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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 March 31, 2025

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.)

1111 Kane Concourse, Suite 301, Bay Harbor Islands, FL 33154
(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(1)

(1) On March 17, 2025, the Nasdaq Stock Market LLC ("Nasdaq") notified the Company that Nasdaq had determined to delist the Company's common stock and that trading of the Company's securities would be suspended at the open of trading on March 19, 2025. Nasdaq will file a Form 25 with the SEC notifying the SEC of Nasdaq's determination to remove the Company's securities from listing on Nasdaq, at which time the common stock will cease to be registered pursuant to Section 12(b) of the Act and immediately be deemed registered pursuant to Section 12(g) of the Act. Since March 19, 2025, the Company's common stock has been traded on the over-the-counter market under the symbol "ATXI".

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 May 14, 2025
Common Stock, $0.0001 par value	3,183,603

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For the Quarter Ended March 31, 2025

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AVENUE THERAPEUTICS, INC.
Unaudited Condensed Consolidated Balance Sheets
($ in thousands, except share and per share amounts)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,502	$ 2,594
Prepaid expenses and other current assets	92	78
Total assets	$ **3,594**	$ **2,672**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,003	$ 654
Accounts payable and accrued expenses - related party	258	146
Warrant liability	1	16
Total current liabilities	1,262	816
Total liabilities	**1,262**	**816**
Commitments and contingencies		
Stockholders' equity		
Preferred stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock ($0.0001 par value), 200,000,000 shares authorized as of March 31, 2025 and December 31, 2024, respectively		
Common shares, 3,183,603 and 2,108,670 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	107,942	105,377
Accumulated deficit	(104,432)	(102,580)
Total stockholders' equity attributed to the Company	3,510	2,797
Non-controlling interests	(1,178)	(941)
Total stockholders' equity	2,332	1,856
Total liabilities and stockholders' equity	$ **3,594**	$ **2,672**

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

AVENUE THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations
($ in thousands, except share and per share amounts)

	For the Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 411	$ 2,392
General and administrative	1,494	1,316
Loss from operations	(1,905)	(3,708)
Other income (expense):		
Interest income	32	49
Loss on settlement of common stock warrant liabilities	—	(574)
Change in fair value of warrant liabilities	15	(116)
Total other income (expense)	47	(641)
Net loss	$ (1,858)	$ (4,349)
Net loss attributable to non-controlling interests	(6)	(9)
Net loss attributable to common stockholders	$ (1,852)	$ (4,340)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.62)	$ (15.40)
Weighted average number of common shares outstanding, basic and diluted	2,970,807	562,031

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

AVENUE THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands, except share amounts)

Three months ended March 31, 2025

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	**250,000**	$ —	**2,108,670**	$ —	$ **105,377**	$ **(102,580)**	$ **(941)**	$ **1,856**
Share based compensation	—	—	284	—	185	—	—	185
Issuance of common stock to Fortress	—	—	135,659	—	55	—	—	55
Issuance of common stock, net of offering costs under open market sales agreement (ATM)	—	—	938,990	—	2,094	—	—	2,094
Non-controlling interest in subsidiaries	—	—	—	—	231	—	(231)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(6)	(6)
Net loss attributable to common stockholders	—	—	—	—	—	(1,852)	—	(1,852)
Balance at March 31, 2025	**250,000**	$ —	**3,183,603**	$ —	$ **107,942**	$ **(104,432)**	$ **(1,178)**	$ **2,332**

Three months ended March 31, 2024

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	**250,000**	$ —	**341,324**	$ **3**	$ **92,507**	$ **(90,928)**	$ **(928)**	$ **654**
Share based compensation	—	—	283	—	191	—	—	191
Common shares issuable - Founders Agreement	—	—	—	—	(363)	—	—	(363)
Issuance of common stock to Fortress	—	—	28,019	—	371	—	—	371
Loss on settlement of common stock warrant liabilities	—	—	—	—	574	—	—	574
Exercise of warrants	—	—	220,538	1	5,261	—	—	5,262
Warrant inducement offering costs	—	—	—	—	(442)	—	—	(442)
Reverse split (1-for-75)	—	—	24	(4)	4	—	—	—
Non-controlling interest in subsidiaries	—	—	—	—	1	—	(1)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(9)	(9)
Net loss attributable to common stockholders	—	—	—	—	—	(4,340)	—	(4,340)
Balance at March 31, 2024	**250,000**	$ —	**590,188**	$ —	$ **98,104**	$ **(95,268)**	$ **(938)**	$ **1,898**

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

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

	For the Three Months Ended	
	March 31, 2025	**March 31, 2024**
Cash flows from operating activities:		
Net loss	$ (1,858)	$ (4,349)
Reconciliation of net loss to net cash used in operating activities:		
Share based compensation	185	191
Loss on settlement of common stock warrant liabilities	—	574
Change in fair value of warrant liabilities	(15)	116
Issuance of common stock to Fortress	55	371
Common shares issuable - Founders Agreement	—	(363)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(14)	(49)
Accounts payable and accrued expenses	349	360
Accounts payable and accrued expenses - related party	112	29
Net cash used in operating activities	(1,186)	(3,120)
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	2,094	—
Exercise of warrants	—	4,973
Warrant transaction costs	—	(442)
Net cash provided by financing activities	2,094	4,531
Net change in cash and cash equivalents	908	1,411
Cash and cash equivalents, beginning of period	2,594	1,783
Cash and cash equivalents, end of period	$ **3,502**	$ **3,194**
Supplemental cash flow information:		
Issuance of common shares - Founders Agreement	$ 55	$ 371

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

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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"). Avenue is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Avenue's current product candidates include intravenous tramadol ("IV tramadol") for the treatment of post-operative acute pain and BAER-101 for the treatment of epilepsy and panic disorders.

Nasdaq Delisting

On March 17, 2025, the Nasdaq Stock Market LLC ("Nasdaq") notified the Company that Nasdaq had determined to delist the Company's common stock and that trading of the Company's securities would be suspended at the open of trading on March 19, 2025. Nasdaq will file a Form 25 with the SEC notifying the SEC of Nasdaq's determination to remove the Company's securities from listing on Nasdaq, at which time the common stock will be formally delisted, cease to be registered pursuant to Section 12(b) of the Act and immediately be deemed registered pursuant to Section 12(g) of the Act. Since March 19, 2025, the Company's common stock has been traded on the over-the-counter market under the symbol "ATXI".

