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

FORM 10-Q

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

For the quarterly period ended March 31, 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 Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

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

Class of Common Stock	Outstanding Shares as of May 6, 2026
Common Stock, $0.0001 par value	3,294,967

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended March 31, 2026

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

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,417	$ 2,855
Prepaid expenses and other current assets	51	76
Total assets	**$ 2,468**	**$ 2,931**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 515	$ 468
Accounts payable and accrued expenses - related party	755	630
Warrant liability	—	1
Total current liabilities	1,270	1,099
Total liabilities	**1,270**	**1,099**
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock ($0.0001 par value), 200,000,000 shares authorized		
Common shares, 3,294,967 and 3,183,558 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	107,382	107,321
Accumulated deficit	(106,184)	(105,489)
Total stockholders' equity	**1,198**	**1,832**
Total liabilities and stockholders' equity	**$ 2,468**	**$ 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 March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 200	$ 411
General and administrative	514	1,494
Loss from operations	(714)	(1,905)
Other income:		
Interest income	18	32
Change in fair value of warrant liabilities	1	15
Total other income	19	47
Net loss	$ (695)	$ (1,858)
Net loss attributable to non-controlling interests	—	(6)
Net loss attributable to common stockholders	$ (695)	$ (1,852)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.21)	$ (0.62)
Weighted average number of common shares outstanding, basic and diluted	3,293,729	2,970,807

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 March 31, 2026

	Class A Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2025	**250,000**	$ —	**3,183,558**	$ —	$ **107,321**	$ **(105,489)**	$ **1,832**
Share-based compensation	—	—	200	—	61	—	61
Issuance of common stock to Fortress	—	—	111,209	—	—	—	—
Net loss attributable to common stockholders	—	—	—	—	—	(695)	(695)
Balance at March 31, 2026	**250,000**	$ —	**3,294,967**	$ —	$ **107,382**	$ **(106,184)**	$ **1,198**

Three months ended March 31, 2025

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

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

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

	For the Three Months Ended	
	March 31, 2026	**March 31, 2025**
Cash flows from operating activities:		
Net loss	$ (695)	$ (1,858)
Reconciliation of net loss to net cash used in operating activities:		
Share-based compensation	61	185
Change in fair value of warrant liabilities	(1)	(15)
Issuance of common stock to Fortress	—	55
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	25	(14)
Accounts payable and accrued expenses	47	349
Accounts payable and accrued expenses - related party	125	112
Net cash used in operating activities	(438)	(1,186)
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	(438)	908
Cash and cash equivalents, beginning of period	2,855	2,594
Cash and cash equivalents, end of period	$ 2,417	$ 3,502
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 5, 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 March 31, 2026, the Company had an accumulated deficit of $106.2 million. Due to uncertainties regarding future operations of the Company for the development of ATX-04 and a potential Phase 3 safety study for IV tramadol, the Company will need to secure additional funds through equity or debt offerings, the timing of which is unknown at this time. The Company cannot be certain that additional funding will be available to it on acceptable terms, or at all. These factors individually and collectively cause substantial doubt about the Company's ability to continue as a going concern to exist within one year from the date of this report. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

Note 2 - Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

The accompanying unaudited interim 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 shares outstanding, including prefunded warrants and shares held in abeyance, during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. 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 March 31,	
	2026	**2025**
Unvested restricted stock units/awards	200	744
Deferred stock units	235,000	235,000
Warrants	772,731	1,476,200
Options	256,474	256,474
Class A Preferred shares(1)	222	223
Total potential dilutive effect	1,264,627	1,968,641

(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 months ended March 31, 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 the Founders Agreement. In connection with the terms of the IV Tramadol License Agreement, Fortress purchased an exclusive license to IV tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland, for $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 is eligible to receive a milestone payment totaling $2.0 million upon the approval of IV tramadol from the FDA, as well as a low single digit royalty on net sales of the product for five years after launch.

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 provision 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 March 31, 2026 and 2025, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively.

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

Annual Equity Fee

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 months ended March 31, 2026, the Company did not have a Financing Equity Fee.

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

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 March 31, 2026	As of December 31, 2025
Accounts payable	$ 99	$ 94
Accrued employee compensation	232	181
Accrued other	184	193
Total accounts payable and accrued expenses	$ 515	$ 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 March 31, 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 in to which the shares of outstanding Class A Preferred Stock are convertible, and the denominator of which is number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority.

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

Common Stock

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

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

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No. 333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). The Company filed a replacement shelf registration on Form S-3 on December 4, 2024 (the "Replacement Shelf"), which has not yet become effective under the Securities Act of 1933, as amended (the "Securities Act"). 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 and therefore unable to use the Shelf or have declared effective the Replacement Shelf.

ATM Facility

On May 10, 2024, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co. LLC (the "ATM Manager") under which the Company 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 three months ended March 31, 2025, the Company sold an aggregate of 938,990 shares of its common stock pursuant to the ATM Agreement, resulting in net proceeds of approximately $2.1 million after deducting underwriting discounts. The Company is no longer able to utilize the ATM Agreement as a result of the suspension of its common stock from trading on Nasdaq. The following describes the Company's ability to use the ATM Agreement until such suspension. Offers and sales of the shares are made pursuant to the Shelf, and the related prospectus supplement dated May 10, 2024 (including such replacement registration statement as may be filed with the SEC, the "ATM Registration Statement") and filed with the SEC on such date pursuant to Rule 424(b) under the Securities Act.

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 expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 4,575,906 shares at March 31, 2026.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 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
Unvested balance at March 31, 2026	235,200	$ 2.53

At March 31, 2026, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $38,000, which is expected to be recognized over the remaining weighted-average vesting period of 0.5 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 March 31, 2026, the Company had 235,000 outstanding deferred restricted stock units.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 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 March 31, 2026	256,474	$ 9.74	8.4	$ —
Expected to vest	81,950	$ 6.46	8.4	$ —
Exercisable	174,524	$ 11.27	8.4	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2026, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.1 million with a weighted average remaining vesting period of 0.6 years.

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

	For the Three Months Ended March 31,	
	2026	2025
Research and development	$ 14	$ 40
General and administrative	47	145
Total stock-based compensation expense	$ 61	$ 185

Stock Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2026:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2025	772,741	$ 10.56	$ —
Expired	(10)	0.11	—
Outstanding, March 31, 2026	772,731	$ 10.56	$ —

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 three months ended March 31, 2025, the Company made payments totaling $0.2 million to InvaGen. No such payments were owed or made during the three months ended March 31, 2026. Approximately $1.4 million in aggregate has been paid to InvaGen under the share repurchase agreement as of March 31, 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 March 31, 2026	$ -

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

	March 31, 2026	December 31, 2025
Stock price	$ 0.29	$ 0.68
Risk-free interest rate	3.73%	3.75%
Expected dividend yield	—	—
Expected term in years	1.5	1.8
Expected volatility	187%	151%

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

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

- *the 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*
- *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 three months ended March 31, 2026 and 2025 was approximately $0.7 million and $1.9 million, respectively. As of March 31, 2026, we had an accumulated deficit of approximately $106.2 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.

Recent Developments

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 preparing a pre-IND meeting to align with the FDA regarding a pivotal study design for Pompe disease, and subsequent to that meeting, 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 indicate that we are in agreement with the FDA on a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the FDA's Division of Anesthesia, Analgesia, and Addiction Products.

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

We are currently evaluating the feasibility of the safety study. 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.

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 March 31, 2026, we had an accumulated deficit of $106.2 million. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are still in development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Comparison of the Three Months Ended March 31, 2026 and 2025

	For The Three Months Ended March 31,		Change	
($ in thousands)	**2026**	**2025**	**$**	**%**
Operating expenses:				
Research and development	$ 200	$ 411	$ (211)	(51)%
General and administrative	514	1,494	(980)	(66)%
Total operating expenses	714	1,905	(1,191)	(63)%
Loss from operations	(714)	(1,905)	1,191	63%
Other income:				
Interest income	18	32	(14)	(44)%
Change in fair value of warrant liabilities	1	15	(14)	(93)%
Total other income	19	47	(28)	(60)%
Net loss	(695)	(1,858)	1,163	63%
Net loss attributable to non-controlling interests	—	(6)	6	100%
Net loss attributable to common stockholders	$ (695)	$ (1,852)	$ 1,157	62%

Research and Development Expenses

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

For the three months ended March 31, 2026 and 2025, research and development expenses were $0.2 million and $0.4 million, respectively. The decrease of $0.2 million was associated with a $0.1 million decrease in personnel related costs, and $0.1 million one-time costs incurred related to the termination of the AnnJi License Agreement in 2025.

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 the following:

- 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

General and administrative expenses consist principally of professional fees for legal and consulting services, market research, personnel-related costs, public reporting company related costs and other general operating expenses not otherwise included in research and development expenses. We expect our general and administrative costs to continue as we seek potential regulatory approval and commercialization of our product candidates.

For the three months ended March 31, 2026 and 2025, general and administrative expenses were $0.5 million and $1.5 million, respectively. The decrease of $1.0 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 $0.1 million decrease in professional fees, and a $0.1 million decrease in personnel-related costs, including salaries, severance, benefits and stock-based compensation.

Interest Income

Interest income was $18,000 and $32,000 for the three months ended March 31, 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 $15,000 for the three months ended March 31, 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 March 31, 2026, we had $2.4 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 Three Months Ended March 31, 2026 and 2025

	For the Three Months Ended March 31,	
($ in thousands)	**2026**	**2025**
Total cash and cash equivalents provided by (used in):		
Operating activities	$ (438)	$ (1,186)
Financing activities	—	2,094
Net increase (decrease) in cash and cash equivalents	$ (438)	$ 908

Operating Activities

Net cash and cash equivalents used in operating activities was $0.4 million for the three months ended March 31, 2026, primarily comprised of our $0.7 million net loss, partially offset by increases of $0.2 million in operating assets and liabilities and $0.1 million in share-based compensation.

