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

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2026**

**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: None

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

| Title of Class | Trading Symbol(s) |
|---|---|
| Common Stock | ATXI (OTC Markets Group, Inc.) |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

| Class of Common Stock | Outstanding Shares as of November 4, 2026 |
|---|---|
| Common Stock, $0.0001 par value | 3,294,967 |

**AVENUE THERAPEUTICS, INC.**
**Form 10-Q**
**For the Quarter Ended September 30, 2026**

**Table of Contents**


| | | Page No. |
|---|---|---|
| **PART I. FINANCIAL INFORMATION** | | |
| Item 1. | Unaudited Consolidated Financial Statements | 1 |
| Item 2. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 14 |
| Item 3. | Quantitative and Qualitative Disclosures About Market Risk | 20 |
| Item 4. | Controls and Procedures | 20 |
| **PART II. OTHER INFORMATION** | | |
| Item 1. | Legal Proceedings | 21 |
| Item 1A. | Risk Factors | 21 |
| Item 2. | Unregistered Sales of Equity Securities and Use of Proceeds | 21 |
| Item 3. | Defaults Upon Senior Securities | 21 |
| Item 4. | Mine Safety Disclosures | 21 |
| Item 5. | Other Information | 21 |
| Item 6. | Exhibits | 22 |
| SIGNATURES | | 23 |

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

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,520 | $ 2,855 |
| Prepaid expenses and other current assets | 10 | 76 |
| **Total assets** | $ **1,530** | $ **2,931** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | $ 599 | $ 468 |
| Accounts payable and accrued expenses - related party | 1,006 | 630 |
| Warrant liability | — | 1 |
| Total current liabilities | 1,605 | 1,099 |
| **Total liabilities** | **1,605** | **1,099** |
| | | |
| **Commitments and contingencies (Note 6)** | | |
| | | |
| **Stockholders' equity (deficit)** | | |
| **Preferred stock ($0.0001 par value), 2,000,000 shares authorized** | | |
| Class A Preferred Stock, 250,000 shares issued and outstanding as of September 30, 2026 and December 31, 2025 | — | — |
| **Common stock ($0.0001 par value), 200,000,000 shares authorized** | | |
| Common shares, 3,294,967 and 3,183,558 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively | — | — |
| Additional paid-in capital | 107,490 | 107,321 |
| Accumulated deficit | (107,565) | (105,489) |
| **Total stockholders' equity (deficit)** | **(75)** | **1,832** |
| **Total liabilities and stockholders' equity (deficit)** | $ **1,530** | $ **2,931** |

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

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

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2026** | **2025** | **2026** | **2025** |
| Revenue | | | | |
| Other revenue | $ — | $ — | $ — | $ 1,404 |
| | | | | |
| Operating expenses: | | | | |
| Research and development | $ 212 | $ 177 | $ 659 | $ 780 |
| General and administrative | 492 | 547 | 1,466 | 2,955 |
| Total operating expenses | 704 | 724 | 2,125 | 3,735 |
| Income (loss) from operations | (704) | (724) | (2,125) | (2,331) |
| | | | | |
| Other income: | | | | |
| Interest income | 13 | 34 | 48 | 96 |
| Change in fair value of warrant liabilities | — | (2) | 1 | 14 |
| Total other income | 13 | 32 | 49 | 110 |
| Net income (loss) | $ (691) | $ (692) | $ (2,076) | $ (2,221) |
| | | | | |
| Net loss attributable to non-controlling interests | — | (9) | — | (21) |
| Net income (loss) attributable to Avenue | $ (691) | $ (683) | $ (2,076) | $ (2,200) |
| | | | | |
| Net income (loss) attributable to common stockholders | $ (691) | $ (683) | $ (2,076) | $ (2,200) |
| | | | | |
| Net income (loss) per common share attributable to common stockholders, basic and diluted | $ (0.20) | $ (0.21) | $ (0.60) | $ (0.71) |
| | | | | |
| Weighted average number of common shares outstanding, basic and diluted | 3,475,687 | 3,183,558 | 3,472,315 | 3,113,464 |

