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

FORM 10-Q

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

For the quarterly period ended June 30, 2023

OR

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

For the transition period from to

Commission File Number 001-38114

AVENUE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-4113275**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1111 Kane Concourse, Suite 301, Bay Harbor Islands, FL 33154
(Address of principal executive offices and zip code)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	Nasdaq Capital Market

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

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

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

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

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

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

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

Class of Common Stock	Outstanding Shares as of August 7, 2023
Common Stock, $0.0001 par value	8,182,985

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2023

Table of Contents

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,571	$ 6,708
Other receivables - related party	26	—
Prepaid expenses and other current assets	69	137
Total assets	$ **1,666**	$ **6,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 886	$ 949
Accounts payable and accrued expenses - related party	54	21
Accrued licenses acquired	1,000	—
Warrant liability	5,872	2,609
Total current liabilities	7,812	3,579
Total liabilities	7,812	3,579
Commitments and contingencies		
Stockholders' equity (deficit)		
Preferred stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock ($0.0001 par value), 75,000,000 shares authorized		
Common shares, 7,920,485 and 4,773,841 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	—
Additional paid-in capital	86,757	84,456
Accumulated deficit	(92,094)	(80,551)
Total stockholders' equity attributed to the Company	(5,336)	3,905
Non-controlling interests	(810)	(639)
Total stockholders' equity (deficit)	(6,146)	3,266
Total liabilities and stockholders' equity	$ **1,666**	$ **6,845**

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 3,027	$ 151	$ 4,242	$ 1,959
Research and development – licenses acquired	—	—	4,230	—
General and administrative	896	454	1,880	1,509
Loss from operations	(3,923)	(605)	(10,352)	(3,468)
Other income (expense)				
Interest income	57	1	94	3
Financing costs – warrant liabilities	—	—	(332)	—
Change in fair value of warrant liabilities	(150)	—	(1,028)	—
Total other income (expense)	(93)	1	(1,266)	3
Net loss	$ **(4,016)**	$ **(604)**	$ **(11,618)**	$ **(3,465)**
Net loss attributable to non-controlling interests	9	—	75	—
Net loss attributable to common stockholders	$ **(4,007)**	$ **(604)**	$ **(11,543)**	$ **(3,465)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.41)	$ (1.73)	$ (2.42)
Weighted average number of common shares outstanding, basic and diluted	7,758,153	1,461,067	6,667,550	1,429,283

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

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

Three months ended June 30, 2023

	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	(Deficit)
Balance at March 31, 2023	**250,000**	**$ —**	**6,828,186**	**$ 1**	**$ 86,634**	**$ (88,087)**	**$ (705)**	**$ (2,157)**
Share based compensation	—	—	—	—	27	—	—	27
Exercise of warrants	—	—	1,092,299	—	—	—	—	—
Non-controlling interest in subsidiaries	—	—	—	—	96	—	(96)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(9)	(9)
Net loss attributable to common stockholders	—	—	—	—	—	(4,007)	—	(4,007)
Balance at June 30, 2023	**250,000**	**$ —**	**7,920,485**	**$ 1**	**$ 86,757**	**$ (92,094)**	**$ (810)**	**$ (6,146)**

Six Months Ended June 30, 2023

	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	(Deficit)
Balance at December 31, 2022	250,000	$ —	4,773,841	$ —	**$ 84,456**	**$ (80,551)**	**$ (639)**	**$ 3,266**
Share based compensation	—	—	—	—	38	—	—	38
Issuance of common stock to Fortress	—	—	374,644	—	72	—	—	72
Issuance of common stock and pre-funded warrants, net of offering costs - registered direct offering and private placement	—	—	448,000	1	865	—	—	866
Issuance of common stock for license expense	—	—	831,618	—	1,230	—	—	1,230
Exercise of warrants	—	—	1,492,382	—	—	—	—	—
Non-controlling interest in subsidiaries	—	—	—	—	96	—	(96)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(75)	(75)
Net loss attributable to common stockholders	—	—	—	—	—	(11,543)	—	(11,543)
Balance at June 30, 2023	**250,000**	**$ —**	**7,920,485**	**$ 1**	**$ 86,757**	**$ (92,094)**	**$ (810)**	**$ (6,146)**