AJ201 Termination

On February 28, 2023, Avenue entered into a license agreement with AnnJi Pharmaceutical Co. Ltd. ("AnnJi"), whereby Avenue obtained an exclusive license (the "AnnJi License Agreement") from AnnJi to the intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA", also known as Kennedy's Disease). Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidates, Avenue paid $3.0 million, issued shares of Avenue stock in two tranches, and agreed to make additional payments including: reimbursement of payments up to $10.8 million in connection with the product's Phase 1b/2a clinical trial, up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S., up to $27.5 million in connection with certain drug development milestones pertaining to additional indications and development outside the U.S., up to $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales, and royalty payments based on a percentage of net sales ranging from mid-single digits to the low-double digits, which were subject to potential diminution in certain circumstances. On March 3, 2025, Avenue received a notice of AnnJi's intent to terminate the AnnJi License Agreement, in which AnnJi asserted several bases for its right to terminate the AnnJi License Agreement.

On April 24, 2025 (the "Termination Effective Date"), Avenue and AnnJi entered into a License Termination and Program Transfer Agreement (the "Termination and Transfer Agreement"), pursuant to which: (i) the AnnJi License Agreement and related agreements were terminated with immediate effect; (ii) the parties dismissed all pending dispute resolution proceedings and provided mutual releases of claims; (iii) Avenue transferred to AnnJi all of its rights, title and interest to and under the assets arising under the AnnJi License Agreement and otherwise related to AJ201 and (iv) Avenue agreed not to, for 48 months following the date of the Termination and Transfer Agreement, develop, commercialize, manufacture or sell any product competing with AJ201 in the US, Canada, the European Union, Great Britain or Israel. Under the Termination and Transfer Agreement, Avenue will repurchase all shares of common stock held by AnnJi for an aggregate payment of $1.00, and Avenue also made a payment of $0.2 million to AnnJi as consideration for legal expenses.

AnnJi agreed to make payments to Avenue of $2.0 million, with $1.0 million due within 30 days after the Termination Effective Date and $1 million due within 90 days after the Termination Effective Date. Additionally, Avenue will be eligible to receive from AnnJi:

- payments totaling up to $5 million in the aggregate upon the occurrence of certain development and regulatory milestone events pertaining to AJ201;
- payments totaling up to $17 million in the aggregate upon AJ201 experiencing certain commercial sales milestone events;
- a 1.75% royalty on net sales of AJ201, which royalty percentage is subject to potential diminution in certain circumstances; and
- in the event that AnnJi enters into one or more subsequent licenses of rights to AJ201 with third party licensee(s), 15% of payments received by AnnJi from such licensee(s), up to a cap of $7.5 million, and with a minimum of $4 million owing under certain mechanism in the event of an approval of a New Drug Application in the U.S. with respect to AJ201.

The Termination and Transfer Agreement also contains customary representations and warranties and provisions related to confidentiality and indemnification.

Going Concern

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, as described below, substantial doubt about the Company's ability to continue as a going concern exists.

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 March 31, 2025, the Company had an accumulated deficit of $104.4 million. Due to uncertainties regarding future operations of the Company for a potential Phase 3 safety study for IV tramadol, and the expansion of the Company's development portfolio within neuroscience with the consummation of the transaction with Baergic Bio, Inc. ("Baergic"), the Company will need to secure additional funds through equity or debt offerings, 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 cause substantial doubt about the Company's ability to continue as a going concern to exist within one year from the date of this report. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

Note 2 - Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with U.S. GAAP, include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented and are stated in U.S. dollars. The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiary. All intercompany balances and transactions have been eliminated.

The accompanying unaudited interim condensed financial statements include the accounts of the Company's subsidiary, Baergic. Because the Company owns less than 100% of Baergic, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic

or ownership interest retained in Baergic by the respective non-controlling parties. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of its subsidiary.

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, 2024, which were included in the Company's Annual Report on Form 10-K (the "2024 Form 10-K") and filed with the U.S. Securities and Exchange Commission ("SEC") on March 31, 2025.

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one operating and reportable segment.

Use of Estimates

The preparation of unaudited condensed consolidated 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 consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Fair Value Measurements

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities.

Non-Controlling Interests

Non-controlling interests in consolidated entities represent the component of equity in consolidated entities held by third parties. Any change in ownership of a subsidiary while the controlling financial interest is retained is accounted for as an equity transaction between the controlling and non-controlling interests. Intercompany activity is eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on ownership interests.

Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common shares outstanding, including prefunded warrants and shares held in abeyance, during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive. Dividends declared are paid and set aside among the holders of shares of common stock and Class A Preferred stock pro-rata on an as-if-converted basis.

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:

	As of March 31,	
	2025	**2024**
Unvested restricted stock units/awards	744	1,028
Deferred stock units	235,000	—
Warrants	1,476,200	745,139
Options	256,474	22,474
Class A Preferred shares(1)	223	223
Total potential dilutive effect	1,968,641	768,864

(1) Class A preferred shares are presented on an as-if converted basis.

In connection with the exercise of certain existing warrants in January 2024, the Company recorded deemed dividends of $4.3 million for the issuance of new warrants. For the three months ended March 31, 2024, net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends.

The Company considers Class A preferred stock to be an additional class of common stock for the purpose of calculating net loss per share, as it does not have preferential rights in liquidation when compared to the Company's common stock, and therefore losses are allocated to these additional classes using the two-class method. The two-class method is an earnings allocation formula that treats participating securities as having rights that would otherwise have been available to common stockholders. Earnings allocated to the Class A preferred stock are not material for the three months ended March 31, 2025 and 2024.

Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2024 Form 10-K.

Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands the disclosures required for income taxes. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09 and will adopt it for fiscal year ending December 31, 2025.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new financial statement disclosures in tabular format, in the notes to financial statements, of specified information about certain costs and expenses. The amendments in this update do not change or remove current expense disclosure requirements. The amendments in this update are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statement disclosures.