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

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

**Three months ended September 30, 2026**

| | Class A Preferred Shares | | Common Shares | | Additional Paid-in | Accumulated | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | (Deficit) |
| **Balance at June 30, 2026** | **250,000** | $ — | **3,294,967** | $ — | $ **107,443** | $ **(106,874)** | $ **569** |
| Share-based compensation | — | — | — | — | 47 | — | 47 |
| Net loss attributable to common stockholders | — | — | — | — | — | (691) | (691) |
| **Balance at September 30, 2026** | **250,000** | $ — | **3,294,967** | $ — | $ **107,490** | $ **(107,565)** | $ **(75)** |

**Nine Months Ended September 30, 2026**

| | Class A Preferred Shares | | Common Shares | | Additional Paid-in | Accumulated | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | (Deficit) |
| **Balance at December 31, 2025** | **250,000** | $ — | **3,183,558** | $ — | $ **107,321** | $ **(105,489)** | $ **1,832** |
| Share based compensation | — | — | 200 | — | 169 | — | 169 |
| Issuance of common stock to Fortress | — | — | 111,209 | — | — | — | — |
| Net loss attributable to common stockholders | — | — | — | — | — | (2,076) | (2,076) |
| **Balance at September 30, 2026** | **250,000** | $ — | **3,294,967** | $ — | $ **107,490** | $ **(107,565)** | $ **(75)** |

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

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

**Three months ended September 30, 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 June 30, 2025** | **250,000** | $ — | **3,183,558** | $ — | $ **108,155** | $ **(104,097)** | $ **(1,226)** | $ **2,832** |
| Share-based compensation | — | — | — | — | 163 | — | — | 163 |
| Non-controlling interest in subsidiaries | — | — | — | — | 19 | — | (19) | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | (9) | (9) |
| Net loss attributable to common stockholders | — | — | — | — | — | (683) | — | (683) |
| **Balance at September 30, 2025** | **250,000** | $ — | **3,183,558** | $ — | $ **108,337** | $ **(104,780)** | $ **(1,254)** | $ **2,303** |

**Nine Months Ended September 30, 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 | — | — | 239 | — | 523 | — | — | 523 |
| 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 |
| Shares receivable from AnnJi | — | — | — | — | (4) | — | — | (4) |
| Non-controlling interest in subsidiaries | — | — | — | — | 292 | — | (292) | — |
| Net loss attributable to non-controlling interest | — | — | — | — | — | — | (21) | (21) |
| Net loss attributable to common stockholders | — | — | — | — | — | (2,200) | — | (2,200) |
| **Balance at September 30, 2025** | **250,000** | $ — | **3,183,558** | $ — | $ **108,337** | $ **(104,780)** | $ **(1,254)** | $ **2,303** |

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

**AVENUE THERAPEUTICS, INC.**
**Unaudited Consolidated Statements of Cash Flows**
**(Unaudited)**
**($ in thousands)**

| | For the Nine Months Ended | |
|---|---|---|
| | **September 30, 2026** | **September 30, 2025** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (2,076) | $ (2,221) |
| Reconciliation of net loss to net cash used in operating activities: | | |
| Share-based compensation | 169 | 523 |
| Change in fair value of warrant liabilities | (1) | (14) |
| Issuance of common stock to Fortress | — | 55 |
| Gain on repurchase of common stock held by AnnJi | — | (4) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 66 | 62 |
| Accounts payable and accrued expenses | 131 | 225 |
| Accounts payable and accrued expenses - related party | 376 | 395 |
| Net cash used in operating activities | (1,335) | (979) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from ATM sales of common stock, net of issuance costs | — | 2,094 |
| Net cash provided by financing activities | — | 2,094 |
| | | |
| Net change in cash and cash equivalents | (1,335) | 1,115 |
| Cash and cash equivalents, beginning of period | 2,855 | 2,594 |
| Cash and cash equivalents, end of period | $ 1,520 | $ 3,709 |
| | | |
| **Supplemental cash flow information:** | | |
| Issuance of common shares - Founders Agreement and equity fee to Fortress | $ 76 | $ 55 |