Three months ended June 30, 2022

	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	(Deficit)
Balance at March 31, 2022	**250,000**	**$ —**	**1,475,652**	**$ 2**	**$ 81,017**	**$ (79,860)**	**$ —**	**$ 1,159**
Share based compensation	—	—	—	—	43	—	—	43
Net loss	—	—	—	—	—	(604)	—	(604)
Balance at June 30, 2022	**250,000**	**$ —**	**1,475,652**	**$ 2**	**$ 81,060**	**$ (80,464)**	**$ —**	**$ 598**

Six Months Ended June 30, 2022

	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	(Deficit)
Balance at December 31, 2021	**250,000**	**$ —**	**1,405,977**	**$ 2**	**$ 80,448**	**$ (76,999)**	**$ —**	**$ 3,451**
Share based compensation	—	—	69,675	—	612	—	—	612
Net loss	—	—	—	—	—	(3,465)	—	(3,465)
Balance at June 30, 2022	**250,000**	**$ —**	**1,475,652**	**$ 2**	**$ 81,060**	**$ (80,464)**	**$ —**	**$ 598**

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

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

	For the Six Months Ended	
	June 30, 2023	**June 30, 2022**
Cash Flows from Operating Activities:		
Net loss	$ (11,618)	$ (3,465)
Reconciliation of net loss to net cash used in operating activities:		
Share based compensation	38	612
Change in fair value of warrant liability	1,028	—
Issuance of common stock for licenses acquired	1,230	—
Research and development-licenses acquired, expense	2,000	—
Issuance of common stock to Fortress	72	—
Changes in operating assets and liabilities:		
Other receivables - related party	(26)	90
Prepaid expenses and other current assets	68	(8)
Accounts payable and accrued expenses	(63)	(54)
Accrued licenses acquired	1,000	—
Accounts payable and accrued expenses - related party	33	(48)
Net cash used in operating activities	(6,238)	(2,873)
Cash flows from Investing Activities:		
Purchase of research and development licenses	(2,000)	—
Net cash used in investing activities	(2,000)	—
Cash flows from Financing Activities:		
Issuance of common stock, pre-funded warrants and warrants, net of offering costs - registered direct offering and private placement	3,101	—
Net cash provided by financing activities	3,101	—
Net change in cash and cash equivalents	(5,137)	(2,873)
Cash and cash equivalents, beginning of period	6,708	3,763
Cash and cash equivalents, end of period	$ **1,571**	$ **890**
Supplemental cash flow information:		
Unpaid research and development licenses acquired	$ 1,000	$ —

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

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

Note 1 - Organization, Plan of Business Operations

Avenue Therapeutics, Inc. (the "Company" or "Avenue") was incorporated in Delaware on February 9, 2015, as a wholly-owned subsidiary of Fortress Biotech, Inc. ("Fortress"). Avenue is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Our current product candidates include AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA"), intravenous tramadol ("IV tramadol") for the management of acute post-operative pain, and BAER-101 for the treatment of CNS diseases. We may in the future acquire additional product candidates.

Reverse Stock Split

As a result of the reverse stock split effective on September 23, 2022, every 15 shares of common stock outstanding immediately prior to the effectiveness of the reverse stock split were combined and converted into one share of common stock without any change in the par value per share. No fractional shares were issued in connection with the reverse stock split. In connection with the reverse stock split, the holders of a majority of the voting power of our capital stock executed a written consent approving the reduction of the number of authorized shares of Common Stock immediately after the reverse stock split from 50,000,000 to 20,000,000 shares, which reduction became effective on September 23, 2022. On February 2, 2023, following the approval of our Board of Directors and our stockholders at the Company's 2022 annual meeting of stockholders, we filed an amendment to our Third Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock from 20,000,000 to 75,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the reverse stock split for all periods presented, unless otherwise indicated.