Note 3 — Licenses/Supplier Agreements

IV Tramadol License

Effective as of February 17, 2015, Fortress transferred the Revogenex license and all other rights and obligations under the IV Tramadol License Agreement to the Company, pursuant to the terms of the Founders Agreement. In connection with the terms of the IV Tramadol License Agreement, Fortress purchased an exclusive license to IV tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland, for $3.0 million and paid an additional $1.0 million following the Company's submission of its NDA for IV Tramadol. In addition, under the terms of the agreement, Revogenex is eligible to receive an additional milestone payment totaling $3.0 million upon the approval of IV tramadol from the U.S. Food and Drug Administration ("FDA") as well as royalty payments on net sales of the product ranging in the high single digits to low double digits.

On October 29, 2018, the Company and Zaklady Farmaceutyczne Polpharma ("Polpharma") extended the term of their exclusive supply agreement for drug product of IV tramadol to eight years from the date of the launch of the product. In addition, under the terms of the amended agreement, Polpharma is eligible to receive a milestone payment totaling $2.0 million upon the approval of IV tramadol from the FDA, as well as a low single digit royalty on net sales of the product for five years after launch.

Baergic Licenses

In December 2019, Baergic entered into two license agreements: (i) a license agreement with AstraZeneca AB ("AZ") to acquire an exclusive license to patent and related intellectual property rights pertaining to their proprietary compound Gamma-aminobutyric acid receptor A alpha 2 & 3 (GABAA α2,3) positive allosteric modulators; and (ii) a license agreement with Cincinnati Children's Hospital Medical Center ("CCHMC") to acquire patent and related intellectual property rights pertaining to a GABA inhibitor program for neurological disorders. Baergic paid an upfront fee of $3.0 million to AZ and $0.2 million to CCHMC, as well as issued common shares of Baergic of approximately 20% and 5% of Baergic to each at the time of the license agreement, respectively.

Development milestones totaling approximately $81.5 million in the aggregate are due upon achievement of each milestone. Commercial and sales-based milestone payments totaling approximately $151 million are due upon achievement of each milestone, as well as royalty payments in the low to high single digits on any future aggregate, annual, worldwide net sales.

AnnJi License Agreement

On February 28, 2023, Avenue entered into a license agreement with AnnJi, whereby Avenue obtained an exclusive license (the "AnnJi License Agreement") from AnnJi to the intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA", also known as Kennedy's Disease). Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidates, Avenue paid $3.0 million, issued shares of Avenue stock in two tranches, and agreed to make additional payments including: reimbursement of payments up to $10.8 million in connection with the product's Phase 1b/2a clinical trial, up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S., up to $27.5 million in connection with certain drug development milestones pertaining to additional indications and development outside the U.S., up to $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales, and royalty payments based on a percentage of net sales ranging from mid-single digits to the low-double digits, which were subject to potential diminution in certain circumstances. On March 3, 2025, Avenue received a notice of AnnJi's intent to terminate the AnnJi License Agreement, in which AnnJi asserted several bases for its right to terminate the AnnJi License Agreement.

On the Termination Effective Date, Avenue and AnnJi entered into the Termination and Transfer Agreement, pursuant to which: (i) the AnnJi License Agreement and related agreements were terminated with immediate effect; (ii) the parties dismissed all pending dispute resolution proceedings and provided mutual releases of claims; (iii) Avenue transferred to AnnJi all of its rights, title and interest to and under the assets arising under the AnnJi License Agreement and otherwise related to AJ201 and (iv) Avenue agreed not to, for 48 months following the date of the Termination and Transfer Agreement, develop, commercialize, manufacture or sell any product competing with AJ201 in the US, Canada, the European Union, Great Britain or Israel. Under the Termination and Transfer Agreement, Avenue will repurchase all shares of common stock held by AnnJi for an aggregate payment of $1.00, and Avenue also made a payment of $0.2 million to AnnJi as consideration for legal expenses.

AnnJi agreed to make payments to Avenue of $2.0 million, with $1.0 million due within 30 days after the Termination Effective Date and $1 million due within 90 days after the Termination Effective Date. Additionally, Avenue will be eligible to receive from AnnJi:

- payments totaling up to $5 million in the aggregate upon the occurrence of certain development and regulatory milestone events pertaining to AJ201;
- payments totaling up to $17 million in the aggregate upon AJ201 experiencing certain commercial sales milestone events;
- a 1.75% royalty on net sales of AJ201, which royalty percentage is subject to potential diminution in certain circumstances; and
- in the event that AnnJi enters into one or more subsequent licenses of rights to AJ201 with third party licensee(s), 15% of payments received by AnnJi from such licensee(s), up to a cap of $7.5 million, and with a minimum of $4 million owing under certain mechanism in the event of an approval of a New Drug Application in the U.S. with respect to AJ201.

The Termination and Transfer Agreement also contains customary representations and warranties and provisions related to confidentiality and indemnification.

Note 4 — Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

In February 2015, Fortress entered into a Management Services Agreement (the "MSA") with the Company to provide services for the Company pursuant to the terms of the MSA. Expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Condensed Consolidated Statements of Operations. For the three months ended March 31, 2025 and 2024, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively.

In February 2015, Fortress entered into a Founders Agreement with the Company, under which the Company agreed to: (i) issue annually to Fortress, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of the Company at the time of issuance (the "Annual Equity Fee") and (ii) issue shares of the common stock equal to two and one half percent (2.5%) of the gross amount of any equity or debt financing (the "Financing Equity Fee").

Annual Equity Fee

For the three months ended March 31, 2025, the Company did not have an Annual Equity Fee expense. There were 102,185 shares of the Company's common stock issued to Fortress in January 2025 related to the 2024 Annual Equity Fee.

For the three months ended March 31, 2024, the Company did not have an Annual Equity Fee expense. There were 22,476 shares of the Company's common stock issued to Fortress in January 2024 related to the 2023 Annual Equity Fee.

Financing Equity Fee

For the three months ended March 31, 2025, the Company recorded a Financing Equity Fee of $0.1 million and issued 23,474 shares of the Company's common stock to Fortress.