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

**AVENUE THERAPEUTICS, INC.**
**NOTES TO UNAUDITED 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 are clenbuterol ("ATX-04"), a selective β2-adrenergic agonist for Pompe disease, intravenous tramadol ("IV tramadol") for the treatment of post-operative acute pain and previously, through November 2025, BAER-101 for the treatment of epilepsy and panic disorders.

Since March 2025, the Company's common stock has been quoted on the over-the-counter market (OTCID) under the symbol "ATXI".

***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 its product development plan and may never become profitable. As of September 30, 2026, the Company had an accumulated deficit of $107.6 million. Due to uncertainties regarding future operations of the Company for the development of ATX-04, 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 included the accounts of the Company and the accounts of the Company's subsidiary, until its sale in November 2025. All intercompany balances and transactions have been eliminated.

The accompanying unaudited interim financial statements previously included the accounts of the Company's subsidiary, Baergic Bio, Inc. ("Baergic") until its sale to Axsome Therapeutics, Inc. in November 2025. Because the Company owned less than 100% of Baergic, the Company recorded 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.

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 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 financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2025, which were included in the Company's Annual Report on Form 10-K (the "2025 Form 10-K") and filed with the SEC on March 30, 2026.

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

***Net Loss per Share***

Basic and diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares outstanding, including vested, settlement deferred restricted stock units, 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. In the periods where the Company has generated a net loss, 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 September 30, | |
|---|---|---|
| | **2026** | **2025** |
| Unvested restricted stock units/awards | 200 | 532 |
| Deferred stock units | — | 235,000 |
| Warrants | 772,731 | 1,476,200 |
| Options | 256,474 | 256,474 |
| Class A Preferred shares(1) | 222 | 222 |
| **Total potential dilutive effect** | 1,029,627 | 1,968,428 |

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

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 and nine months ended September 30, 2026 and 2025.

***Summary of Significant Accounting Policies***

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2025 Form 10-K.

***Accounting Standards Not Yet Adopted***

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**

***ATX-04***

In February 2026, Avenue entered into a license agreement with Duke University ("Duke"), pursuant to which Avenue obtained an exclusive worldwide license (the "ATX-04 License") from Duke to certain patents and know-how pertaining to ATX-04 for the treatment of lysosomal storage diseases.

Under the ATX-04 License, Avenue made upfront payments totaling approximately $19,000 to Duke and has an obligation to make development, regulatory, and commercial milestone payments totaling approximately $15.6 million upon the achievement of certain milestones. In addition, Avenue is obligated to pay a tiered low single-digit royalty on future net sales of ATX-04.

Beginning with calendar year 2028 and until the first regulatory approval, Avenue is obligated to make minimum annual royalty payments. In the event the ATX-04 License is terminated, minimum royalty obligations will cease, and Avenue will only be responsible for amounts due up to the termination date.

***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 a Founders Agreement, which was subsequently amended and restated on September 13, 2016. 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 $2.0 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 was 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. In September 2026, the Company and Polpharma entered into a termination agreement, pursuant to which the parties terminated the manufacturing agreement related to the manufacture of IV tramadol.

***AJ201 Termination***

In February 2023, the Company entered into a license agreement with AnnJi Pharmaceutical Co. Ltd. ("AnnJi"), whereby Avenue obtained an exclusive license (the "AnnJi License Agreement") for exclusive rights to intellectual property related to AJ201, a clinical-stage product candidate. Under the AnnJi License Agreement, the Company made an upfront payment of $3.0 million, issued shares of Avenue stock in two tranches, and agreed to certain development, regulatory, and commercial milestone payments, as well as royalties on net sales.