Liquidity and Capital Resources

Going Concern

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

The Company is not yet generating revenue, has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of June 30, 2023, the Company had an accumulated deficit of $92.1 million. Due to uncertainties regarding future operations of the Company for a study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV tramadol, and the expansion of the Company's development portfolio within neuroscience with the consummation of the transaction with Fortress for the acquisition of Baergic Bio, Inc. ("Baergic"), the Company will need to secure additional funds through equity or debt offerings, or other potential sources, the timing of which is unknown at this time. The Company will require additional funds to cover operational expenses over the next 12 months. 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 the issuance 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

The Company's consolidated financial statements have been prepared in conformity with U.S. GAAP, include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented and are stated in U.S. dollars. The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's subsidiary, Baergic. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the balances and results for the periods presented.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These unaudited interim condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Therefore, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2022, which were included in the Company's Annual Report on Form 10-K (the "2022 Form 10-K") and filed with the U.S. Securities and Exchange Commission ("SEC") on March 31, 2023.

The accompanying consolidated financial statements include the accounts of the Company's subsidiary. For consolidated entities where the Company owns less than 100% of the subsidiary, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective non-controlling parties. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of partner companies.

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period.

Use of Estimates

The Company's consolidated financial statements include certain amounts that are based on management's best estimates and judgements. The Company's significant estimates include, but are not limited to, fair value of warrants, stock-based compensation, common stock issued to acquire licenses, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Other Receivables – Related Party

Other receivables consist of amounts due from Urica Therapeutics, Inc. ("Urica"), a consolidated entity under Fortress, and are recorded at the invoiced amount.

Non-Controlling Interests

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

Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2022 Form 10-K.

Note 3 — Licenses/Supplier Agreements

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. Fortress made an upfront payment of $2.0 million to Revogenex upon execution of the exclusive license, and on June 17, 2015, Fortress paid an additional $1.0 million to Revogenex after receiving all the assets specified in the agreement. In December 2019, $1.0 million became due to Revogenex in accordance with the Company's submission of its NDA. In addition, under the terms of the agreement, Revogenex is eligible to receive an additional milestone payment totaling $3.0 million upon the approval of IV tramadol from the U.S. Food and Drug Administration ("FDA")as well as royalty payments on net sales of the product ranging in the high single digits to low double digits.

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

Baergic Licenses

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

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

AnnJi License Agreement

On February 28, 2023, the Company entered into a license agreement with AnnJi Pharmaceutical Co. Ltd. ("AnnJi"), whereby the Company obtained an exclusive license (the "AnnJi License Agreement") from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of SBMA, also known as Kennedy's Disease. Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidates, the Company agreed to pay $3.0 million, of which $2.0 million was paid on April 27, 2023 and $1.0 million is payable within 180 day after the effective date of the AnnJi License Agreement.

The license provided under the AnnJi License Agreement is exclusive as to all oral forms of AJ201 for use in all indications (other than androgenetic alopecia and Alzheimer's disease) in the United States, Canada, the European Union, the United Kingdom and Israel. The AnnJi License Agreement also contains customary representations and warranties and provisions related to confidentiality, diligence, indemnification and intellectual property protection. The Company will initially be obligated to obtain both clinical and commercial supply of AJ201 exclusively through AnnJi. AnnJi retains the manufacturing rights for AJ201 and the Company has the option to acquire those rights from AnnJi as described in the AnnJi License Agreement.

The Company is also obligated to issue shares of its common stock under the Subscription Agreement and make additional payments over the course of the AnnJi License Agreement including: reimbursement payments of up to $10.8 million in connection with the product's Phase 1b/2a clinical trial, (which AnnJi is administering with Joint Steering Committee Oversight before assigning the Investigational New Drug Application ("IND") to the Company upon such trial's conclusion, and which is reflective of market pricing for the services to be received), up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S., up to $27.5 million in connection with certain drug development milestones pertaining to additional indications and development outside the U.S., up to $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales, and royalty payments based on a percentage of net sales ranging from mid-single digits (on annual net sales at or below $50 million) to the low double digits (on annual net sales equal to or greater than $300 million), which are subject to potential diminution in certain circumstances.