For the three months ended March 31, 2024, the Company recorded a Financing Equity Fee of $0.1 million and issued 5,543 shares of the Company's common stock to Fortress.

Founders Agreement and Management Services Agreement with Baergic

Pursuant to the Share Contribution Agreement between Avenue and Fortress, the Founders Agreement and Management Services Agreement that had previously been existing between Fortress and Baergic were assigned to Avenue, such that they now exist between Avenue and Baergic; those agreements are referred to herein as the Avenue-Baergic Founders Agreement and the Avenue-Baergic MSA, as applicable. The Annual Stock Dividend payable to the Company is 2.5% of common stock calculated as a percentage of fully diluted outstanding capital and became effective as of November 8, 2022.

The Avenue-Baergic Founders Agreement has an effective date of March 9, 2017, and a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Avenue and Baergic or a Change in Control (as defined in the Avenue-Baergic Founders Agreement) occurs.

As additional consideration under the Avenue-Baergic Founders Agreement, Baergic will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Baergic that occurs after the effective date of the Avenue-Baergic Founders Agreement and ends on the date when Avenue no longer has majority voting control in the Baergic's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Baergic's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, Baergic will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%).

The Avenue-Baergic MSA has an effective date of March 9, 2017, pursuant to which Avenue renders management, advisory and consulting services to the Company. The Avenue-Baergic MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the Avenue-Baergic MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Baergic's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Baergic with accountants, attorneys, financial advisors and other professionals (collectively, the "Avenue Services"). Baergic 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 Avenue, provided those services are offered at market prices. However, Baergic is not obligated to take or act upon any advice rendered from Avenue and Avenue shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the Avenue-Baergic MSA and Baergic's Certificate of Incorporation, Avenue and its affiliates, including all members of Baergic's Board of Directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to Baergic or to refrain from engaging in business that is similar to that of Baergic. In consideration for the Avenue Services, Baergic will pay Avenue an annual consulting fee of $0.5 million (the "Avenue-Baergic 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 Avenue-Baergic Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Baergic has net assets in excess of $100 million at the beginning of the calendar year.

Note 5 — Accounts Payable and Accrued Expenses

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

	As of March 31, 2025	As of December 31, 2024
Accounts payable	$ 173	$ 155
Accrued employee compensation	85	18
Accrued contracted services and other	745	481
Total accounts payable and accrued expenses	$ 1,003	$ 654

Note 6 - Commitments and Contingencies

Leases

The Company is not party to any leases for office space or equipment.

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company will accrue the most likely amount of such loss, and if such amount is not determinable, then the Company will accrue the minimum of the range of probable loss. As of March 31, 2025, there was no litigation against the Company.

Note 7 - Stockholder's Equity

Class A Preferred Stock

On September 13, 2016, 2,000,000 shares of Preferred Stock were authorized, of which 250,000 have been designated as Class A Preferred Stock and the remainder are undesignated preferred stock. The Class A Preferred Stock, with a par value of $0.0001 per share, is identical to undesignated Common Stock other than as to voting rights, conversion rights, and the Annual Stock Dividend right (as described below). The undesignated Preferred Stock may be issued from time to time in one or more series. The Company's Board of Directors is authorized to determine or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions, if any), the redemption price or prices, the liquidation preferences and other designations, powers, preferences and relative, participating, optional or other special rights, if any, and the qualifications, limitations and restrictions granted to or imposed upon any wholly unissued series of Preferred Stock, and to fix the number of shares of any series of Preferred Stock (but not below the number of shares of any such series then outstanding).

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A Preferred Stock shall be entitled to cast for each share of Class A Preferred Stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the number of shares of outstanding Common Stock and (B) the whole shares of Common Stock in to which the shares of outstanding Class A Preferred Stock are convertible, and the denominator of which is number of shares of outstanding Class A Preferred Stock (the "Class A Preferred Stock Ratio"). Thus, the Class A Preferred Stock will at all times constitute a voting majority.

Each share of Class A Preferred Stock is convertible, at the option of the holder, into one fully paid and nonassessable share of Common Stock (the "Conversion Ratio"), subject to certain adjustments. If the Company, at any time effects a subdivision or combination of the outstanding Common Stock (by any stock split, stock dividend, recapitalization, reverse stock split or otherwise), the applicable Conversion Ratio in effect immediately before that subdivision is proportionately decreased or increased, as applicable, so that the number of shares of Common Stock issuable on conversion of each share of Class A Preferred Stock shall be increased or decreased, as applicable, in proportion to such increase or decrease in the aggregate number of shares of Common Stock outstanding. Additionally, if any reorganization, recapitalization, reclassification, consolidation or merger involving the Company occurs in which the Common Stock (but not the Class A Preferred Stock) is converted into or exchanged for securities, cash or other property, then each share of Class A Preferred Stock becomes convertible into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Company issuable upon conversion of one share of the Class A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction. Pursuant to the reverse stock splits by the Company in September 2022 and April 2024, the Class A Preferred Stock has a Conversion Ratio of 1,125 Class A Preferred to one share of Common Stock.

Common Stock

Holders of the Company's common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by the stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by the Company's Board of Directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of the Company's liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that the Company may designate and issue in the future.

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No. 333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). The Company filed a replacement shelf registration on Form S-3 on December 4, 2024 (the "Replacement Shelf"), which has not yet become effective under the Securities Act of 1933, as amended (the "Securities Act"). However, upon the Company's formal delisting from Nasdaq, effective upon Nasdaq's filing of a Form 25 with the SEC, the Company will be ineligible to use Form S-3 and therefore unable to use the Shelf or the Replacement Shelf.

ATM Facility

On May 10, 2024, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co. LLC (the "ATM Manager") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share, through or to the ATM Manager. Offers and sales of the shares are made pursuant to the Shelf, and the related prospectus supplement dated May 10, 2024 (including such replacement registration statement as may be filed with the SEC, the "ATM Registration Statement") and filed with the SEC on such date pursuant to Rule 424(b) under the Securities Act. As a result of the limitations of General Instruction I.B.6 of Form S-3, the Company may currently sell up to a maximum of $3,850,000 of its shares pursuant to the ATM Agreement.