On April 24, 2025, the Company 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 repurchased all shares previously issued to AnnJi for nominal consideration and paid approximately $0.2 million as consideration for legal expenses, which was accounted for as consideration payable to a customer and recorded as a reduction of revenue.

Under the Termination and Transfer Agreement, AnnJi agreed to pay the Company $1.6 million (net of withholding taxes), which was received in 2025. The Company recognized $1.4 million as other revenue during the quarter ended June 30, 2025, representing the consideration for the transfer of rights less the consideration for legal expenses.

The Company remains eligible to receive development and regulatory milestones relating to AJ201 of up to $5.0 million, commercial milestones of up to $17.0 million, a 1.75% royalty on future net sales of AJ201, and certain sublicense income subject to specified caps and conditions. Such amounts are considered variable consideration and are constrained until the achievement of the specified milestones. 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 Consolidated Statements of Operations. For the three months ended September 30, 2026 and 2025, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively. For the nine months ended September 30, 2026 and 2025, the Company recorded expense related to the MSA of $0.4 million and $0.4 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*

Pursuant to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), the Company issued 111,209 shares of common stock to Fortress as the Annual Stock Dividend on January 1, 2026 (as such term is defined in the Certificate of Incorporation), representing 2.5% of the fully-diluted outstanding equity of the Company on December 31, 2025. The value of these shares was recorded as common stock issuable to Fortress in the Statement of Stockholders' Equity at December 31, 2025. The Company recorded an expense of approximately $0.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2025.

*Financing Equity Fee*

For the three and nine months ended September 30, 2026, the Company did not have a Financing Equity Fee.

For the three months ended September 30, 2025, the Company recorded no Financing Equity Fee. For the nine months ended September 30, 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.

***Payables and Accrued Expenses Related Party***

In the normal course of business, Fortress incurs certain expenses on behalf of the Company. Such expenses are recorded as accounts payable and accrued expenses – related party and are recorded at the invoiced amount and reimbursed to Fortress in the normal course of business. The Company believes that the difference, if any, between the amounts invoiced and the amounts that would have been incurred if the Company operated as an unaffiliated entity is not material.

***Founders Agreement and Management Services Agreement with Baergic***

In connection with the Company's previous ownership of Baergic, the Company was party to a Founders Agreement ("Avenue-Baergic Founders Agreement") and a Management Services Agreement ("Avenue-Baergic MSA") with Baergic, which were assigned to the Company in November 2022. Under the Avenue-Baergic Founders Agreement, the Company was entitled to (i) an annual stock dividend equal to 2.5% of Baergic's fully-diluted equity, (ii) equity-based fees equal to 2.5% of certain financing transactions, (iii) a cash fee equal to 4.5% of Baergic's annual net sales, and (iv) a change-in-control fee based on a multiple of net sales. Under the Avenue-Baergic MSA, the Company provided management and advisory services to Baergic and received an annual consulting fee of $0.5 million, which was subject to an increase of $1.0 million in years when Baergic's net assets exceeded $100 million.

The Avenue-Baergic Founders Agreement and Avenue-Baergic MSA were terminated on November 5, 2025 in connection with the sale of Baergic.

**Note 5 — Accounts Payable and Accrued Expenses**

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

| | As of September 30, 2026 | As of December 31, 2025 |
|---|---|---|
| Accounts payable | $ 76 | $ 94 |
| Accrued employee compensation | 324 | 181 |
| Accrued other | 199 | 193 |
| Total accounts payable and accrued expenses | $ 599 | $ 468 |

**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 September 30, 2026, there was no litigation against the Company.

**Note 7 - Stockholders' 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 into 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. 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, including the adjustment for reverse stock splits described below. 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"). On July 17, 2025, Nasdaq filed a Form 25 with the SEC, and as of this date, the Company is ineligible to use Form S-3. The Replacement Shelf was later withdrawn. On December 15, 2025, we filed a Post-Effective Amendment No. 1 for Form S-3 on Form S-1 (File No. 333-279125), which Post-Effective Amendment was declared effective on December 16, 2025.

