the Company's development portfolio within neuroscience with the consummation of the transaction with Baergic, the Company will need to secure additional funds through equity or debt offerings, or other potential sources, the timing of which is unknown at this time. The Company cannot be certain that additional funding will be available to it on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing this Quarterly Report on Form 10-Q. The unaudited interim condensed financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainty.

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 the 2021 Form 10-K.

Recently Adopted and Issued Accounting Pronouncements

Not applicable.

Cash Flows for the Nine Months Ended September 30, 2022 and 2021

($ in thousands)	For The Nine Months Ended September 30, 2022	2021
Total cash and cash equivalents used in:		
Operating activities	$ (3,427)	$ (2,547)
Financing activities	(119)	—
Net decrease in cash and cash equivalents	$ (3,546)	$ (2,547)

Operating Activities

Net cash and cash equivalents used in operating activities was $3.4 million for the nine months ended September 30, 2022, primarily comprised of our $4.1 million net loss partially offset by $0.6 million in share based compensation.

Net cash and cash equivalents used in operating activities was $2.5 million for the nine months ended September 30, 2021, primarily comprised of our $2.8 million net loss partially offset by $0.3 million in share based compensation.

Financing Activities

Net cash and cash equivalents used in financing activities was $0.1 million for the nine months ended September 30, 2022, primarily comprised of amounts payable due to expenses related to the October 2022 public offering.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

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 interim Chief 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 September 30, 2022, 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 interim Chief 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 September 30, 2022 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

We have disclosed under the heading "Risk Factors" in the 2021 Form 10-K a number of risks which may materially affect our business, financial condition or results of operations. You should carefully consider the "Risk Factors" set forth in the 2021 Form 10-K, the information below, and the other information set forth elsewhere in this Quarterly Report on Form 10-Q. You should be aware that these risk factors and other information may not describe every risk facing our Company. Additional risks and uncertainties not currently known to us may also materially adversely affect our business, financial condition and/or results of operations. Below are material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2021.

If we fail to satisfy applicable listing standards, our common stock may be delisted from The Nasdaq Capital Market.

On September 2, 2021, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market ("Nasdaq") notifying us that, based upon its review for the last 30 consecutive business days, we did not meet the continuing listing requirements of Nasdaq Marketplace Rule 5550(b)(2), which requires that we maintain a minimum market value of listed securities of at least $35 million (the "Minimum-Bid Price Requirement"). Nasdaq also informed us that we did not meet the requirements of Listing Rules 5550(b)(1) and 5550(b)(3). Under Nasdaq's Listing Rules, we had 180 calendar days from the date of the notification to regain compliance, which expired on March 1, 2022. We were unable to regain compliance during this 180-day period. Subsequently, on March 2, 2022, we received an additional notification from the Listing Qualifications Department stating that due to the deficiency, our securities would be delisted from Nasdaq on March 11, 2022, unless we appealed Nasdaq's determination to a Hearings Panel (the "Panel"). A hearing request would stay the suspension of our securities pending the Panel's decision. On March 9, 2022, we submitted the hearing request. On April 1, 2022, we received a letter from the Office of the General Counsel of The Nasdaq Stock Market LLC the which stated that the Nasdaq staff had determined that the Company has regained compliance with The Nasdaq Capital Market's $2.5 million stockholders' equity requirement for continued listing and that, consequently, the previously announced hearing before the Nasdaq Hearings Panel on April 14, 2022, had been cancelled.

On May 24, 2022, we received a deficiency letter (the "Nasdaq Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq"), notifying us that we were not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires us to maintain a minimum of $2,500,000 in stockholders' equity for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"), nor was it in compliance with either of the alternative listing standards, market value of listed securities of at least $35 million or net income of $500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. Our failure to comply with the Stockholders' Equity Requirement was based on the Company's filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders' equity of $1,159,000.

Pursuant to the Nasdaq Letter, we submitted a compliance plan on July 8, 2022. On August 9, 2022, we received written notice (the "Notice") from Nasdaq, stating that Nasdaq had determined that we were was not in compliance with the Minimum-Bid Requirement or the Stockholders' Equity Requirement. The Notice indicated that our common stock would be suspended from trading on Nasdaq unless we requested a hearing before the Panel by August 16, 2022.

The Company timely requested a hearing before the Panel, which took place on September 22, 2022. On September 29, 2022, the Panel issued a decision granting our request for continued listing on Nasdaq, through October 31, 2022, to demonstrate compliance with the Stockholders' Equity Requirement, and through October 6, 2022 to satisfy the Minimum Bid Price Requirement. Although we received notice on October 18, 2022, from Nasdaq that it has evidenced compliance with the Minimum Bid-Price Requirement and the Stockholders' Equity Requirement, there can be no assurances, however, that we will be successful in continuing to maintain compliance with applicable Nasdaq listing standards. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets where an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under requirements of state "blue sky" laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market.

There is no assurance that we will be able to successfully integrate Baergic or develop BAER-101.

There can be no assurance that we will have sufficient capital resources to adequately pursue the development of BAER-101. In addition, as with any of our product candidates, we are subject to many external third party risks including regulatory and manufacturing, which are outlined in the 2021 Form 10-K. We could experience financial or other setbacks if the transaction encounters unanticipated problems, including problems related to execution, integration or underperformance relative to prior expectations. Our management may not be able to successfully integrate any acquired business into our operations or maintain our standards, controls and policies, which could have a material adverse effect on our business, results of operations and financial condition. Consequently, any acquisition we complete may not result in long-term benefits to us or we may not be able to further develop the acquired business in the manner we anticipated. Following the completion of the Baergic acquisitions, we may need to rely on Fortress to provide administrative and other support, including financial reporting and internal controls, and other transition services to the acquired business for a period of time. The failure of the Company to receive such support in a manner that is acceptable to us, could result in a material adverse effect on our business, results of operations and financial condition.

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
3.1	Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 27, 2017 (File No. 001-38114) and incorporated herein by reference.
3.2	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-Q filed on August 14, 2018 (File No. 001-38114) and incorporated herein by reference.
3.3	Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 11, 2019 (File No. 000-38114) and incorporated herein by reference.
31.1	Certification of Principal 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 November 10, 2022. *
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 November 10, 2022. *
32.1	Certification of Principal 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 November 10, 2022. **
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 November 10, 2022. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30 , 2022, 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. *
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). *

* Filed herewith.
** Furnished herewith.

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: November 10, 2022

By: /s/ David Jin
David Jin
Interim Chief Financial Officer and Chief Operating Officer
(Duly Authorized Officer, Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934,
As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Alexandra MacLean, 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/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
November 10, 2022

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934,
As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David Jin, 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/ David Jin
David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
November 10, 2022

Exhibit 32.1

Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Alexandra MacLean, M.D., Chief Executive Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to 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 September 30, 2022 (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/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
November 10, 2022

Exhibit 32.2

Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, David Jin, Interim Chief Financial Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to 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 September 30, 2022 (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/ David Jin
David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
November 10, 2022