Under the ATM Agreement, the ATM Manager may sell shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act. The ATM Manager will use commercially reasonable efforts to sell the shares from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company agreed to pay the ATM Manager a commission of 3.0% of the gross proceeds from the sales of shares sold through the ATM Manager under the ATM Agreement and has provided the ATM Manager with customary indemnification and contribution rights. The Company also agreed to reimburse the ATM Manager for certain expenses incurred in connection with the ATM Agreement. The Company and the ATM Manager may each terminate the ATM Agreement at any time upon specified prior written notice.

For the three months ended March 31, 2025, the Company sold an aggregate of 938,990 shares of its common stock pursuant to the ATM Agreement, resulting in net proceeds of approximately $2.1 million after deducting underwriting discounts. The Company is no longer able to utilize the ATM Agreement as a result of the suspension of its common stock from trading on the Nasdaq.

January 2024 Warrant Inducement and Private Placement

On January 5, 2024, the Company entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 of the Company's common stock originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November

2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company's agreement to issue in a private placement (x) new Series A common stock purchase warrants (the "January 2024 Series A Warrants") to purchase up to 220,538 shares of common stock (the "January 2024 Series A Warrants Shares") and (y) new Series B common stock purchase warrants (the "January 2024 Series B Warrants" and, together with the January 2024 Series A Warrants, the "January 2024 Warrants") to purchase up to 220,538 shares of common stock (the "January 2024 Series B Warrants Shares"). The January 2024 Series A Warrants were to expire five years following the issuance date and the January 2024 Series B Warrants were to expire eighteen months following the issuance date. The January 2024 Warrants were all subsequently exercised, and none remain outstanding as of the date of this report.

The approximately $0.6 million of the January 2024 Warrants' fair value allocated to the January 2023 Warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the January 2024 Warrants fair value was allocated to the November 2023 Warrants and deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the "2015 Incentive Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and, in December 2021, the Company's stockholders approved an amendment to the plan to increase the number of authorized shares issuable to 3,556 shares. On January 30, 2023, the Company's stockholders approved an amendment to the 2015 Incentive Plan to increase the number of authorized shares issuable to 70,223 shares. On June 24, 2024, the Company's stockholders approved an amendment to the 2015 Incentive Plan to increase the number of authorized shares issuable to 5,070,223 shares, which extended the term of the 2015 Incentive Plan to June 24, 2034, to increase the limit of the number of shares that may be issued upon exercise of incentive stock options by 5,000,000 shares, and to increase the annual share limit awards for non-employee directors to 500,000. 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 2015 Incentive Plan authorizes grants to issue up to 5,070,223 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.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 4,575,701 shares at March 31, 2025.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 2025:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2024	236,028	$ 3.44
Granted	—	—
Forfeited	—	—
Vested	(284)	85.50
Unvested balance at March 31, 2025	235,744	$ 3.34

At March 31, 2025, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.1 years. This amount does not include, as of March 31, 2025, 45 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 awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

The Company offers certain executives and key employees the opportunity to defer settlement of vested restricted stock units as part of our nonqualified deferred compensation plan. As of March 31, 2025, the Company had 235,000 outstanding deferred restricted stock units.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	256,474	$ 9.74	9.6	$ —
Granted	—	$ —		$ —
Exercised	—	$ —		$ —
Cancelled/forfeited	—	$ —		$ —
Expired	—	$ —		$ —
Outstanding at Balance at March 31, 2025	256,474	$ 9.74	9.4	$ —
Expected to vest	166,125	$ 7.52	9.4	$ —
Exercisable	90,349	$ 13.81	9.3	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2025, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.5 million with a weighted average remaining vesting period of 1.2 years.

Stock-based compensation expense has been reported in the Company's condensed consolidated statements of operations as follows:

	For the Three Months Ended March 31,	
	2025	2024
Research and development	$ 40	$ 45
General and administrative	145	146
Total stock-based compensation expense	**$ 185**	**$ 191**

Stock Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2025:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	1,476,200	$ 8.64	$ —
Granted	—		
Exercised	—		
Outstanding, March 31, 2025	1,476,200	$ 8.64	$ —

Upon the exercise of warrants, the Company will issue new shares of its common stock.

InvaGen Share Repurchase

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 $4.0 million. In connection with the common share sales pursuant to the ATM Agreement, the Company made payments totaling approximately $0.2 million to InvaGen during the three months ended March 31, 2025. Approximately $1.4 million in aggregate has been paid to InvaGen under the Share Repurchase Agreement through the three months ended March, 31, 2025. Payments to InvaGen are recorded in general and administrative expense on the condensed consolidated statements of operations.

Note 8 - Common Stock Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each consolidated balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a gain or loss on the condensed consolidated statements of operations.

Warrant Liability

The Company has previously issued freestanding warrants to purchase shares of its common stock in connection with financing activities. The outstanding warrants to purchase common stock originally issued by the Company in October 2022 (the "October 2022 Warrants") are classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside the Company's control. The previously outstanding warrants to purchase common stock originally issued by the Company in January 2023 (the "January 2023 Warrants") classified as liabilities were fully exercised during the three months ended March 31, 2024. The Black-Scholes Model is used to value the warrants classified as liabilities and the approach required management to estimate inputs including expected volatility and expected term and is most significantly impacted by the volatility of the Company's common stock price. These inputs are inherently subjective and require significant analysis and judgment to develop.

The fair value of the warrants was measured at the time of issuance and is re-measured at each financial reporting date with any changes in fair value being recognized in change in fair value of warrant liabilities, a component of other income (expense), in the consolidated statements of operations and comprehensive income (loss). The Company will continue to re-measure the fair value of the October 2022 Warrant liabilities until exercise or expiration of the warrants on October 10, 2027.