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

Financing Activities

During the three months ended March 31, 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 three months ended March 31, 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 (7.5%) of the proceeds of future financings, as defined in the agreement, up to $4.0 million in aggregate. For the three months ended March 31, 2025, the Company made payments totaling $0.2 million to InvaGen. No such payments were made during the three months ended March 31, 2026. Approximately $1.4 million in aggregate has been paid to InvaGen under the share repurchase agreement as of March 31, 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 March 31, 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 March 31, 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 March 31, 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. 000-38114) and incorporated herein by reference.
10.1	Patent License Agreement, dated February 18, 2026, by and between Avenue Therapeutics, Inc. and Duke University.*
31.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 8, 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 May 8, 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 May 8, 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 May 8, 2026. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 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 Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Avenue Therapeutics, Inc.
(Registrant)

Date: May 8, 2026

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

Date: May 8, 2026

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

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

PATENT LICENSE AGREEMENT

This Agreement (this "Agreement") is effective as of February 18, 2026 (the "EFFECTIVE DATE"), between Avenue Therapeutics, Inc. ("LICENSEE") having the address in Article 12 below, and Duke University, a nonprofit educational and research institution organized under the laws of North Carolina ("DUKE"). LICENSEE and DUKE hereby agree as follows:

ARTICLE 1 – DEFINITIONS

1.1 "AFFILIATE" means any corporation or non-corporate entity that controls, is controlled by or is under the common control with a specified entity. A corporation or a non-corporate entity, as applicable, is deemed to be in control of another corporation if (a) it owns or directly or indirectly controls at least 50% of the voting stock of the other corporation or (b) in the absence of ownership of at least 50% of the voting stock of a corporation, or in the case of a non-corporate entity, if it possesses directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable. An AFFILIATE shall remain an AFFILIATE only for so long as such entity meets the requirements of this definition. The term "LICENSEE" will only include AFFILIATES(s) to the extent that this Agreement is assigned to such AFFILIATE or an AFFILIATE is granted a SUBLICENSE. All rights and obligations of LICENSEE set forth in this Agreement may be exercised or performed by or through LICENSEE's AFFILIATES as if such AFFILIATES were LICENSEE, provided that LICENSEE shall be responsible for the failure of such of its AFFILIATES to comply with this Agreement. Notwithstanding the foregoing, an entity meeting the foregoing criteria shall not be deemed an AFFILIATE for purposes of this Agreement if such entity is: (i) organized under, owned or controlled (directly or indirectly) by, or otherwise affiliated with, a government, person, or jurisdiction subject to U.S. sanctions, export controls, or identified as a 'country or entity of concern' under applicable Federal regulations (including, without limitation, 28 C.F.R. Part 202, Executive Order 14117, and any successor regulations); and (ii) reasonably objected to in writing by DUKE on such basis. DUKE may withhold such approval in its sole discretion where required to comply with applicable law

1.2 "CHANGE OF CONTROL" means with respect to LICENSEE, (a) a merger or consolidation of LICENSEE with a third party that results in the voting securities of LICENSEE outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its AFFILIATES, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding voting securities of LICENSEE, or (c) the sale or other transfer to a third party of all or substantially all of such LICENSEE'S business (or that portion thereof to which the subject matter of this Agreement relates). For clarity, a CHANGE OF CONTROL does not include (i) an internal consolidation, merger, share exchange or other reorganization of LICENSEE between or among LICENSEE and one or more of its AFFILIATES, (ii) a sale of assets, merger, or other transaction effected exclusively for the purpose of changing domicile of LICENSEE, or (iii) any public offering of a LICENSEE'S or its AFFILIATES' equity securities or other issuance of stock by a LICENSEE or an AFFILIATE in an equity financing (whether or not such offering or issuance results in the circumstances described in clause (b)).

1.3 "COMMERCIALLY REASONABLE EFFORTS" means, with respect to an obligation regarding development of a LICENSED PRODUCT, such efforts that are consistent with those typically used by a biotechnology or pharmaceutical company of comparable size and with comparable resources in the performance of such an obligation for a similar pharmaceutical or biological product (including the research, development, manufacture, and commercialization of a pharmaceutical or biological product), as applicable, at a similar stage in its research, development, or commercial life as such LICENSED PRODUCT, and that has commercial and market potential similar to such LICENSED PRODUCT, taking into account issues of intellectual property coverage, safety and efficacy, stage of development, costs, product profile, competitiveness of the marketplace, proprietary position, regulatory exclusivity, anticipated or approved labeling, corporate resources, present and future market and commercial potential, the likelihood of receipt of REGULATORY APPROVAL, profitability (including pricing and reimbursement status achieved or likely to be achieved), the existence and developmental stages of alternative products and programs, and legal issues.

1.4 "COMBINATION PRODUCT" means a LICENSED PRODUCT that is sold, packaged, blended, or otherwise combined with one (1) or more other products or technologies (other than LICENSED PRODUCTS) that (i) have significant independent utility, or are (or can serve as the basis of) a tangible, separately saleable pharmaceutical product or medical component, and (ii) are not covered by a VALID CLAIM of the PATENT RIGHTS (such other products or technologies, but excluding any intangible rights or assets, including trademarks, trade names, logos, marketing rights, regulatory exclusivity, software, services, or any other intangible rights or assets, the "OTHER PRODUCTS").

1.5 "COVER" or "COVERED BY" means (a) with respect to a product, method, or service, that the manufacture/making, use, sale, offer to sell, or import of such product, method or service would, absent the licenses to be granted in accordance with this Agreement, infringe, or induce or contribute to infringement of, a VALID CLAIM, and/or (b) with respect to a product, method, or service and KNOW HOW, that such product, method, or service uses, incorporates, or is discovered, developed, or produced through the use of any KNOW-HOW.

1.6 "DUKE," as used in Articles 9 and 10, shall include its trustees, officers, employees, students, and agents.

1.7 "DUKE IND" means: (a) the Investigational New Drug application having the IND number [***], and the contents thereof; and (b) all amendments, supplements, reports, submissions, correspondence, or the like with respect thereto.

1.8 "FIELD OF USE" means all uses and applications, including, without limitation, the prevention, treatment, diagnosis, detection, monitoring or predisposition testing of all diseases, states or conditions in humans or animals.

1.9 "FIRST COMMERCIAL SALE" means the first SALE through a bona fide arm's length transaction, or commercial use, of any LICENSED PRODUCT by a SELLING PARTY, excluding the SALE of a LICENSED PRODUCT for use in research, development, trials, evaluation purposes, as a sample, for resale by a SELLING PARTY, or that is of temporary availability.

1.10 "IMPROVEMENT" means any invention, patentable or otherwise, conceived under the direction of Professor Dwight D. Koeberl where the invention is (a) not encumbered by any third party rights, (b) has been disclosed to DUKE's Office for Translation & Commercialization within two (2) years of the EFFECTIVE DATE, and (c) for patentable IMPROVEMENTS, would necessarily infringe at least one issued VALID CLAIM in the FIELD OF USE.

1.11 "KNOW-HOW" means as of the EFFECTIVE DATE: (a) the DUKE IND; and (b) any know-how, technical information, tangible materials, processes, procedures, compositions, devices, methods, formulae, protocols, techniques, designs, drawings and/or data, expressly identified in Exhibit B.

1.12 "LICENSED PRODUCT(S)" means any product, method or service that is COVERED BY a VALID CLAIM or by KNOW-HOW.

1.13 "MAJOR MARKET COUNTRY" means any of Japan, Taiwan, the United Kingdom, Germany, France or the European Union as a whole.

1.14 "NET SALES" means, with respect to a LICENSED PRODUCT sold in a county during the applicable ROYALTY TERM therefor, the total amount billed or invoiced on SALES of such LICENSED PRODUCT by a SELLING PARTY in the TERRITORY to third parties (including third party wholesalers and third party distributors), in bona fide arm's length transactions, less the following deductions, and in each case related specifically (or reasonably allocated by such SELLING PARTY in accordance with its standard policies and procedures consistently applied across its products) to the LICENSED PRODUCT:

(a) trade, cash, quantity, and other discounts, charge-back payments, and rebates, including but not limited to those actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, and national, state, or local governments;

(b) credits, chargebacks, rebates, or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections, or returns of such LICENSED PRODUCT, including in connection with recalls and retroactive price reductions;

(c) taxes (excluding income or franchise taxes of any kind), duties, tariffs, mandated contribution, or other governmental charges levied on the sale of such LICENSED PRODUCT, including VAT (net of reimbursement of any value added taxes actually received), excise taxes and sales taxes;

(d) any invoiced amounts from a prior period which are not collected and are written off by the SELLING PARTY, including bad debts (provided that if the debt is thereafter paid, the corresponding amount shall be added to the NET SALES for the period during which it is paid);

(e) packaging, freight, postage, shipping, transportation, warehousing, handling, export/import and insurance charges, in each case, actually allowed or paid for delivery of such LICENSED PRODUCT, and any customary payments with respect to such LICENSED PRODUCT actually made to wholesalers or other distributors, in each case, actually allowed or paid for distribution, delivery, or inventory management of such LICENSED PRODUCT;

(f) any sales, credits, or allowances given or made with respect to such LICENSED PRODUCT for wastage replacement;

(g) any other similar and customary deductions that are consistent with GAAP or IFRS as consistently applied by SELLING PARTY to all of its products, but which may not be duplicative of the above deductions;

(h) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans relating to such LICENSED PRODUCT;

(i) that portion of the sales value associated with drug delivery systems; and

(j) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) to the extent reasonably allocable to sales of such LICENSED PRODUCT in a manner consistent with that the applicable SELLING PARTY uses to calculate net sales for its other products in accordance with GAAP or IFRS.