In connection with the signing of the AnnJi License Agreement, the Company issued 831,618 shares of its common stock to AnnJi ("First Tranche Shares") at a fair value of $0.9 million on March 30, 2023. The Company will issue an additional 276,652 shares of common stock, recorded at a fair value of $0.3 million, upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial ("Second Tranche Shares"). The fair value was calculated based on the closing price of the Company's stock as of February 28, 2023. The Company and AnnJi entered into a Subscription Agreement, dated as of February 28, 2023, that provided for the issuance of First Tranche Shares which were issued March 30, 2023. The Company and AnnJi will enter into a subsequent subscription agreement, in substantially the same form as the Subscription Agreement, with respect to the issuance of the Second Tranche Shares. In the event that the common stock of the Company ceases to be traded on a national securities exchange, AnnJi has the right to sell common stock of the Company back to the Company at a price of $2.10 per share subject to the terms in the AnnJi License Agreement.

In connection with execution of the AnnJi License Agreement, Avenue entered into a registration rights agreement with AnnJi ("AnnJi Registration Rights Agreement"), pursuant to which Avenue filed a registration statement to register the resale of the First Tranche Shares and Second Tranche Shares issued to AnnJi. The Company filed such registration statement on Form S-3 with the SEC on June 16, 2023, which was declared effective on June 27, 2023.

Note 4 — Fair Value Measurements

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

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

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

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

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

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

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

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	January 2023 Warrants	Total
Fair value of warrants outstanding as of December 31, 2022	$ 2,609	$ —	$ 2,609
Fair value of warrants at issuance as of January 31, 2023	—	2,235	2,235
Change in fair value of warrants	1,458	(430)	1,028
Fair value of warrants outstanding as of June 30, 2023	$ 4,067	$ 1,805	$ 5,872

Warrant Liability

The Company has issued freestanding warrants to purchase shares of our common stock in connection with financing activities (Warrants as described in Note 8). The Company's outstanding common stock warrants issued in connection with the equity offering completed in October 2022 ("October 2022 Warrants") and January 2023 ("January 2023 Warrants") are classified as liabilities in the balance sheet as they contain terms for redemption of the underlying security that are outside our control. The Company used a Monte Carlo simulation approach, which allows to factor in the effect of a down-round protection feature, to value the October 2022 Warrants at the time of issuance on October 11, 2022 and for the period ending December 31, 2022. The Black-Scholes model was used to value the January 2023 Warrants at the time of issuance on January 31, 2023. The approach required management to estimate inputs including expected volatility and expected term, and is most significantly impacted by the volatility of our common stock price. These inputs are inherently subjective and require significant analysis and judgment to develop.

The fair value of the warrants 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 condensed 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 and the January 2023 Warrants until exercise or expiration of the warrants on January 31, 2026. The October 2022 Warrants originally contained a one-time down-round price protection feature. In connection with the January 31, 2023 Registered Direct and Private Placement, the down-round price protection feature was used and the exercise price for the October 2022 Warrants was permanently adjusted to $1.55. The Black-Scholes model was used to value the October 2022 Warrants and January 2023 Warrants as of June 30, 2023.

The key inputs for the October 2022 Warrants for the Monte Carlo simulation and Black-Scholes model were as follows:

	June 30, 2023 (Black-Scholes model)	December 31, 2022 (Monte Carlo simulation)
Stock price	$ 1.17	$ 1.16
Risk-free interest rate	4.13%	4.02%
Expected dividend yield	—	—
Expected term in years	4.3	4.8
Expected volatility	137%	93%

The key inputs for the January 2023 Warrants using the Black-Scholes model were as follows:

	June 30, 2023	January 31, 2023 (Initial measurement)
Stock price	$ 1.17	$ 1.38
Risk-free interest rate	4.49%	3.90%
Expected dividend yield	—	—
Expected term in years	2.6	3.0
Expected volatility	162%	160%