Fair Value of Warrant Liabilities

Warrant liabilities are categorized within Level 3 of the fair value hierarchy and are measured at fair value on a recurring basis as follows (in thousands):

	October 2022 Warrants
Fair value of warrants outstanding as of December 31, 2024	$ 16
Change in fair value of warrants	(15)
Fair value of warrants outstanding as of March 31, 2025	$ 1

The key inputs for the October 2022 Warrants using the Black-Scholes model were as follows:

	March 31, 2025	December 31, 2024
Stock price	$ 0.30	$ 2.00
Risk-free interest rate	4.35%	4.27%
Expected dividend yield	—	—
Expected term in years	2.5	2.8
Expected volatility	160%	155%

Note 9 - Subsequent Events

AnnJi Termination and Transfer Agreement

On April 24, 2025, the Company and AnnJi entered into the Termination and Transfer Agreement. See Note 3 for additional details.

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Certain matters discussed in this report may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of current or historical fact contained in this report, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "predict," "should," "project," "will," "would," and similar expressions are generally intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from:

- *the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized;*
- *the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates;*
- *our ability to successfully develop, partner, or commercialize any of our current or future product candidates including IV tramadol and BAER-101;*
- *the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing;*
- *the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future;*
- *our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability could force us to delay, reduce or eliminate our product development programs or commercialization efforts;*
- *our reliance on third parties for several aspects of our operations;*
- *our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate, unreliable, or unacceptable to regulatory authorities;*
- *the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons;*
- *the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny;*
- *the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations;*
- *the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications;*
- *the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products;*
- *our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates;*
- *our exposure to potential product liability claims;*
- *related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;*
- *our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business;*
- *the fact that Fortress Biotech, Inc. ("Fortress") controls a majority of the voting power of our outstanding capital stock and has rights to receive significant share grants annually;*
- *the fact that the OTC Pink Open Market is a thinly traded market lacking in liquidity, and subject to volatility;*
- *our common stock may be considered a "penny stock" and, therefore, may be subject to certain rules that make it difficult for brokers, dealers, or investors to sell the shares; and*
- *and the risks described under the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 (the "2024 Form 10-K").*

The forward-looking statements contained in this report reflect our views and assumptions as of the effective date of this report. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us. Except as required by law, we assume no responsibility for updating any forward-looking statements to reflect events or circumstances that may arise after the date of this report, except as required by applicable law.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Overview

Avenue Therapeutics, Inc. (“Avenue” or the “Company”) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Our product candidates include an intravenous formulation of tramadol ("IV tramadol"), a schedule IV opioid for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders. We may in the future acquire additional product candidates.

Our net loss for the three months ended March 31, 2025 and 2024 was approximately $1.9 million and $4.3 million, respectively. As of March 31, 2025, we had an accumulated deficit of approximately $104.4 million. Substantially all our net losses resulted from costs incurred for research and development, and general and administrative purposes.

We expect to continue to incur research and development costs and general and administrative costs and incur operating losses for at least the next several years as we continue the development of our product candidates.

We intend to obtain additional capital through the sale of debt or equity securities 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 or securities convertible into or exercisable for 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 stockholders. We may also seek financing through strategic partnerships for some or all of our portfolio assets. 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 4 to our financial statements included in this Quarterly Report on Form 10-Q.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 1111 Kane Concourse, Suite 301, Bay Harbor Islands, FL 33154. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

Recent Developments

Nasdaq Delisting

On March 17, 2025, The Nasdaq Stock Market LLC (“Nasdaq”) notified us that the Nasdaq Hearings Panel (the “Panel”) had determined to delist our common stock due to a violation of Nasdaq Listing Rule 5550(b)(1), which requires companies listed on The Nasdaq Capital Market to maintain stockholders’ equity of at least $2,500,000. As a result, trading of our common stock was suspended from Nasdaq at the open of trading on March 19, 2025, with formal delisting to occur upon Nasdaq's expected filing of a Form 25 with the SEC.

Our common stock began trading under its current trading symbol (“ATXI”) on the OTC Markets system effective upon the open of the markets on March 19, 2025. We plan to continue to file our required periodic reports and other filings with the SEC. We can provide no assurance that our common stock will continue to trade on this market, whether broker-dealers will continue to provide public quotes of our common stock on this market, or whether the trading volume of our common stock will be sufficient to provide for an efficient trading market for existing and potential holders of our common stock.

AJ201

In February 2023, we announced that we entered into a license agreement (the “AnnJi License Agreement”) with AnnJi Pharmaceutical Co., Ltd. (“AnnJi”) whereby the Company obtained an exclusive license from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the United States (“U.S.”) for the treatment of SBMA.

Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidate, the Company paid an initial cash license fee of $3.0 million. The Company issued shares of its common stock and was obligated to make additional payments over the course of the AnnJi License Agreement including reimbursement payments of up to $10.8 million in connection with the product’s Phase 1b/2a clinical trial.

On April 24, 2025 (the "AnnJi Termination Effective Date"), we and AnnJi entered into a License Termination and Program Transfer Agreement (the “Termination and Transfer Agreement”), pursuant to which: (i) the AnnJi License Agreement (as well as the Subscription Agreement and the Registration Rights Agreement entered into in connection therewith) was terminated with immediate effect; (ii) the parties dismissed all pending dispute resolution proceedings between them and provided mutual releases of claims; (iii) we transferred to AnnJi all of our rights, title and interest to and under the assets arising under the AnnJi License Agreement and otherwise related to AJ201 and (iv) we agreed not to, for 48 months following the date of the Termination and Transfer Agreement, develop, commercialize, manufacture or sell any product competing with AJ201 in the US, Canada, the European Union, Great Britain or Israel. Under the Termination and Transfer Agreement, we will repurchase, for an aggregate payment of $1.00, all 14,777 shares of our common stock that are held by AnnJi, and we also made a payment of $0.2 million to AnnJi as consideration for legal expenses.

AnnJi agreed to make payments to us of $2.0 million, with $1.0 million due within 30 days after the AnnJi Termination Effective Date and $1 million due within 90 days after the AnnJi Termination Effective Date. Additionally, we will be eligible to receive from AnnJi:

- payments totaling up to $5 million in the aggregate upon the occurrence of certain development and regulatory milestone events pertaining to AJ201;
- payments totaling up to $17 million in the aggregate upon AJ201 experiencing certain commercial sales milestone events;
- a 1.75% royalty on net sales of AJ201, which royalty percentage is subject to potential diminution in certain circumstances; and in the event that AnnJi enters into one or more subsequent licenses of rights to AJ201 with third party licensee(s), 15% of payments received by AnnJi from such
- licensee(s), up to a cap of $7.5 million, and with a minimum of $4 million owing under certain mechanism in the event of an approval of a New Drug Application in the U.S. with respect to AJ201.