*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 was previously able to 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. During the nine months ended September 30, 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 Nasdaq. The following describes the Company's ability to use the ATM Agreement until such suspension. Offers and sales of the shares were 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.

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.

***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 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 4,575,906 shares at September 30, 2026.

***Restricted Stock Units and Restricted Stock Awards***

The following table summarizes the restricted stock unit and award activity during the nine months ended September 30, 2026:

| | Number of Units and Awards | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested balance at December 31, 2025 | 235,400 | $ 3.19 |
| Vested | (200) | 85.50 |
| Vested - settlement deferred | (235,000) | 2.46 |
| Unvested balance at September 30, 2026 | 200 | $ 85.50 |

At September 30, 2026, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of approximately $1,000, which is expected to be recognized over the remaining weighted-average vesting period of 0.3 years. The expense is recognized over the vesting period of the awards.

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 September 30, 2026, the Company had 235,000 vested, settlement deferred restricted stock units.

***Stock Options***

The following table summarizes stock option activity during the nine months ended September 30, 2026:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2025 | 256,474 | $ 9.74 | 8.6 | $ — |
| Outstanding at September 30, 2026 | 256,474 | $ 9.74 | 7.9 | $ — |
| Expected to vest | 78,452 | $ 2.94 | 8.0 | $ — |
| Exercisable | 178,022 | $ 12.73 | 7.8 | $ — |

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 September 30, 2026, the total compensation cost related to non-vested options awards not yet recognized is approximately $21,000 with a weighted average remaining vesting period of 0.3 years.

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

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Research and development | $ 9 | $ 31 | $ 38 | $ 102 |
| General and administrative | 38 | 132 | 131 | 421 |
| **Total stock-based compensation expense** | **$ 47** | **$ 163** | **$ 169** | **$ 523** |

***Stock Warrants***

The following table summarizes the warrant activity for the three and nine months ended September 30, 2026:

| | Warrants | Weighted Average Exercise Price | Aggregate Intrinsic Value (in thousands) | Weighted Average Remaining Contractual Life (in years) |
|---|---|---|---|---|
| Outstanding, December 31, 2025 | 772,741 | $ 10.56 | $ — | 3.3 |
| Expired | (10) | 0.11 | — | — |
| Outstanding, September 30, 2026 | 772,731 | $ 10.56 | $ — | 2.5 |

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

***InvaGen Share Repurchase***

In July 2022, the Company entered into a share repurchase agreement with InvaGen Pharmaceuticals, Inc. ("InvaGen") under which the Company repurchased all of InvaGen's shares in Avenue, the Company agreed to pay InvaGen seven and a half percent (7.5%) of the proceeds of future financings, up to $4.0 million, which the Company accounts for as a derivative. Due to the uncertainty related to future financings, the estimated fair value of the derivative is not material. The Company recognizes changes in fair value within general and administrative expenses in the Unaudited Consolidated Statement of Operations. For the nine months ended September 30, 2025, the Company made payments totaling $0.2 million to InvaGen. No such payments were owed or made during the nine months ended September 30, 2026. Approximately $1.4 million in aggregate has been paid to InvaGen under the share repurchase agreement as of September 30, 2026.

**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 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 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 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, 2025 | $ 1 |
| Change in fair value of warrants | (1) |
| Fair value of warrants outstanding as of September 30, 2026 | $ — |

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

| | September 30, 2026 | December 31, 2025 |
|---|---|---|
| Stock price | $ 0.27 | $ 0.68 |
| Risk-free interest rate | 4.02% | 3.75% |
| Expected dividend yield | — | — |
| Expected term in years | 1.0 | 1.8 |
| Expected volatility | 242% | 151% |