Note 5 — Accounts Payable and Accrued Expenses

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

	As of June 30, 2023	As of December 31, 2022
Accounts payable	$ 446	$ 129
Accrued employee compensation	154	199
InvaGen contingent fee	—	208
Accrued contracted services and other	286	413
Total accounts payable and accrued expenses	$ 886	$ 949

Note 6 - Related Party Transactions

Founders Agreement and Management Services Agreement with Fortress

Fortress entered into a Founders Agreement with Avenue in February 2015 (as amended, the "Fortress-Avenue Founders Agreement"), pursuant to which Fortress assigned to Avenue all of its rights and interest under Fortress's license agreement with Revogenex for IV tramadol (the "IV Tramadol License Agreement"). As additional consideration for the transfer of rights under the original Fortress-Avenue Founders Agreement, Avenue also agreed to: (i) issue annually to Fortress, on the anniversary date of the Fortress-Avenue Founders Agreement, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of Avenue; (ii) pay an equity fee in shares of Avenue common stock, payable within five (5) business days of the closing of any equity or debt financing for Avenue or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Avenue's voting equity, equal to two and one half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Avenue's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Fortress will be paid a one-time change in control fee equal to five (5x) times the product of (i) net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective as of February 17, 2015, Fortress entered into a Management Services Agreement (the "Fortress-Avenue MSA") with Avenue pursuant to which Fortress provides advisory and consulting services to Avenue pursuant to the terms thereof. The Fortress-Avenue MSA contained an initial five-year term and shall be automatically extended for additional five-year periods unless Fortress or the Company provides written notice of its desire not to automatically extend the term of the Fortress-Avenue MSA at least 90 days prior to the applicable expiration date. Services provided under the Fortress-Avenue MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Avenue's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Avenue with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Avenue is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Avenue is not obligated to take or act upon any advice rendered from Fortress, and Fortress shall not be liable for any of Avenue's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Avenue's Board of Directors, have been contractually exempt from fiduciary duties to Avenue relating to corporate opportunities. In consideration for the Services, Avenue will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Avenue has net assets in excess of $100.0 million at the beginning of the calendar year. The Fortress-Avenue MSA fee was reinstated upon the consummation of the InvaGen Share Repurchase Agreement and termination of any prior investment agreements between InvaGen, Avenue and Fortress.

Founders Agreement and Management Services Agreement with Baergic

Pursuant to the Share Contribution Agreement between Avenue and Fortress, the Founders Agreement and Management Services Agreement that had previously been existing between Fortress and Baergic were assigned to Avenue, such that they now exist between Avenue and Baergic; those agreements are referred to herein as the Avenue-Baergic Founders Agreement and the Avenue-Baergic MSA, as applicable. The Annual Stock Dividend payable to the Company is 2.5% of common stock calculated as a percentage of fully diluted outstanding capital and became effective as of November 8, 2022. For the year ended December 31, 2022, Baergic recorded an Annual Stock Dividend of $10.5 thousand to Avenue on December 31, 2022, which was paid in shares on January 1, 2023.

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

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

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

Shared Services Agreement with Urica Therapeutics

Effective February 1, 2023, and amended on April 30, 2023, the Company and Urica entered into a sharing arrangement for a certain Avenue employee to be shared with Urica. During the arrangement, Urica has the authority to supervise the Avenue employee and will reimburse the Company for the employee's salary and salary-related costs. The term of this agreement lasted until July 31, 2023 and can be extended for consecutive three-month periods. The amounts reimbursable to Avenue was $39,634 and $66,762 for the three and six months ended June 30, 2023. The amounts were recorded as a reduction in research and development expenses on the Company's consolidated statements of operations. The amount due to the Company as of June 30, 2023 that is related to the shared services agreement is $26,025 and is included in "Other receivables – related party" on the Company's consolidated balance sheets.