The Termination and Transfer Agreement also contains customary representations and warranties and provisions related to confidentiality and indemnification.

IV Tramadol

We participated in a Type C meeting with the FDA in March 2023 to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV tramadol relative to an approved opioid analgesic. We announced in April 2023 that we received official meeting minutes from the Type C meeting with the FDA. The Type C meeting minutes indicate that we are in agreement with the FDA on a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the FDA's Division of Anesthesia, Analgesia, and Addiction Products.

In January 2024, we announced that we reached final agreement with the FDA on the Phase 3 safety study protocol and statistical analysis approach, including the primary endpoint. The final non-inferiority study is designed to assess the risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine. The study will randomize approximately 300 post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Of note, this study design was used in the first of two Phase 3 trials. In a Phase 3 safety study to be conducted, patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression.

We do not currently have any plans to initiate the study, unless we obtain financing for this purpose.

BAER-101 (novel α2/3–subtype-selective GABA A PAM)

Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of neurologic disorders. Baergic was acquired by the Company pursuant to a stock contribution agreement (the "Contribution Agreement") with Fortress, in order to strategically align with Avenue's goals of building a rare and neurologic pipeline. Baergic's pipeline currently consists of a single compound, BAER-101, a novel α2/3–subtype-selective GABA A positive allosteric modulator. BAER-101 (formerly known as AZD7325) was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

In August 2023, we reported preclinical data for BAER-101 from an in vivo evaluation in SynapCell's Genetic Absence Epilepsy Rat from the Strasbourg ("GAERS") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti-seizure drug development. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg administered orally. The data were subsequently presented at the American Epilepsy Society 2023 Annual Meeting in December 2023 and at the American Society for Experimental Neurotherapeutics 2024 Annual Meeting in March 2024. The data were also published in *Drug Development Research* in February 2024.

We are currently exploring strategic alternatives for Baergic and/or BAER-101, which may involve engaging a development or licensing partner or a sale, license, divestiture of Baergic and/or BAER-101, or we may initiate a Phase 2a study for the program if we receive additional financing.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. 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 consolidated 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 Company's Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 31, 2025 (the "2024 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2024.

Accounting Pronouncements

See Note 2, "Significant Accounting Policies", to our unaudited condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Smaller Reporting Company Status

We are a "smaller reporting company," meaning that either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we chose to present only the two most recent fiscal years of audited financial statements in the 2024 Form 10-K, have reduced disclosure obligations regarding executive compensation and certain other matters, and smaller reporting companies are permitted to delay adoption of certain recent accounting.

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with U.S. GAAP, include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented and are stated in U.S. dollars. The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiary, Baergic. All intercompany balances and transactions have been eliminated. Because the Company owns less than 100% of Baergic, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in Baergic by the respective non-controlling parties. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of its subsidiary.

Results of Operations

General

At March 31, 2025, we had an accumulated deficit of $104.4 million. 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 candidates 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 March 31, 2025 and 2024

	For The Three Months Ended March 31,		Change	
($ in thousands)	**2025**	**2024**	**$**	**%**
Operating expenses:				
Research and development	$ 411	$ 2,392	$ (1,981)	(83)%
General and administrative	1,494	1,316	178	14%
Loss from operations	(1,905)	(3,708)	1,803	(49)%
Other income (expense):				
Interest income	32	49	(17)	(35)%
Loss on settlement of common stock warrant liabilities	—	(574)	574	(100)%
Change in fair value of warrant liabilities	15	(116)	131	(113)%
Total other income (expense)	47	(641)	688	(107)%
Net loss	(1,858)	(4,349)	2,491	(57)%
Net loss attributable to non-controlling interests	(6)	(9)	3	(33)%
Net loss attributable to common stockholders	$ (1,852)	$ (4,340)	$ 2,488	(57)%

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 March 31, 2025 and 2024, research and development expenses were $0.4 million and $2.4 million, respectively. The decrease of $2.0 million was associated with a $1.9 million decrease in pre-clinical and clinical development costs for AJ201, prior to its sale to AnnJi, and $0.1 million in IV tramadol supply costs.

We expect our research and development activities to decrease due to no further development obligations for AJ201, however we will continue to develop and attempt to gain regulatory approval for our existing product candidates, 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 interactions, submissions, and 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 commercialization of our product candidates and explore strategic alternatives for our Baergic subsidiary.

For the three months ended March 31, 2025 and 2024, general and administrative expenses were $1.5 million and $1.3 million, respectively. The increase of $0.2 million is related to an increase of $0.4 million in legal expenses, partially offset by a decrease of $0.1 million in personnel-related costs, including salaries, benefits, and stock-based compensation and $0.1 million in professional fees.

Interest Income

Interest income was $32,000 and $49,000 for the three months ended March 31, 2025 and 2024, respectively.

Loss on Settlement of Common Stock Warrant Liabilities

The loss on common stock warrant liabilities was $0 and $0.6 million for the three months ended March 31, 2025 and 2024, respectively. The January 2024 Series A Warrants and January 2024 Series B Warrants had a fair value of $0.6 million allocated to the January 2023 Warrants at the time of issuance as a cost of inducement, which was recorded as a loss on settlement of common stock warrant liabilities.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a gain of $15 thousand and a loss of $0.1 million for the three months ended March 31, 2025 and 2024, respectively. Warrants to purchase common stock that are required to be classified as a liability are valued at fair market value at each reporting period. The change in the fair value of warrant liabilities was primarily due to the modification of the exercise price as part of a warrant inducement, the exercise of warrants classified as liabilities, and fluctuation in our stock price.