Where a SELLING PARTY receives any consideration other than cash for such transactions otherwise qualifying as NET SALES, fair market cash value for such consideration, as reasonably determined in good faith by such SELLING PARTY, shall be included in NET SALES. Notwithstanding anything to the contrary, NET SALES shall not include, and shall be deemed zero with respect to, (i) the distribution of reasonable quantities of promotional samples of LICENSED PRODUCTS, (ii) LICENSED PRODUCTS provided for research, development, or evaluation purposes at a price that is at or below LICENSEE's or the applicable SUBLICENSEE's reasonable, documented direct cost to manufacture, procure, or provide such LICENSED PRODUCTS, calculated in a reasonable, good faith manner consistent with such party's standard accounting practices for its other products and services, or (iii) LICENSED PRODUCTS provided by or on behalf of a SELLING PARTY for purposes of resale, provided such resale is subject to royalties on which payments are due under Paragraph 3.1(b).

If a COMBINATION PRODUCT is sold in a country during the applicable ROYALTY TERM, NET SALES thereof in such country for the purposes of calculating royalties due on such COMBINATION PRODUCT shall be calculated by multiplying the actual NET SALES of such COMBINATION PRODUCT in such country by the result of the formula "*A / (A + B)*", where "*A*" is the weighted average selling price of the LICENSED PRODUCT included within such COMBINATION PRODUCT when sold separately (*i.e.*, not as a COMBINATION PRODUCT) during the ROYALTY PERIOD in question in such country, and "*B*" is the weighted average selling price of the OTHER PRODUCT(S) in the COMBINATION PRODUCT when sold separately (*i.e.*, not in combination with any other products) during the ROYALTY PERIOD in question in such country.

If the weighted average selling price of the LICENSED PRODUCT in a country can be determined, but the weighted average selling price of the Other Product(s) in such country cannot be determined, then NET SALES in such country, for purposes of determining royalty payments due on such COMBINATION PRODUCT, shall be calculated by multiplying the NET SALES of the COMBINATION PRODUCT in such country by the fraction "*A / C*", where "*A*" is the weighted average selling price of the LICENSED PRODUCT when sold separately in finished form in such country and "*C*" is the weighted average selling price of the COMBINATION PRODUCT in such country.

If the weighted average selling price of the Other Product(s) in a country can be determined but the weighted average selling price of the LICENSED PRODUCT cannot be determined in such country, then NET SALES in such country, for purposes of determining royalty payments due on such COMBINATION PRODUCT, shall be calculated by multiplying the NET SALES of the COMBINATION LICENSED PRODUCT in such country by the result of the formula "*1 – (B / C)*", where "*B*" is the weighted average selling price of the OTHER PRODUCT(S) when sold separately in finished form in such country and "*C*" is the weighted average selling price of the COMBINATION PRODUCT in such country.

If neither the LICENSED PRODUCT nor the Other Product(s) are sold separately in such country during the relevant period, then NET SALES allocable to such COMBINATION PRODUCT in such country during such ROYALTY PERIOD for royalty calculation purposes will be reasonably determined in good faith by mutual agreement between the parties, such agreement not to be unreasonably withheld, based on an equitable method that takes into account the relative values of the LICENSED PRODUCT and Other Product portions of such COMBINATION PRODUCT.

1.15 "NDA" means: (a) a New Drug Application (within the meaning of 21 C.F.R. 314.50); or (b) any corresponding foreign application for approval for the commercial marketing and sale of a product for human therapeutic or prophylactic use in the applicable country or jurisdiction.

1.16 "PATENT RIGHTS" means DUKE'S rights under the following:

(a) the United States and foreign patent(s) and/or patent application(s) as provided in Exhibit A;

(b) any non-provisional patent applications that claim priority to any provisional patent applications listed in Exhibit A;

(c) any divisionals and continuations of patents or patent applications included in (a) or (b) above (but not continuations-in-part, except as provided in (d) below);

(d) any claims of continuation-in-part applications that claim priority to the patent applications listed in Exhibit A, but only to the extent such claims are directed specifically to subject matter described in at least one of the patents or patent applications identified in Exhibit A that meet the written description requirements of the first paragraph of 35 U.S.C. Section 112;

(e) any foreign patent applications, foreign patents or related foreign patent documents that claim priority to a patent or patent application included in (a), (b), (c), or (d) above; and

(f) any patents, reissues, re-examinations, renewals, substitutions, and extensions issuing from any of the preceding items referenced in (a), (b), (c), (d), or (e) above.

1.17 "PHASE III TRIAL" a human clinical trial of a LICENSED PRODUCT, which trial is designed to: (a) establish that a LICENSED PRODUCT is safe and efficacious for its intended use; (b) define warnings, precautions, and adverse reactions that are associated with the LICENSED PRODUCT in the dosage range to be prescribed; (c) support an application for REGULATORY APPROVAL of such LICENSED PRODUCT for human therapeutic use; and (d) generally consistent with 21 CFR 312.21(c).

1.18 "PIVOTAL TRIAL" means: (a) a PHASE III TRIAL; or (b) any other human clinical trial of a LICENSED PRODUCT that is intended, as evidenced by public statements or public disclosures made by or on behalf of LICENSEE, its AFFILIATES, or a SUBLICENSEE, or the contents of any clinical trial protocol or regulatory filing, to support the submission and acceptance of an application for REGULATORY APPROVAL, and receipt of REGULATORY APPROVAL, without conduct of any subsequent human clinical trial.

1.19 "PRV" means a "Priority Review Voucher" as defined in 21 U.S.C. §360ff, as the same may be amended from time-to-time, that may be issued to LICENSEE in connection with LICENSEE's receipt of REGULATORY APPROVAL in the US.

1.20 "REGULATORY APPROVAL" means any and all approvals, licenses, registrations, or authorizations of the relevant regulatory authority, necessary for the development, manufacture, use, storage, import, transport and commercialization of a given LICENSED PRODUCT in a particular country or jurisdiction. For the avoidance of doubt, REGULATORY APPROVAL outside of the United States shall include any pricing or marketing approval needed prior to the sale of a LICENSED PRODUCT in the FIELD OF USE.

1.21 "ROYALTY PERIOD(S)" means the six-month periods ending on the last days of June and December each year.

1.22 "ROYALTY TERM" means, on a LICENSED PRODUCT-by-LICENSED PRODUCT and country-by-country basis, the period beginning on the date of FIRST COMMERCIAL SALE of such LICENSED PRODUCT in such country and ending on the later to occur of: (a) the date on which such LICENSED PRODUCT is no longer COVERED by a VALID CLAIM in the country in which the sale of such LICENSED PRODUCT occurs, or (b) eight (8) years from the FIRST COMMERCIAL SALE of such LICENSED PRODUCT in such country.

1.23 "SALE" means sale, rental, or lease, however characterized, and SOLD means the past tense of SALE.

1.24 "SELLING PARTY" means either LICENSEE or SUBLICENSEE, as the case may be.

1.25 "SUBLICENSE AGREEMENT" means any agreement pursuant to which any rights licensed to LICENSEE under Paragraph 2.1 of this Agreement are sublicensed to the applicable SUBLICENSEE.

1.26 "SUBLICENSEE(S)" means any person or entity in writing sublicensed, or granted a written sublicense to any rights licensed to LICENSEE under Paragraph 2.1 of this Agreement.

1.27 "SUBLICENSING INCOME" means the sum of any cash payments plus the fair market value of all equity consideration (as reasonably determined in good faith by LICENSEE) received by LICENSEE from a SUBLICENSEE in consideration of the grant of a sublicense under the PATENT RIGHTS or KNOW-HOW (net of any tax or similar withholding obligations imposed by any tax or other government authority(ies) that are not reasonably recoverable by LICENSEE), including any license fee, license maintenance fee, option fee, milestone payments, and annual fees in excess of earned royalties, but excluding: (a) royalties paid by or on behalf of a SUBLICENSEE, (b) amounts received for equity or debt investments in, or loan proceeds to, LICENSEE provided that any such amounts paid in excess of fair market value thereof (as reasonably determined in good faith by LICENSEE) shall be deemed SUBLICENSING INCOME, (c) payments by SUBLICENSEES for payment or reimbursement of patent prosecution, defense, enforcement and maintenance and other related expenses, (d) payments by SUBLICENSEES for bona fide research, development, manufacturing or commercialization activities (including, without limitation, payments for FTEs), (e) any profit share for any product, and (f) payment received in a transaction that constitutes a CHANGE OF CONTROL of LICENSEE.

1.28 "TERRITORY" means worldwide.

1.29 "VALID CLAIM" means, with respect to a particular country, (a) any claim of an issued and unexpired PATENT RIGHT in such country that (i) has not been held revoked, unenforceable, canceled or invalid by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country, or (b) a claim of a pending PATENT RIGHT application that has not been finally abandoned or finally rejected or expired and which has been pending seven (7) years from the date of filing of the earliest priority PATENT RIGHT application to which such pending PATENT RIGHT application is entitled to claim benefit. Any claim in a pending patent application that is filed after seven (7) years from its earliest priority date will not be considered a VALID CLAIM until such claim is granted and meets the requirement of clause (a) of this definition.

ARTICLE 2 – GRANT OF LICENSE

2.1 DUKE hereby grants to LICENSEE an exclusive license under the PATENT RIGHTS and a non-exclusive license to KNOW-HOW, in each case with the right to grant sublicenses through multiple tiers, subject to the terms and conditions of this Agreement, in the FIELD OF USE and the TERRITORY to research, develop, have developed, make, have made, import, have imported, export, have exported, use, have used, market, offer for sale, sell, and otherwise exploit LICENSED PRODUCTS.