Note 7 - Net Loss per Share

Loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding, excluding unvested restricted stock and stock options and preferred shares, during the period. 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:

	For the Three and Six Months Ended June 30,	
	2023	**2022**
Unvested restricted stock units/awards	98,137	21,412
Warrants	6,078,132	—
Options	1,685,000	—
Class A Preferred shares	16,666	16,666
Total potential dilutive effect	7,877,935	38,078

Note 8 - Stockholders' Equity

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 our stockholders and an amendment to the plan to increase the number of authorized shares issuable to 266,666 shares was approved by our stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 5,266,666 shares and approved by our stockholders on January 30, 2023. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan authorizes grants to issue up to 5,266,666 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 3,352,489 shares at June 30, 2023.

Stock Options

The following table summarizes stock option activity during the six months ended June 30, 2023:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	—	$ —	—	$ —
Granted	1,685,000	$ 1.14	10.0	$ —
Exercised	—	$ —	—	$ —
Cancelled/forfeited	—	$ —	—	$ —
Expired	—	$ —	—	$ —
Outstanding at June 30, 2023	1,685,000	$ 1.14	10.0	$ 51
Expected to vest	1,685,000	$ 1.14	10.0	$ 51
Exercisable	—	$ —	—	$ —

There were no options granted in the first three months of 2023 or for the six month period ending June 30, 2022. 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 June 30, 2023, the total compensation cost related to non-vested options awards not yet recognized is approximately $1.7 million with a weighted average remaining vesting period of 1.6 years.

The Company estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-pricing model utilizing the following assumptions:

	Six Months Ended June 30,	
	2023	2022
Volatility	124.9 - 125.7%	—%
Expected term (in years)	5.8 - 5.9	—
Risk-free rate	4.1%	—%
Expected dividend yield	—%	—%

Restricted Stock Units ("RSU") and Restricted Stock Awards ("RSA")

The following table summarizes the aggregate RSU and RSA activity during the six months ended June 30, 2023:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested balance at December 31, 2022	13,137	$ 12.08
Unvested balance at March 31, 2023	13,137	$ 12.08
Granted	85,000	1.14
Unvested balance at June 30, 2023	98,137	$ 2.60

At June 30, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.9 years. This amount does not include, as of June 30, 2023, 3,333 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

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

	For the three months ended June 30,		For the six months ended June 30,	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Research and development	$ 6	$ 18	$ 6	$ 289
General and administrative	21	25	32	323
Total stock-based compensation expense	**$ 27**	**$ 43**	**$ 38**	**$ 612**

Stock Warrants

The following table summarizes the warrant activity for the six months ended June 30, 2023 and 2022:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	4,137,916	$ 3.30	$ 1
Granted	3,432,598	0.88	—
Exercised	(400,083)	—	—
Outstanding, March 31, 2023	7,170,431	$ 1.32	1,272
Exercised	(1,092,299)	—	—
Outstanding, June 30, 2023	6,078,132	$ 1.55	$ 1

There was no warrant activity for the 6 months ended June 30, 2022.

Capital Raises

January 2023 Registered Direct and Private Placement

On January 27, 2023, the Company entered into a Securities Purchase Agreement (the "Registered Purchase Agreement") with a single institutional accredited investor, pursuant to which the Company agreed to issue and sell (i) 448,000 shares (the "Shares") of the Companies' common stock at a price per Share of $1.55, and (ii) pre-funded warrants (the "Pre-funded Warrants") to purchase 1,492,299 shares of common stock, at a price per Pre-funded Warrant equal to the price per Share, less $0.001 (the "Registered Offering"). The Pre-funded Warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full. The Company received approximately $3.0 million in gross proceeds from the Registered Offering, before deducting placement agency fees and estimated offering expenses.