Liquidity and Capital Resources

At March 31, 2025, we had $3.5 million in cash and cash equivalents. To date, we have funded our operations primarily with proceeds from various public and private offerings of our common stock. We expect that our expenses will continue for the foreseeable future as we continue to advance our candidates through clinical development and ultimately regulatory approval, and seek opportunities to license or acquire additional products. We will require additional financing to carry out our business plan and implement our strategy, and continue to analyze various alternatives, including potentially obtaining lines of credit, debt or equity financings. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to our product candidates or marketing territories. Without additional capital, we do not expect our cash will be sufficient to fund our projected operating requirements or allow us to fund our operating plan for more than 12 months from the date of issuance of the accompanying unaudited condensed consolidated financial statements. We regularly evaluate market conditions, our liquidity profile, and various financing alternatives for opportunities to enhance our capital structure.

Cash Flows for the Three Months Ended March 31, 2025 and 2024

	For the Three Months Ended March 31,	
($ in thousands)	**2025**	**2024**
Total cash and cash equivalents provided by (used in):		
Operating activities	$ (1,186)	$ (3,120)
Financing activities	2,094	4,531
Net increase (decrease) in cash and cash equivalents	$ 908	$ 1,411

Operating Activities

Net cash and cash equivalents used in operating activities was $1.2 million for the three months ended March 31, 2025, primarily comprised of our $1.9 million net loss, partially offset by $0.2 million in share-based compensation, $0.1 million for common shares issued to Fortress and an increase of $0.4 million in operating assets and liabilities.

Net cash and cash equivalents used in operating activities was $3.1 million for the three months ended March 31, 2024, primarily comprised of our $4.3 million net loss and $0.4 million reduction in common share issuable to Fortress, partially offset by a $0.6 million loss on settlement of common stock warrant liabilities, an increase of $0.3 million in operating assets and liabilities, $0.4 million for shares issued to Fortress, $0.1 million change in fair value of warrant liabilities and $0.2 million in share-based compensation.

Financing Activities

Net cash and cash equivalents provided by financing activities was $2.1 million for the three months ended March 31, 2025, primarily due to $2.1 million in net proceeds received from the sale of common stock pursuant to the At the Market Offering Agreement.

Net cash and cash equivalents provided by financing activities was $4.5 million for the three months ended March 31, 2024, primarily comprised of $4.5 million in net proceeds from the January 2024 Warrant Inducement.

Contractual Obligations

We enter into contracts in the normal course of business with licensors, CROs, contract manufacturing organizations (CMOs) and other third parties for the procurement of various products and services, including without limitation biopharmaceutical development, biologic assay development, commercialization, clinical and preclinical development, clinical trials management, pharmacovigilance and manufacturing and supply. These contracts typically do not contain minimum purchase commitments (although they may) and are generally terminable by us upon written notice. Payments due upon termination or cancelation/delay consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation; in certain cases, our contractual arrangements with CROs and CMOs include cancelation and/or delay fees and penalties.

We have obligations under various license agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory, and commercial milestones (such as clinical trial development, product approval by the FDA or other regulatory agencies, product launch, or product sales). These commitments include:

Our subsidiary, Baergic, has entered into two license agreements with: (i) AstraZeneca AB to acquire an exclusive license to patent and related intellectual property rights pertaining to their proprietary compound and (ii) Cincinnati Children's Hospital Medical Center to acquire patent and related intellectual property rights pertaining to a program for neurological disorders. Development milestones totaling up to approximately $81.5 million in the aggregate are due upon achievement of such milestones, and commercial and sales-based milestone payments totaling up to approximately $151.0 million may be payable. Royalties are payable on net sales of products covered by the licensed intellectual property in the low to high single digits.

We entered into a license agreement with Revogenex, pursuant to which we received a worldwide exclusive license to make, market and sell IV tramadol. A regulatory milestone of $3.0 million is payable on approval high single-digit to low double-digit royalties are payable on net sales.

We entered into a share repurchase agreement with InvaGen, which requires us to pay InvaGen seven and a half (7.5%) of the proceeds of future financings, as defined in the agreement, up to $4 million in aggregate. For the three months ended March 31, 2025 and 2024, we have paid $0.2 million and $0.3 million, respectively, towards this aggregate amount. Approximately $1.4 million in aggregate has been paid to InvaGen under the Share Repurchase Agreement through the three months ended March, 31, 2025.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of 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 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 March 31, 2025, 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 concluded that, as of such date, 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 March 31, 2025 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.

To our knowledge, there are no legal proceedings pending against us, other than routine actions and administrative proceedings, and other actions that are not expected to have a material adverse effect on our business, financial condition, results of operations, or cash flows. In the ordinary course of business, however, we may be subject to both insured and uninsured litigation. Suits and claims may be brought against us by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of our product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages.

Item 1A. Risk Factors

We have disclosed under the heading “Risk Factors” in the 2024 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 2024 Form 10-K and the other information set forth elsewhere in this Quarterly Report on Form 10-Q, including under "Forward-Looking Statements." You should be aware that these risk factors and other information may not describe every risk our Company faces. Additional risks and uncertainties not currently known to us may also materially adversely affect our business, financial condition and/or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

N/A.

Item 3. Defaults Upon Senior Securities.

N/A.

Item 4. Mine Safety Disclosures.

N/A.

Item 5. Other Information.

During the three months ended March 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified, or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act).

Item 6. 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	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on September 22, 2022 (File No. 001-38114) and incorporated herein by reference.
3.4	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 3, 2023 (File No. 001-38114) and incorporated herein by reference.
3.5	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., as filed on February 20, 2024, filed as Exhibit 3.1 to Form 8-K filed on February 23, 2024 (File No. 001-38114) and incorporated herein by reference.
3.6	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc. as filed on April 25, 2024, filed as exhibit 3.1 to Form 8-K filed on April 26, 2024 (File No. 001-38114) and incorporated herein by reference.
3.7	Second Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 10, 2023 (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 May 15, 2025. *
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 May 15, 2025. *
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 May 15, 2025. **
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 May 15, 2025. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated 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: May 15, 2025

By: /s/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer and Director

Date: May 15, 2025

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 Quarterly 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
May 15, 2025

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 Quarterly 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ David Jin
David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
May 15, 2025

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 my knowledge:

- The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025 (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)
May 15, 2025

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 my knowledge:

- The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025 (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)
May 15, 2025