2.2 DUKE shall disclose to LICENSEE all IMPROVEMENTS in writing, promptly after DUKE becomes aware of the creation of any such IMPROVEMENT. LICENSEE shall have an option for a period of three (3) months from disclosure of an IMPROVEMENT to request that: (a) patentable IMPROVEMENTS be added to the list of PATENT RIGHTS and/or (b) non-patentable IMPROVEMENTS be added as KNOW-HOW to Exhibit B of the Agreement, in both cases by mutual agreement of the parties and on the same terms of the Agreement.

2.3 DUKE retains the right to practice or license any invention, product, or method covered by the PATENT RIGHTS for its own educational, non-commercial research and clinical purposes without restriction and without payment of royalties or other fees, including without limitation the right to provide licenses to the PATENT RIGHTS to governmental laboratories and to other non-profit or not-for-profit institutions for such purposes. For the purposes of this Agreement, "non-commercial research" means the

use of PATENT RIGHTS for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use PATENT RIGHTS in the production or manufacture of a LICENSED PRODUCT.

2.4 This Agreement will begin on the EFFECTIVE DATE and will expire upon the expiration of the last to expire ROYALTY TERM, unless sooner terminated as provided in another specific provision of this Agreement. Following expiration of the applicable ROYALTY TERM for any LICENSED PRODUCT in a given country, no further royalties would be payable in respect of sales of such LICENSED PRODUCT in such country, the SALES of such LICENSED PRODUCT will no longer be counted for purposes of establishing royalty tiers, and thereafter the licenses granted to LICENSEE with respect to such LICENSED PRODUCT in such country will automatically become fully paid-up, perpetual, irrevocable, freely transferable, and royalty-free.

2.5 The licenses granted in this Agreement are subject to any rights required to be granted under applicable law, or required to be retained by the U.S. government, for example in accordance with Chapter 18 of Title 35 of U.S.C. 200-212 and the regulations thereunder (37 CFR Part 401), when applicable. To the extent applicable, LICENSEE agrees to comply in all respects, including LICENSED PRODUCTS used, leased or sold in the United States shall be manufactured substantially in the United States; and shall provide DUKE with all reasonably requested information and cooperation for DUKE to comply with applicable provisions of the same and any requirements of any agreements between DUKE and any agency of the U.S. government that provided funding for the subject matter covered by the PATENT RIGHTS. LICENSEE agrees to mark the LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers as necessary to meet the requirements of 35 U.S.C. 287 so that the full benefits of patent enforcement may be realized. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked to comply with the patent laws and practices of the countries of manufacture, use and SALE.

2.6 DUKE hereby grants to LICENSEE an exclusive right to reference the DUKE IND for the research, development, manufacture, and commercialization of LICENSED PRODUCTS in the FIELD OF USE and the TERRITORY, which right shall be sublicensable through multiple tiers. Upon LICENSEE's request, DUKE shall provide LICENSEE with a copy of the DUKE IND.

2.7 Promptly after the EFFECTIVE DATE, DUKE shall assign to LICENSEE, and hereby does assign to LICENSEE, all of DUKE's right, title, and interest in and to any orphan drug designation with the Orphan Drug Designation number 16-5463, obtained prior to the EFFECTIVE DATE from the FDA pursuant to 21 C.F.R. Part 316 for any LICENSED PRODUCT, including any amendments or supplements thereto and any related applications, submissions, notifications, registrations, or other filings or correspondence to or from the FDA. DUKE shall reasonably cooperate with LICENSEE in the filing of any reasonably appropriate transfer letters with the FDA with respect thereto.

ARTICLE 3 - CONSIDERATION

3.1 During the ROYALTY TERM, LICENSEE shall pay the following to DUKE:

(a) A License Issue Fee equal to Ten Thousand U.S. Dollars ($10,000), due within thirty (30) days after the EFFECTIVE DATE.

(b) Royalties, on a LICENSED PRODUCT-by-LICENSED PRODUCT basis, equal to:

(1) [***] of the first [***] of NET SALES in a particular calendar year; and

(2) [***] of NET SALES exceeding [***] in a particular calendar year;

provided, *however*, that the above royalty rates will be reduced by 50% with respect to any royalties payable on NET SALES of any LICENSED PRODUCT in any country in which such LICENSED PRODUCT is not COVERED by a VALID CLAIM.

Notwithstanding anything to the contrary, if LICENSEE or a SUBLICENSEE pays consideration to any third party for the grant of rights to any patent rights or other intellectual property rights that, in the reasonable judgment of LICENSEE or a SUBLICENSEE, would be infringed by or are otherwise necessary or useful for the manufacture, importation, use, offer for SALE, or SALE of a LICENSED PRODUCT, then LICENSEE shall be entitled to deduct fifty percent (50%) of such consideration paid to such third party from the amounts payable to DUKE under this Paragraph 3.1(b) or Paragraph 3.1(e). However, in no event shall the amount payable to DUKE under such Paragraphs for any ROYALTY PERIOD be reduced to less than fifty percent (50%) of such amounts that would, absent the effects of this paragraph, otherwise be due thereunder, provided that LICENSEE shall have the right to carry forward (and apply against such payments due for any future ROYALTY PERIOD) any amounts that it was not able to credit on account of the royalty floor set forth in this paragraph, subject to such floor in each ROYALTY PERIOD. In the event that LICENSEE or a SUBLICENSEE exercises its rights under this Paragraph, the Parties shall, on DUKE's request, meet in good faith to discuss any reductions or offsets applicable to third party licenses to ensure that the offset in this Paragraph does not disproportionally impact DUKE in relation to such other licensors.

(c) A percentage of all SUBLICENSING INCOME, determined as follows:

(1) [***] of all SUBLICENSING INCOME received prior to the earlier to occur of (A) dosing of the 3rd subject in the first PIVOTAL TRIAL sponsored by or on behalf of LICENSEE, or (B) submission by LICENSEE of an NDA for a LICENSED PRODUCT (such earlier time, the "SUBLICENSING INCOME REDUCTION DATE"); and

(2) [***] of all SUBLICENSING INCOME received following the SUBLICENSING INCOME REDUCTION DATE.

(d) In addition to payment of ongoing patent expenses pursuant to Article 7 hereof, LICENSEE shall reimburse DUKE for patent expenses incurred by DUKE for filing and prosecution of PATENT RIGHTS prior to the EFFECTIVE DATE, such payment due within thirty (30) days of receipt of invoice from DUKE, which amount totals, as of the EFFECTIVE DATE, estimated at [***] ("PAST PATENT EXPENSES").

(e) Minimum Annual Royalties. Minimum annual royalties are due with respect to each calendar year set forth below on January 31 of the following calendar year ("MINIMUM ANNUAL ROYALTIES"). MINIMUM ANNUAL ROYALTIES shall only be payable with respect to a particular calendar year to the extent the aggregate amounts payable to DUKE under Paragraphs 3.1(b), 3.1(c), and 3.1(f) with respect to NET SALES made, SUBLICENSING INCOME received, and MILESTONE PAYMENTS due for MILESTONES achieved during such calendar year do not equal or exceed such calendar year's MINIMUM ANNUAL ROYALTIES. The MINIMUM ANNUAL ROYALTIES are:

(1) for calendar year 2028 and each calendar year thereafter through the calendar year in which the first REGULATORY APPROVAL of a LICENSED PRODUCT is granted to LICENSEE in the US: [***]; and

(2) for each year following the calendar year in which the first REGULATORY APPROVAL of a LICENSED PRODUCT is granted to LICENSEE in the US: [***].

(f) Each of the following payments (each a "MILESTONE PAYMENT") shall be due upon achieving the indicated milestone ("MILESTONE") for each LICENSED PRODUCT(S). LICENSEE shall make each such MILESTONE PAYMENT irrespective of whether the associated MILESTONE was reached by

LICENSEE itself, by a SUBLICENSEE and/or a third party acting on behalf of LICENSEE or a SUBLICENSEE. MILESTONE PAYMENTS are due within sixty (60) days of LICENSEE achieving the associated MILESTONE and are non-refundable and non-creditable. For purposes of this Agreement, a particular LICENSED PRODUCT shall only be considered different from another LICENSED PRODUCT if such LICENSED PRODUCTS contain different active pharmaceutical ingredients (or combinations thereof). Each MILESTONE PAYMENT is due only once per LICENSED PRODUCT, regardless of how many times the corresponding MILESTONE may be achieved, and regardless of the number of dosages, formulations, or indications thereof.

(1) Dosing of the 3rd subject in the first PIVOTAL TRIAL sponsored by or on behalf of LICENSEE, its AFFILIATE, or a SUBLICENSEE: [***]

(2) Upon the first submission by LICENSEE, its AFFILIATE or SUBLICENSEE of an NDA for a LICENSED PRODUCT in the US: [***]

(3) Upon REGULATORY APPROVAL of the first LICENSED PRODUCT in the US: [***]

(4) Upon REGULATORY APPROVAL of the first LICENSED PRODUCT being granted to LICENSEE, its AFFILIATE, or a SUBLICENSEE in a MAJOR MARKET COUNTRY: [***]

(5) Following conclusion of the first calendar year in which aggregate annual NET SALES meet or exceed [***]: [***]

(6) Following conclusion of the first calendar year in which aggregate annual NET SALES meet or exceed [***]: [***]

3.2 LICENSEE is not obligated to pay multiple royalties if any LICENSED PRODUCT is COVERED BY more than one VALID CLAIM or the same LICENSED PRODUCT is COVERED BY VALID CLAIMS in two or more countries.

3.3 All payments due to DUKE under this Agreement shall be made payable to "Duke University." Payments drawn directly on a U.S. bank may be made by either check to the address in Article 12 or by wire transfer. Any payment drawn on a foreign bank or foreign branch of a U.S. bank shall be made only by wire transfer. Wire transfers shall be made in accordance with the following or any other instructions as may be specified by DUKE. If payments are made by wire, the wiring instructions below must be followed.