**Item 2. Management's Discussion and Analysis of Financial Condition and 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 termination of our license agreement for AJ201 with AnnJi Pharmaceutical Co., Ltd. ("AnnJi"), and disposal of our equity interest in Baergic Bio, Inc. ("Baergic") and rights to BAER-101;*
- *the uncertainty related to the timing and amounts expected to be realized from future milestone and royalty payments, if at all;*
- *the fact that we currently have no drug products for sale and that our success is dependent on our current or future 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 ATX-04;*
- *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 current or future 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 current or future 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 current or future 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 current or future product candidates;*
- *our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our current or future product candidates;*
- *our exposure to potential product liability claims;*
- *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 OTCID 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*

- *the risks described under the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025 (the "2025 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 ATX-04, a selective β2-adrenergic agonist for Pompe disease and an intravenous tramadol ("IV tramadol"), a schedule IV opioid for the treatment of post-operative acute pain. We may in the future acquire additional product candidates.

Our net loss for the nine months ended September 30, 2026 and 2025 was approximately $2.1 million and $2.2 million, respectively. As of September 30, 2026, we had an accumulated deficit of approximately $107.6 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 consolidated 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.

**Current Product Candidates**

***ATX-04***

In February 2026, we entered into a license agreement with Duke University ("Duke"), pursuant to which we obtained an exclusive worldwide license (the "ATX-04 License") from Duke to certain patents and know-how pertaining to clenbuterol ("ATX-04") for the treatment of lysosomal storage diseases.

Under the ATX-04 License, we made upfront payments totaling approximately $19,000 to Duke and have an obligation to make development, regulatory, and commercial milestone payments upon the achievement of certain milestones. In addition, we are obligated to pay a tiered low single-digit royalty on future net sales of ATX-04. Beginning with calendar year 2028 and until the first regulatory approval, we are obligated to make minimum annual royalty payments. In the event the ATX-04 License is terminated, minimum royalty obligations will cease, and we will only be responsible for amounts due up to the termination date.

ATX-04 was studied in a 52-week Phase I/II clinical study conducted at Duke in patients with Pompe disease on baseline ERT and demonstrated that ATX-04 treatment was associated with meaningful improvements across multiple clinically and biologically relevant domains. Treatment with ATX-04 resulted in improvements in six-minute walk distance, reflecting enhanced functional capacity, as well as increased respiratory muscle strength, including maximal inspiratory pressure. ATX-04 was also associated with reductions in muscle glycogen burden assessed by biopsy, increased GAA activity with improved intracellular trafficking, and broad normalization of disease-relevant gene expression. The therapy was generally well tolerated with chronic, titrated dosing.

Based on this data, Avenue is currently in discussions with the FDA regarding a pivotal study design for Pompe disease, and subsequent to those discussions, will seek to raise the necessary capital to fund the pivotal study and initiate the trial.

***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 indicated that we were in agreement with the FDA on a majority of the proposed protocol. The minutes indicated that the FDA also agreed 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, patients would 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 are currently evaluating the path forward for IV tramadol as a product candidate. The initiation of the study is subject to the Company obtaining the necessary financing or partnership.

**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 involve a significant level of estimation uncertainty and 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 2025 Form 10-K. There were no material changes in our critical accounting estimates or accounting policies from December 31, 2025.

**Accounting Pronouncements**

See Note 2, “Significant Accounting Policies”, to our unaudited 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 2025 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 standards.

**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. Prior to the sale of Baergic in November 2025, the Company’s consolidated financial statements included the accounts of the Company and the accounts of the Company’s subsidiary, Baergic. All intercompany balances and transactions were eliminated. Because the Company owned less than 100% of Baergic, the Company recorded 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.