Account name: [***]Account number: [***]Account type: [***]
ACH/Wire routing number: [***]
SWIFT/BIC code: [***]
Bank name and address: [***]Attention: [***]Email: [***]
All payments due to DUKE under this Agreement must be paid in United States Dollars in Durham, North Carolina, or at such place as DUKE may reasonably designate consistent with the laws and regulations controlling in any foreign country. If any currency conversion is required in connection with such payments due, such conversion must be made by using the exchange rate prevailing at Wells Fargo Bank (N.A.) (or its successor, as the case may be) on the last business day of the reporting period to which such payments relate.

3.4 Royalty payments made pursuant to Paragraph 3.1(b) shall be made on a semi-annual basis with submission of the reports required by Article 4 (*i.e.*, within 60 days after the end of the applicable ROYALTY PERIOD). All amounts due under this Agreement, including amounts due for the payment of patent expenses, shall, if overdue, be subject to a charge of interest compounded monthly until payment, at a per annum rate of two percent (2%) above the prime rate in effect at the JP Morgan Chase Bank, N.A. or its successor bank on the due date (or at the highest allowed rate if a lower rate is required by law) or $500, whichever is greater. The payment of such interest shall not foreclose DUKE from exercising any other rights it may have resulting from any late payment. LICENSEE shall reimburse DUKE for its reasonable and documented out-of-pocket expenses, including reasonable external attorney fees, incurred to collect any undisputed amounts overdue more than 120 days.

3.5 All payments and fees, including all milestone fees, made under this Agreement are and shall be non-refundable and, except as explicitly set forth herein, non-creditable. DUKE shall have no obligation whatsoever to pay, return, credit, or refund any amounts paid hereunder, except as may be specifically provided herein. By way of example only, notwithstanding the deductions permitted to NET SALES, DUKE shall have no obligation to pay any amounts to LICENSEE even if such deductions should result in a negative amount for NET SALES in any given ROYALTY PERIOD.

3.6 Should LICENSEE be required under any law or regulation of any government entity or authority to withhold or deduct any portion of the payments on royalties due to DUKE, then the sum payable to DUKE (if any) shall be increased by the amount necessary to yield to DUKE an amount equal to the sum it would have received had no withholdings or deductions been required. DUKE shall cooperate reasonably with LICENSEE or any SUBLICENSEE in the event LICENSEE or any SUBLICENSEE elects to seek or assert, at its own expense, any exemption from, refund of, or credit with respect to any such tax or deduction. Additionally, if DUKE is issued or awarded any credit or refund, the amount of any such credit or refund shall be applied against future amounts payable to DUKE under this Agreement.

3.7 If LICENSEE sells a PRV to a third party in a bona fide sale transaction, then LICENSEE will pay to DUKE a payment based on the fair market value of the gross consideration (in any form) received by LICENSEE from such third party for such sale, less reasonable, out-of-pocket, transaction-related costs and expenses incurred by LICENSEE in connection with such sale ("PRV NET PROCEEDS"), which payment shall be in an amount equal to: (i) [***] of such PRV NET PROCEEDS, if such PRV NET PROCEEDS are less than or equal to [***]; (ii) [***], if such PRV NET PROCEEDS are greater than [***], but less than or equal to [***]; or (iii) [***] of such PRV NET PROCEEDS, if such PRV NET PROCEEDS are greater than [***].

ARTICLE 4 - REPORTS

4.1 Until the FIRST COMMERCIAL SALE, by July 31 of each year LICENSEE shall provide to DUKE a written annual report that includes reports on progress since the prior annual report and general future plans regarding, with respect to LICENSED PRODUCTS: research and development, REGULATORY APPROVALS, manufacturing, sublicensing, marketing and SALES, including each MILESTONE under Article 3 or DILIGENCE MILESTONE Article 5 having a deadline during the ROYALTY PERIOD, and a specific identification of whether or not it was achieved.

Within sixty (60) days after a FIRST COMMERCIAL SALE, LICENSEE shall specifically report to DUKE the approximate date of such SALE, a brief description of the LICENSED PRODUCT subject of the SALE, full name under which such LICENSED PRODUCT was sold, and country or U.S. state of manufacturing.

4.2 After the FIRST COMMERCIAL SALE, LICENSEE shall provide semi-annual reports to DUKE for each ROYALTY PERIOD. Specifically, within 60 days after each ROYALTY PERIOD closes, including the close of the ROYALTY PERIOD immediately following any termination of this Agreement, LICENSEE shall report to DUKE for the applicable ROYALTY PERIOD:

(a) number of LICENSED PRODUCTS sold, leased, or distributed, however characterized, by LICENSEE and each SUBLICENSEE;

(b) NET SALES, excluding the deductions provided therefor, of LICENSED PRODUCTS SOLD by LICENSEE and all SUBLICENSEES;

(c) deductions applicable as provided in the definition for NET SALES;

(d) SUBLICENSING INCOME due on payments from SUBLICENSEES under Paragraph 3.1 above, including supporting figures;

(e) foreign currency conversion rate and calculations (if applicable) and total royalties due;

(f) each MILESTONE achieved under Article 3, or each DILIGENCE MILESTONE under Article 5, having a deadline during the ROYALTY PERIOD, and a specific identification of whether or not it was achieved;

(g) for each SUBLICENSE AGREEMENT or amendment thereto completed in the particular ROYALTY PERIOD (including agreements under which LICENSEE will have LICENSED PRODUCTS made by a third party): names, addresses, and U.S.P.T.O. Entity Status (as discussed in Paragraph 6) of such SUBLICENSEE; the date of each agreement and amendment; the territory of the sublicense; the scope of the sublicense; and the nature, timing and amounts of all fees and royalties to be paid thereunder;

(h) summary of progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and SALES, and general plans for the future with respect to LICENSED PRODUCTS;

(i) the approximate date of FIRST COMMERCIAL SALE in each country, to the extent reasonably ascertainable, by LICENSEE and all SUBLICENSEES and AFFILIATES of LICENSEE; and

(j) the country or U.S. state of manufacturing of LICENSED PRODUCTS by LICENSEE and all SUBLICENSEES.

LICENSEE shall include the amount of all payments due, and the various calculations used to arrive at those amounts, including the quantity, description, country of manufacture and country of SALE of LICENSED PRODUCTS.

If no payment is due, LICENSEE shall so report to DUKE that no payment is due. Failure to provide reports as required under this Article 4 shall be a material breach of this Agreement. LICENSEE agrees to reasonably cooperate with DUKE regarding any questions it may have relating to compliance with this Agreement, for example to discuss the information in reports.

4.3 LICENSEE shall keep, and shall require SUBLICENSEES to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. LICENSEE shall: (a) open its records for inspection upon reasonable notice during business hours, and no more than once per year, by an independent certified accountant selected by DUKE and reasonably acceptable to LICENSEE, for the purpose of verifying the amount of payments due, and shall provide information to DUKE's accountant to facilitate such inspection; and (b) retain such records for three (3) years from date of origination. LICENSEE shall, upon DUKE's reasonable written request, at DUKE's expense, and subject to the applicable audit provisions of any such SUBLICENSE, exercise its audit rights with respect to royalties payable on LICENSED PRODUCTS under sublicenses granted by LICENSEE and report the results thereof to DUKE.

The terms of this Article shall survive any termination of this Agreement. DUKE is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than five percent of royalties due DUKE, then LICENSEE shall pay all reasonable, documented, out-of-pocket expenses of that inspection and the amount of the underpayment and interest to DUKE within twenty-one days of written notice thereof. LICENSEE shall also reimburse DUKE for its reasonable, documented, out-of-pocket expenses required to collect the amount underpaid if LICENSEE fails to pay the underpaid amount within such twenty-one (21)-day period. Any overpayment revealed by any such inspection shall be credited against future amounts due hereunder or promptly refunded to LICENSEE, as elected by LICENSEE.

ARTICLE 5 - DILIGENCE

5.1 LICENSEE shall use COMMERCIALLY REASONABLE EFFORTS to bring at least one (1) LICENSED PRODUCT to market within the TERRITORY.

5.2 Without limiting Paragraph 5.1, LICENSEE agrees to reach the following commercialization and research and development milestones for the LICENSED PRODUCTS (together the "DILIGENCE MILESTONES") by the dates set forth below (the "ACHIEVEMENT DATE"):

(a) Enrollment of 1st subject in a PIVOTAL TRIAL sponsored by LICENSEE, its AFFILIATE, or a SUBLICENSEE, within three (3) years after the EFFECTIVE DATE

(b) First submission by LICENSEE, its AFFILIATE, or a SUBLICENSEE of an NDA for a LICENSED PRODUCT, within three (3) years after receipt by LICENSEE of the final clinical study report pertaining to the first PIVOTAL TRIAL

5.3 LICENSEE must achieve each DILIGENCE MILESTONE on or before the ACHIEVEMENT DATE and DUKE shall have the sole discretion to determine the validity of a DILIGENCE MILESTONE being reached. LICENSEE shall notify DUKE within thirty days after each ACHIEVEMENT DATE as to whether or not such DILIGENCE MILESTONE was met. If LICENSEE fails to meet any DILIGENCE MILESTONE under this Article by the ACHIEVEMENT DATE, LICENSEE will be deemed to be in material breach of this Agreement, and DUKE may terminate the Agreement effective on thirty days' notice, unless LICENSEE achieves the DILIGENCE MILESTONE within this thirty-day period. If LICENSEE in unable to meet a DILIGENCE MILESTONE (for any reason), then LICENSEE may, in its sole discretion, elect to extend each DILIGENCE MILESTONE by one (1) year by making a per-extension payment of [***] to DUKE. LICENSEE may effect up to two (2) such extensions.

ARTICLE 6 - SUBLICENSING

6.1 LICENSEE shall notify DUKE in writing of every SUBLICENSE AGREEMENT and each amendment thereto within thirty days after their execution, and indicate the name of the SUBLICENSEE, the territory of the SUBLICENSE AGREEMENT, the scope of the SUBLICENSE AGREEMENT, and the nature, timing and amounts of all fees and royalties to be paid thereunder, and whether or not the SUBLICENSEE has greater or fewer than 500 employees. Upon written request by DUKE, LICENSEE shall provide DUKE with a copy of SUBLICENSE AGREEMENTS, which may be reasonably redacted to remove any confidential financial terms or proprietary scientific information to the extent such redactions do not prevent DUKE from ensuring such SUBLICENSE AGREEMENT complies with the requirements set forth in this Article 6.

6.2 LICENSEE shall not receive from SUBLICENSEES anything of value other than cash payments in consideration for any SUBLICENSE AGREEMENT under this Agreement, without the express prior written permission of DUKE.

6.3 LICENSEE shall require that all SUBLICENSE AGREEMENTS: (a) be consistent with the terms and conditions of this Agreement; (b) contain the SUBLICENSEE'S acknowledgment of the disclaimer of warranty and limitation on DUKE's liability, as provided by Article 9 below; and (c) contain provisions under which the SUBLICENSEE accepts duties at least equivalent to those accepted by the LICENSEE in the following Paragraphs: 4.4 (duty to keep records), 10.1 (duty to defend, hold harmless, and indemnify DUKE), 10.3 (duty to maintain insurance), 2.5 (duty to properly mark LICENSED PRODUCTS with patent notices), and 15.5 (duty to restrict the use of DUKE's name).

6.4 If the Agreement terminates for any reason, any sublicenses granted hereunder shall, to the extent provided in the applicable SUBLICENSE AGREEMENT, remain in effect as a direct license from, and be automatically assigned to, DUKE, provided that such SUBLICENSE AGREEMENT requires the SUBLICENSEE to thereafter pay

DUKE any consideration that would have been due to LICENSEE with respect to, and to the extent corresponding to, the exercise of the rights hereunder that are granted in such SUBLICENSE AGREEMENT; provided that (a) upon DUKE's written request, DUKE and SUBLICENSEE will discuss in good faith any appropriate modifications to the terms and conditions of such SUBLICENSE AGREEMENT and (b) DUKE shall not be obligated to be assigned a SUBLICENSE AGREEMENT to the extent having a scope of PATENT RIGHTS, FIELD OF USE, TERRITORY, or other obligation on the part of DUKE that would exceed those in this Agreement.

DUKE's obligation above will apply only if: (a) DUKE is permitted to be assigned such SUBLICENSE AGREEMENT under applicable law; (b) SUBLICENSEE provides written notice to both DUKE and LICENSEE within 90 days after such termination of its desire for such assignment; (c) SUBLICENSEE is not an AFFILIATE of LICENSEE; (d) SUBLICENSEE is not in material breach of the SUBLICENSE AGREEMENT; and (e) LICENSEE or its AFFILIATE remains responsible for all other obligations under the agreement granting such sublicense to the extent applicable to LICENSEE or its AFFILIATE and in excess of DUKE's obligations under this Agreement.

ARTICLE 7 - PATENT APPLICATIONS AND MAINTENANCE

7.1 Subject to the terms of this Agreement, LICENSEE shall have the first right (but not obligation) and responsibility, at its sole expense, to control the preparation, filing, prosecution (including any interferences, reissue proceedings, reexaminations, post-grant proceedings, or oppositions), and maintenance of the PATENT RIGHTS, provided that it obtains DUKE's written approval of the legal counsel that LICENSEE shall retain for such purposes, such approval not to be unreasonably withheld or delayed.

LICENSEE will provide, or direct outside patent counsel to provide, DUKE with copies of all applications in the PATENT RIGHTS and all patents that issue from the PATENT RIGHTS, including copies of all office actions, responses and all other material communications from the U.S. Patent and Trademark Office and the patent offices in any other jurisdictions.

LICENSEE shall keep DUKE reasonably informed of the status of all such activities and shall provide any proposed responses to substantive office actions or other communications to the U.S. Patent and Trademark Office or any foreign patent office in a timely manner to allow DUKE a reasonable opportunity to review and comment. The Parties agree to meet, as needed, to discuss prosecution strategy and make good faith efforts to align interests. DUKE shall have the right, but not the obligation, and at its sole expense, to provide input on such matters relating to prosecution and maintenance, and LICENSEE shall consider DUKE's comments in good faith.

7.2 LICENSEE shall, on an ongoing basis: (i) prosecute or maintain the PATENT RIGHTS with reasonable diligence; and (ii) keep DUKE reasonably informed regarding the filing, prosecution, maintenance, and defense of the PATENT RIGHTS by LICENSEE, and shall allow DUKE to review, comment, and advise upon such filing, prosecution, maintenance, and defense.

7.3 LICENSEE will not abandon the filing, prosecution, or maintenance of any patent(s) and/or patent application(s) within the PATENT RIGHTS, except upon sixty (60) days' prior written notice provided to DUKE, and which notice is provided at least sixty (60) days in advance of any material deadlines for the filing, prosecution, or maintenance of such patent(s) or patent application(s), as applicable. Upon the expiration of such sixty (60)-day period, such patents and/or patent applications will no longer be included in the PATENT RIGHTS (and this Agreement is deemed to be so amended accordingly), and LICENSEE surrenders all rights under this Agreement to such patents, patent applications, and any patent or patent applications arising therefrom.

7.4 In the event of LICENSEE's uncured material breach of Paragraph 7.2 or Paragraph 7.3, or LICENSEE's abandonment of any PATENT RIGHTS in accordance with Paragraph 7.3, DUKE shall have the right, effective upon thirty (30) days written notice, to assume control over the filing, defense, prosecution, and/or maintenance of the applicable PATENT RIGHTS. In such case, LICENSEE shall promptly transfer all relevant files, documents, and rights necessary for DUKE to assume such responsibilities.

ARTICLE 8 – ENFORCEMENT

8.1 Each party shall promptly advise the other in writing of any known acts of potential infringement of the PATENT RIGHTS by a third party. After the earlier of (a) the FIRST COMMERCIAL SALE or (b) LICENSEE or any SUBLICENSEES makes any Investigational Device Exemption, Investigational New Drug Application (or equivalent), filing with the Food and Drug Administration or any foreign equivalent of any of the foregoing with any foreign authority, LICENSEE has the first right, but not the obligation, to enforce any PATENT RIGHTS against infringement by other parties within the TERRITORY and the FIELD OF USE, including those prior to the EFFECTIVE DATE. LICENSEE shall not file any suit without (a) first performing a reasonably thorough, diligent investigation of the merits of such suit, including with respect to the validity and enforceability of the PATENT RIGHTS; and (b) notifying DUKE twenty days before any such filing. This right to enforce includes filing, prosecuting, and settling all infringement actions at its expense, except that LICENSEE shall make any such settlement only after providing DUKE a reasonable opportunity to comment thereon. LICENSEE or any SUBLICENSEES has the right to file suit using counsel of its choosing, subject to DUKE's approval, which shall not be unreasonably withheld or delayed. LICENSEE may grant to SUBLICENSEES the right to enforce hereunder.

8.2 If LICENSEE has complied with Paragraph 8.1, DUKE shall provide reasonable assistance to LICENSEE with respect to such actions, including becoming a party to such suit if required by a court of competent jurisdiction to prosecute such infringement, but only if promptly reimburses DUKE for out-of-pocket expenses incurred in connection with any such assistance rendered at LICENSEE'S request or reasonably required by DUKE, including but not limited to expenses incurred in complying with discovery duties. DUKE retains the right to participate, with counsel of its own choosing and at its own expense, in any action under this Article. LICENSEE shall defend, indemnify and hold harmless DUKE with respect to any claims asserted by an alleged infringer reasonably related to the enforcement of the PATENT RIGHTS under this Article, including but not limited to antitrust counterclaims and claims for recovery of attorney fees.

8.3 DUKE and its employees have a vital interest in lawsuits relating to the validity and enforceability of the PATENT RIGHTS. If a third party files a suit, including as a counterclaim, alleging that any of the PATENT RIGHTS is invalid or unenforceable, then the parties shall jointly control the defense of such claim. Each party shall consult with the other with respect to the defense of such claim, and shall reasonably consider the other party's input. In furtherance of such joint control, at the onset of such claim and as reasonable during the pendency of any such claim, the parties shall meet and confer in good faith to set a plan for handling the defense thereof. The parties expect that in general (a) LICENSEE will have the right to lead daily activities, including but not limited to discovery, relating to the defense and (b) the parties would make joint filings. Notwithstanding, in the event that the parties cannot agree on how to proceed with respect to such claim, DUKE shall have the right to control the defense thereof on either a temporary or permanent basis. LICENSEE shall be responsible for the reasonable costs and fees associated with the activities under this Paragraph 8.3, except with respect to DUKE's activities resulting from DUKE's exercise of its right to control such defense. The parties shall consider reasonable controls on costs and fees as part of an aforementioned meet and confer with respect to the handling of the defense. Notwithstanding, if a third party asserts jurisdiction for any such action solely as the result of acts of DUKE, then DUKE shall be responsible for such reasonable costs and fees.

8.4 If LICENSEE recovers damages in patent litigation or settlement thereof, the award shall be applied first to satisfy LICENSEE's and DUKE's reasonable expenses and legal fees for the litigation or settlement. The remaining balance shall be distributed between the LICENSEE (85% of the total remaining balance) and DUKE (15% of the total remaining balance).