**Results of Operations**

***General***

At September 30, 2026, we had an accumulated deficit of $107.6 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 September 30, 2026 and 2025***

| | For The Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | **2026** | **2025** | **$** | **%** |
| Operating expenses: | | | | |
| Research and development | $ 212 | $ 177 | $ 35 | 20% |
| General and administrative | 492 | 547 | (55) | (10)% |
| Total operating expenses | 704 | 724 | (20) | (3)% |
| Income (loss) from operations | (704) | (724) | 20 | (3)% |
| Other income: | | | | |
| Interest income | 13 | 34 | (21) | (62)% |
| Change in fair value of warrant liabilities | — | (2) | 2 | (100)% |
| Total other income | 13 | 32 | (19) | (59)% |
| Net income (loss) | (691) | (692) | 1 | (0)% |
| Net loss attributable to non-controlling interests | — | (9) | 9 | 100% |
| Net income (loss) attributable to common stockholders | $ (691) | $ (683) | $ (8) | 1% |

***Research and Development Expenses***

For the three months ended September 30, 2026 and 2025, research and development expenses were relatively consistent at approximately $0.2 million and $0.2 million, respectively, reflecting increased consulting costs offset by a decrease in personnel-related expenses.

We expect our research and development activities to increase as we begin to develop ATX-04 and attempt to gain regulatory approval for our existing product candidates, reflecting costs associated with employee-related expenses, license fees and milestone payments related to in-licensed product and technology, expenses incurred under agreements with contract research organizations ("CROs"), 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***

For the three months ended September 30, 2026 and 2025, general and administrative expenses were relatively consistent at approximately $0.5 million and $0.5 million, respectively, reflecting increased professional service-related costs, offset by decreased personnel-related expenses.

***Interest Income***

Interest income was $13,000 and $34,000 for the three months ended September 30, 2026 and 2025, respectively.

***Change in Fair Value of Warrant Liabilities***

There was no material change in fair value for the three months ended September 30, 2026. The change in fair value of warrant liabilities was a loss of approximately $2,000 for the three months ended September 30, 2025. 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 fluctuation in our stock price.

***Comparison of the Nine Months Ended September 30, 2026 and 2025***

| | For the Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| *($ in thousands)* | **2026** | **2025** | **$** | % |
| Revenue | | | | |
| Other revenue | $ — | $ 1,404 | $ (1,404) | (100)% |
| | | | | |
| Operating expenses: | | | | |
| Research and development | 659 | 780 | (121) | (16)% |
| General and administrative | 1,466 | 2,955 | (1,489) | (50)% |
| Total operating expenses | 2,125 | 3,735 | (1,610) | (43)% |
| Loss from operations | (2,125) | (2,331) | 206 | 9% |
| | | | | |
| Other income: | | | | |
| Interest income | 48 | 96 | (48) | (50)% |
| Change in fair value of warrant liabilities | 1 | 14 | (13) | (93)% |
| Total other income | 49 | 110 | (61) | (55)% |
| Net loss | (2,076) | (2,221) | 145 | 7% |
| | | | | |
| Net loss attributable to non-controlling interests | — | (21) | 21 | 100% |
| Net loss attributable to common stockholders | $ (2,076) | $ (2,200) | $ 124 | 6% |

***Revenue***

No revenue was recognized for the nine months ended September 30, 2026. For the nine months ended September 30, 2025, we generated $1.4 million of net revenue related to the AnnJi license termination and program transfer.

***Research and Development Expenses***

For the nine months ended September 30, 2026 and 2025, research and development expenses were $0.7 million and $0.8 million, respectively. The decrease of $0.1 million was associated with a $0.2 million decrease in personnel related costs, including salaries, benefits and stock-based compensation, partially offset by a $0.1 million increase in consulting costs.

We expect our research and development activities to increase as we begin to develop ATX-04 and attempt to gain regulatory approval for our existing product candidates, reflecting costs associated with employee-related expenses, license fees and milestone payments related to in-licensed product and technology, expenses incurred under agreements with CROs, 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***

For the nine months ended September 30, 2026 and 2025, general and administrative expenses were $1.5 million and $3.0 million, respectively. The decrease of $1.5 million is related to a decrease of $0.8 million in legal expenses due to costs incurred related to the AnnJi License Agreement termination in 2025, a $0.5 million decrease in personnel-related costs, including salaries, severance, benefits and stock-based compensation, a $0.1 million decrease in equity fees to Fortress associated with financing activities in 2025, and a $0.1 million decrease in consulting costs.