ARTICLE 9 - WARRANTIES; LIMITATION ON DUKE'S LIABILITY

9.1 DUKE makes no representations or warranties that any claim within the PATENT RIGHTS is or will be held valid, patentable, or enforceable, or that the manufacture, importation, use, offer for SALE, SALE or other distribution of any LICENSED PRODUCTS will not infringe upon any patent or other rights. DUKE's

Office for Translation & Commercialization as of the EFFECTIVE DATE represents that, except for the rights, if any, of the Government of the United State of America: (a) DUKE is the owner of the right, title, and interest in and to the PATENT RIGHTS and the DUKE IND; (b) DUKE has the right to grant licenses thereunder and a right to reference the DUKE IND; (c) DUKE has not granted licenses thereunder to any other entity that would restrict rights granted hereunder except as stated herein; and (d) neither the execution of this Agreement nor the performance of DUKE's obligations hereunder will constitute a breach under the terms and provisions of any other agreement to which DUKE is a party.

9.2 EXCEPT AS EXPRESSLY SET FORTH IN PARAGRAPH 9.1, DUKE MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS. LICENSEE AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS.

9.3 In no event shall either party be responsible or liable hereunder for any direct, indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS or the PATENT RIGHTS or KNOW-HOW or any other individual or entity regardless of legal or equitable theory.

9.4 LICENSEE shall not make any statements, representations or warranties whatsoever to any person or entity, or accept any liabilities or responsibilities whatsoever from any person or entity that are inconsistent with any disclaimer or limitation included in this Article 9.

ARTICLE 10 - INDEMNITY; INSURANCE

10.1 LICENSEE shall defend, indemnify and hold harmless and shall require SUBLICENSEES to defend, indemnify and hold harmless DUKE for and against any and all claims, demands, damages, losses, and expenses of any nature (including attorneys' fees and other litigation expenses) excluding any breach of contract claims brought by or on behalf of DUKE (hereinafter, a "Claim"), resulting from, but not limited to, death, personal injury, illness, property damage, economic loss or products liability, including errors and omissions, arising from or in connection with, any of the following: (a) any manufacture, use, SALE or other disposition by LICENSEE, SUBLICENSEES or transferees of LICENSED PRODUCTS; (b) the use by any person of LICENSED PRODUCTS made, used, sold or otherwise distributed by LICENSEE or SUBLICENSEES; (c) the use or practice by LICENSEE or SUBLICENSEES of any invention or computer software related to the PATENT RIGHTS; (d) any violation of applicable laws, rules, or regulations by LICENSEE or SUBLICENSEES in connection with this Agreement or the PATENT RIGHTS; and (e) any Claim of infringement and/or invalidity of any claim(s) of the PATENT RIGHTS.

10.2 DUKE is entitled to participate at its option and expense through counsel of its own selection, and may join in any legal actions related to any such claims, demands, damages, losses and expenses under Paragraph 10.1 above. LICENSEE shall not settle any such legal action with an admission of wrongdoing or non-indemnified liability of DUKE without DUKE's written approval. DUKE and other parties indemnified hereunder shall reasonably cooperate with LICENSEE as requested in connection with the foregoing.

10.3 Prior to any distribution or commercial use of any LICENSED PRODUCT by LICENSEE, LICENSEE shall purchase and maintain in effect commercial general liability insurance, product liability insurance, and errors and omissions insurance which shall protect LICENSEE and DUKE with respect to the events covered by Paragraph 10.1, and LICENSEE shall require the same of any SUBLICENSEE. Each such insurance policy must provide reasonable coverage for all claims with respect to any LICENSED PRODUCTS manufactured, used, sold, licensed or otherwise distributed by LICENSEE – or, in the case of a SUBLICENSEE's policy, by said SUBLICENSEE – and must specify DUKE as an additional insured. LICENSEE shall furnish proof of such insurance to DUKE, upon request.

10.4 In no event shall either party hereunder be liable to the other for any special, indirect, punitive, or consequential damages of any kind whatsoever resulting from any breach or default of this Agreement, provided that the foregoing shall not apply to breaches of Article 13.

ARTICLE 11 - TERM AND TERMINATION

11.1 This Agreement shall immediately terminate if the LICENSEE enters liquidation, has a receiver or administrator appointed over any assets related to this Agreement (who is not dismissed within sixty (60) days), makes an assignment for the benefit of its creditors, ceases to carry on business, files for bankruptcy, an involuntary petition is filed against LICENSEE and not dismissed within sixty (60) days, or any similar event occurs under the law of any foreign jurisdiction. Except as set forth in Paragraph 15.8, this Agreement cannot be assumed or assigned by LICENSEE, any trustee acting on behalf of the assets of LICENSEE, or otherwise.

11.2 If at any time the LICENSEE ceases to pursue commercial development of the PATENT RIGHTS as contemplated herein in any country in the TERRITORY, then the license grants to LICENSEE set forth in Article 2 with respect to that country in the TERRITORY shall automatically terminate without obligation on the part of DUKE to refund any of the fees or royalties which may have been paid by LICENSEE prior to such termination. LICENSEE must provide notice to DUKE immediately in writing if LICENSEE ceases to pursue commercial development of the PATENT RIGHTS or KNOW-HOW in any specific country in the TERRITORY as contemplated herein.

11.3 If LICENSEE fails to make any payment due to DUKE, by the applicable due date therefor, then such failure shall be deemed to be a material breach of this Agreement, subject to the cure period set forth in Paragraph 4.3 or 11.4. A termination of this Agreement stemming from such a breach shall not foreclose DUKE from collection of any amounts remaining unpaid or seeking other legal relief.

11.4 Upon any material breach or default of this Agreement by LICENSEE (other than as specifically provided herein (including with respect to any failure to achieve a DILIGENCE MILESTONE on or before the applicable ACHIEVEMENT DATE, as set forth in Paragraph 5.3), the terms of which shall take precedence over the handling of any other material breach or default under this Paragraph), DUKE has the right to terminate this Agreement effective on sixty (60) days' (or, in the event of failure to pay, thirty (30) days') written notice to LICENSEE. Such termination shall become automatically effective upon expiration of the applicable period unless LICENSEE cures the material breach or default before the period expires. LICENSEE's right to cure a material breach will apply only to the first three (3) material breaches properly noticed under the terms of this Agreement within any two (2)-year period, regardless of the nature of those breaches. Any subsequent uncured material breach by LICENSEE during such two (2) year period will entitle DUKE to terminate this Agreement by written notice without opportunity to cure.

11.5 LICENSEE has the right to terminate this Agreement at any time on sixty (60) days' written notice to DUKE. Upon termination pursuant to this Paragraph, LICENSEE shall:

(a) pay all amounts due DUKE through the effective date of the termination;

(b) submit a final report of the type described in Paragraph 4.2;

(c) return any patent documentation (including that exchanged under Article 7) concerning the PATENT RIGHTS and any other confidential information or physical materials provided to LICENSEE by DUKE in connection with this Agreement, or, with prior approval by DUKE, destroy such materials, and certify in writing that such materials have all been returned or destroyed;

(d) suspends its manufacture, use and SALE of the LICENSED PRODUCT(S); and

(e) provide DUKE copies of any regulatory information filed with any U.S. or foreign government agency by LICENSEE or any AFFILIATE thereof with respect to LICENSED PRODUCTS.

11.6 Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the parties hereunder shall cease, except any previously accrued rights and obligations and further as follows: (a) obligations to pay royalties and other sums, including any outstanding patent fees and costs pursuant to Article 7 up to the termination date, or to transfer equity or other consideration, accruing hereunder up to the day of such termination, whether or not this Agreement provides for a number of days before which actual payment is due and such date is after the day of termination and whether or not a required funding event or other stock transfer trigger has yet been met; (b) DUKE's rights to inspect books and records as described in Article 4, and LICENSEE's obligations to keep such records for the required time; (c) any cause of action or claim of LICENSEE or DUKE accrued or to accrue because of any breach or default by the other party hereunder; (d) the provisions of Articles 1, 3.7, 9, 10, 13, 15; (e) LICENSEE may, within one hundred eighty (180) days after the effective date of any termination, sell all LICENSED PRODUCT that it has on hand as of the effective date of termination, provided that LICENSEE pays to DUKE any royalties thereon pursuant to Paragraph 3.1(b); and (f) all other terms, provisions, representations, rights and obligations contained in this Agreement that by their sense and context are intended to survive until performance thereof by either or both parties.

Termination by either party hereunder shall not alter or affect any other rights or relief that either party may be entitled to under law.

11.7 Upon termination of this Agreement, if LICENSEE has filed patent applications or obtained patents to any modification or improvement to LICENSED PRODUCTS within the scope of the PATENT RIGHTS, LICENSEE agrees upon DUKE's written request, subject to the rights of any SUBLICENSEES or other third parties with respect thereto, to enter into good faith negotiations with DUKE or DUKE's future licensee(s) with respect to the PATENT RIGHTS for the purpose of granting DUKE or such future licensee(s) rights to said modifications or improvements, with such negotiations to be undertaken in a timely fashion and any such agreement to be under commercially reasonable terms.

11.8 If LICENSEE or a SUBLICENSEE, or any AFFILIATE thereof, asserts the invalidity or unenforceability of any claim included in the PATENT RIGHTS, including by way of litigation or administrative proceedings, either directly or through any other party, then DUKE shall have the right to immediately terminate this Agreement upon written notice to LICENSEE, provided that, in the case of such an assertion by a SUBLICENSEE, such termination shall not become effective until the thirtieth (30th) day following DUKE's notice to LICENSEE of such assertion and shall only become effective as of such date if (i) such SUBLICENSEE has not withdrawn or terminated such assertion or proceeding and (ii) the applicable SUBLICENSE AGREEMENT has not been terminated. Notwithstanding the foregoing, the Parties agree that this Paragraph 11.8 shall not apply to any such assertion by any SUBLICENSEE with respect to any PATENT RIGHT to which such SUBLICENSEE is not sublicensed rights under this Agreement.

ARTICLE 12 - NOTICES

Any notice, request, or report required or permitted to be given or made under this Agreement by either party is effective when mailed if sent by recognized overnight carrier, certified or registered mail, or electronic mail, to the address set forth below or such other address as set forth below and as such party specifies by written notice given in conformity herewith. Any notice, request, or report not sent to an address provided below is not effective until actually received by the other party.

To DUKE:
For delivery via the U.S. Postal Service
[***]
[***]
[***]
[***]

To LICENSEE:
[***]
[***]
[***]
[***]

For delivery via nationally/internationally recognized courier
DUKE UNIVERSITY
[***]
For delivery via electronic mail
[***]

ARTICLE 13 - CONFIDENTIALITY

13.1 DUKE and LICENSEE will treat any Confidential Information disclosed to it by the other party with reasonable care and will not disclose such information to any other person, firm or corporation, except AFFILIATES bound by the obligations of confidentiality and restricted use set forth in this Article. The receiving party may not use the disclosing Party's Confidential Information other than for the benefit of the Parties hereto and for the performance of this Agreement. These obligations of non-disclosure and restricted use will remain in effect for each subject disclosure of CONFIDENTIAL INFORMATION for five (5) years from the date of disclosure. However, neither Party is obligated, with respect to Confidential Information disclosed to it, or any part thereof, which:

(a) is already known to the receiving party at the time of the disclosure;

(b) becomes publicly known without the wrongful act or breach of this Agreement by the receiving party;

(c) is rightfully received by the receiving party from a third party on a non-confidential basis;

(d) is subsequently and independently developed by employees of the receiving party who had no knowledge of the information, as verified by written records;

(e) is approved for release by prior written authorization of the disclosing Party; or

(f) is disclosed pursuant to the requirements of applicable law or pursuant to any judicial or government requirement or order, provided that the party so disclosing takes reasonable steps to provide the other party sufficient prior notice in order to contest such request, requirement or order and provided that such disclosed confidential information otherwise remains subject to the obligations of confidentiality set forth in this Article.

13.2 DUKE and LICENSEE agree that any information to be treated as Confidential Information under this Article must be disclosed in writing or in another tangible medium and must be clearly marked "CONFIDENTIAL." Confidential Information disclosed orally must be summarized and reduced to writing and communicated to the other party within 30 days of such disclosure. Notwithstanding the foregoing, any information which by its nature is confidential and a person in the industry would reasonably be expected to know that the information should be treated as confidential shall be considered CONFIDENTIAL INFORMATION regardless of whether it has been marked "CONFIDENTIAL" or a party has otherwise provided notice confirming the confidentiality of the information.

13.3 LICENSEE may use and disclose any CONFIDENTIAL INFORMATION related to the PATENT RIGHTS to actual or prospective investors, SUBLICENSEES, licensors, licensees, lenders, bankers, acquirers, acquisition, or merger targets, contractors, employees, officers, directors, consultants and agents with a need to know,

collaborators, prospective collaborators and other third parties in the chain of development, manufacturing, commercialization and distribution, but if and only if LICENSEE obtains from each such recipient a written confidentiality agreement, the provisions of which are at least as protective of DUKE's confidential information as those provided in this Article.

13.4 "CONFIDENTIAL INFORMATION" shall mean, with respect to a party hereto, all information regarding such party's technology, products, business, finances, or objectives, that is disclosed to the other party and marked "CONFIDENTIAL". Notwithstanding anything to the contrary in this Agreement, all information relating to filing, prosecution, maintenance, defense, infringement, and the like regarding the PATENT RIGHTS (no matter how disclosed) is the Confidential Information of both Parties and subject to the provisions of this Article. DUKE acknowledges that other than information relating to PATENT RIGHTS, DUKE has not disclosed any Confidential Information to LICENSEE.

ARTICLE 14 – DISPUTE RESOLUTION

14.1 In the event of any dispute, claim, question, or disagreement arising from or relating to this agreement or the breach thereof, the Parties hereto shall use their best efforts to settle the dispute, claim, question, or disagreement. To this effect, they shall consult and negotiate with each other in good faith and, recognizing their mutual interests, attempt to reach a just and equitable solution satisfactory to both parties. If they do not reach such solution within a period of sixty (60) days of the first written notice of dispute by either party to the other, then, upon written request for mediation by either party to the other, the parties agree to try in good faith to settle the dispute by mediation administered by the American Arbitration Association under its Commercial Mediation Procedures and to be scheduled within sixty (60) days of the written notice requesting mediation. If the parties fail to reach agreement by mediation, then all disputes, claims, questions, or differences shall be finally settled by arbitration administered by the American Arbitration Association in accordance with the provisions of its Commercial Arbitration Rules. The arbitration panel shall consist of three members, selected as follows: one member to be selected by each party, and those two members are to select a third member who will chair the panel. Judgment on the award rendered by the arbitrators may be entered in any court having jurisdiction thereof and shall be binding on the parties. The negotiation, mediation, and arbitration described above shall take place at a mutually agreed upon location in Durham, North Carolina.

14.2 Either Party may seek to enforce any written agreement reached by the Parties during mediation, or to confirm and enforce any final award entered in arbitration, in any court of competent jurisdiction, provided that any Party moving to enforce, confirm or vacate any such agreement or award, as the case may be, will file such motion under seal unless prohibited under applicable court rules. Notwithstanding the agreement to such procedures, either Party may seek equitable relief to enforce its rights in any court of competent jurisdiction.

ARTICLE 15 - MISCELLANEOUS PROVISIONS

15.1 This Agreement shall be governed by and construed under the laws of the state of North Carolina without regard for principles of choice of law, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted.

15.2 DUKE and LICENSEE agree that this Agreement sets forth their entire understanding concerning the subject matter of this Agreement. The parties may amend this Agreement from time to time, such as to add new rights, but no modification will be effective unless both DUKE and LICENSEE agree to it in writing.

15.3 If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

15.4 No waiver by either party of any breach of this Agreement, no matter how long continuing or how often repeated, is a waiver of any subsequent breach thereof, nor is any delay or omission on the part of either party to exercise or insist on any right, power, or privilege hereunder a waiver of such right, power or privilege. In no event shall any waiver be deemed valid unless it is in writing and signed by an authorized representative of each party.

15.5 LICENSEE shall, and shall require its AFFILIATES exercising or performing LICENSEE's rights or obligations hereunder and SUBLICENSEES to, refrain from using the name, mark, logo, image or any adaption thereof of DUKE or its employees in publicity or advertising without the prior written approval of DUKE, provided that the foregoing shall not apply to the extent such use is required by applicable law, rule, or regulation. Reports in scientific literature and presentations of joint research and development work are not publicity or advertising for purposes hereof. Notwithstanding this provision, without prior written approval of DUKE, LICENSEE and SUBLICENSEES may state publicly that LICENSED PRODUCTS were developed by LICENSEE based upon an invention(s) developed at Duke University and/or that the PATENT RIGHTS were licensed from Duke University. However, in no event, shall LICENSEE or SUBLICENSEE represent, either directly or indirectly, that any product or service is a product or service of DUKE.

15.6 LICENSEE agrees to comply with all applicable laws and regulations, including but not limited to all United States laws and regulations controlling the export of commodities and technical data.

15.7 It is expressly understood and agreed that DUKE and LICENSEE are independent contractors. Neither party is an agent of the other in connection with the exercise of any rights hereunder, and neither has any right or authority to assume or create any obligation or responsibility on behalf of the other. Nothing in this Agreement shall be deemed to create or constitute a partnership or joint venture between DUKE and LICENSEE.

15.8 LICENSEE may not assign this Agreement without the prior written consent of DUKE and shall not pledge any of the license rights granted in this Agreement as security for any creditor. Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement not permitted under this Paragraph 15.8 will be void from the beginning. No assignment by LICENSEE will be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement, and such writing is provided to DUKE. Notwithstanding the foregoing, LICENSEE may, without DUKE's consent, assign this Agreement to a purchaser or assignee (by operation of law, contract or otherwise) of all or substantially all of LICENSEE's assets or business relating to the subject matter of this Agreement, so long as (a) LICENSEE is not then in material breach of this Agreement and (b) within thirty (30) days of such transaction, the assignee provides a statement in writing to DUKE that it agrees to accept all the terms and conditions of this Agreement (including, to the extent LICENSEE does not remain liable therefor to DUKE, obligations existing as of the time of such assignment) in the place of LICENSEE. The transfer of this Agreement by LICENSEE to an AFFILIATE shall not be considered to be an assignment subject to this Paragraph 15.8 and shall be permitted without DUKE's consent.

15.9 If the registration, recordation, or reporting to a national or supranational agency of this Agreement, its terms, or assignment thereof is or becomes required or advisable (e.g., as a prerequisite to enforceability of the Agreement in such nation), LICENSEE shall at its expense, promptly undertake such action. However prior to such action, LICENSEE shall provide prompt notice thereof to DUKE along with copies of relevant documentation to be submitted for DUKE's approval, such approval not to be unreasonably withheld.

15.10 This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via email in "PDF" form with any electronic signature complying with the U.S. federal ESIGN Act of 2000 (*e.g.*, DocuSign), or via other transmission method.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

FOR LICENSEE		FOR DUKE UNIVERSITY	
By	/s/ Alexandra MacLean	By	/s/ Robin L. Rasor
Name:	Alexandra MacLean	Name:	Robin L. Rasor
Title:	President and CEO	Title:	Associate Vice President, Translation and Commercialization

EXHIBIT A

PATENT RIGHTS

[Exhibit A to Duke – Avenue License Agreement]

EXHIBIT B

KNOW-HOW

[Exhibit B to Duke – Avenue License Agreement]

Exhibit 31.1

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

I, Alexandra MacLean, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avenue Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

/s/ Alexandra MacLean, M.D.
Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
May 8, 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)
May 8, 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 March 31, 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)
May 8, 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 March 31, 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)
May 8, 2026