***Interest Income***

Interest income was $48,000 and $96,000 for the nine months ended September 30, 2026 and 2025, respectively.

***Change in Fair Value of Warrant Liabilities***

The change in fair value of warrant liabilities was a gain of approximately $1,000 and $14,000 for the nine months ended September 30, 2026 and 2025, 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 fluctuation in our stock price.

***Liquidity and Capital Resources***

At September 30, 2026, we had $1.5 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 product 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. Since March 2025, our common stock has been quoted on the over-the-counter market ("OTCID") under the symbol “ATXI”. Being listed on the OTCID may make it more difficult for us to obtain additional funding. For example, we are no longer eligible to use our shelf registration statement on Form S-3, which means we cannot access our ATM facility under the At the Market Offering Agreement (the “ATM Agreement”) with H.C. Wainwright & Co. LLC dated May 10, 2024. 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 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 Nine Months Ended September 30, 2026 and 2025***

| | For the Nine Months Ended September 30, | |
|---|---|---|
| *($ in thousands)* | **2026** | **2025** |
| Total cash and cash equivalents provided by (used in): | | |
| Operating activities | $ (1,335) | $ (979) |
| Financing activities | — | 2,094 |
| Net increase (decrease) in cash and cash equivalents | $ (1,335) | $ 1,115 |

*Operating Activities*

Net cash and cash equivalents used in operating activities was $1.3 million for the nine months ended September 30, 2026, primarily comprised of our $2.1 million net loss, partially offset by increases of $0.6 million in operating assets and liabilities and $0.2 million in share-based compensation.

Net cash and cash equivalents used in operating activities was $1.0 million for the nine months ended September 30, 2025, primarily comprised of our $2.2 million net loss, partially offset by an increase of $0.7 million in operating assets and liabilities and $0.5 million in share-based compensation.

*Financing Activities*

During the nine months ended September 30, 2026, no net cash and cash equivalents was used in or provided by financing activities.

Net cash and cash equivalents provided by financing activities was $2.1 million for the nine months ended September 30, 2025 primarily due to $2.1 million in net proceeds from the sale of common stock pursuant to the ATM Agreement.

***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:

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

We are party to a license agreement with Duke, pursuant to which we maintain a worldwide exclusive license to develop ATX-04. A regulatory milestone of $0.3 million is payable on approval and low single-digit royalties are payable on net sales. Additionally, beginning with calendar year 2028, we are obligated to make minimum annual royalty payments. In the event the ATX-04 License is terminated, minimum royalty obligations will cease, and we will only be responsible for amounts due up to the termination date.

We are party to a share repurchase agreement with InvaGen, which requires us to pay InvaGen seven and a half percent (7.5%) of the proceeds of future financings, as defined in the agreement, up to $4.0 million in aggregate. For the nine months ended September 30, 2025, the Company made payments totaling $0.2 million to InvaGen. No such payments were made during the nine months ended September 30, 2026. Approximately $1.4 million in aggregate has been paid to InvaGen under the share repurchase agreement as of September 30, 2026.

**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 September 30, 2026, 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 September 30, 2026 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 2025 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 2025 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 quarter ended September 30, 2026, 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. 001-38114) and incorporated herein by reference. |
| 31.1 | Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 6, 2026. * |
| 31.2 | Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 6, 2026. * |
| 32.1 | Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2026. ** |
| 32.2 | Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2026. ** |
| 101 | The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to the 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 Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Avenue Therapeutics, Inc.**
**(Registrant)**

Date: November 6, 2026

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

Date: November 6, 2026

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)
November 6, 2026

**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)
November 6, 2026

**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 September 30, 2026 (the "Report") filed with the Securities and Exchange Commission fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
November 6, 2026

**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 September 30, 2026 (the "Report") filed with the Securities and Exchange Commission fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ David Jin
David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
November 6, 2026