On January 27, 2023, the Company also entered into a Securities Purchase Agreement (the "PIPE Purchase Agreement") with the same institutional accredited investor for a private placement offering ("Private Placement") of the January 2023 Warrants to purchase 1,940,299 shares of common stock. Pursuant to the PIPE Purchase Agreement, we agreed to issue and sell the January 2023 Warrants at an offering price of $0.125 per January 2023 Warrant to purchase one share of common stock. The January 2023 Warrants have an exercise price of $1.55 per share (subject to adjustment as set forth in the January 2023 Warrants), are exercisable immediately after issuance and will expire three years from the date on which the January 2023 Warrants become exercisable. The January 2023 Warrants contain standard anti-dilution adjustments to the exercise price including for share splits, share dividend, rights offerings and pro rata distributions. The Private Placement closed on January 31, 2023, concurrently with the Registered Offering. The gross proceeds to us from the Private Placement, before deducting placement agent fees and other estimated offering expenses payable by us, were approximately $0.24 million.

InvaGen Share Repurchase

Under the Share Repurchase Agreement, we agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4.0 million. In connection with the closing of the January 2023 Registered Direct and Private Placement, we made a payment of $0.2 million to InvaGen on February 3, 2023.

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"), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "will," "could," "project," "should," "intend" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in or implied by these forward-looking statements due to a variety of factors, including, without limitation:

- *the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized;*
- *the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates;*
- *our ability to successfully integrate Baergic Bio, Inc. or develop BAER-101 or AJ201;*
- *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 or unreliable;*
- *the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons;*
- *the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny;*
- *the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations;*
- *the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications;*
- *the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products;*
- *our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates;*
- *our exposure to potential product liability claims;*
- *related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;*
- *our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business;*
- *the fact that Fortress controls a voting majority of our common stock and has rights to receive significant share grants annually; and*
- *and the risks described in under the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 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.

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 AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA"), intravenous tramadol ("IV tramadol") for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders.

Our net loss for the six months ended June 30, 2023 and 2022 was approximately $11.6 million and $3.5 million, respectively. As of June 30, 2023, we had an accumulated deficit of approximately $92.1 million. Substantially all our net losses resulted from costs incurred in connection with the ongoing AJ201 Phase 1b/2a clinical trial, our research and development program of IV tramadol, and from general and administrative costs associated with our operations.

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

We intend to obtain additional capital through the sale of debt or equity financings or other arrangements including partnering our assets to fund our operations, research and development activity or regulatory approval activity; however, there can be no assurance that we will be able to raise the necessary capital under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding shares of our common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to stockholders. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

We are a majority-controlled subsidiary of Fortress. For related party transactions, see Note 4 to our financial statements included in this Quarterly Report on Form 10-Q.

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

AJ201

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

Under the AnnJi License Agreement, in exchange for exclusive rights to the intellectual property underlying the AJ201 product candidate, the Company will pay an initial cash license fee of $3.0 million, of which $2.0 million was paid on April 27, 2023 and $1.0 million payable within 180 days after the effective date of the AnnJi License Agreement. The Company is also obligated to issue shares of its common stock under the Subscription Agreement (described below) and make additional payments over the course of the AnnJi License Agreement including reimbursement payments of up to $10.8 million in connection with the product's Phase 1b/2a clinical trial.

In connection with the signing of the AnnJi License Agreement, the Company agreed to issue 831,618 shares of its common stock to AnnJi (the "First Tranche Shares"), and then to issue an additional 276,652 shares of Common Stock upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial (the "Second Tranche Shares" and, together with the First Tranche Shares, the "Consideration Shares"). The license provided under the AnnJi License Agreement is exclusive as to all oral forms of AJ201 for use in all indications (other than androgenetic alopecia and Alzheimer's disease) in the United States, Canada, the European Union, the United Kingdom and Israel. The AnnJi License Agreement also contains customary representations and warranties and provisions related to confidentiality, diligence, indemnification and intellectual property protection. The Company will initially be obligated to obtain both clinical and commercial supply of AJ201 exclusively through AnnJi. The Company and AnnJi entered into a subscription agreement, dated as of February 28, 2023 (the "Subscription Agreement") that provides for the issuance of First Tranche Shares, which contains customary representations and warranties of the Company and AnnJi, respectively, and is subject to customary closing conditions. The Company and AnnJi will enter into a subsequent subscription agreement, in substantially the same form as the Subscription Agreement, with respect to the issuance of the Second Tranche Shares. In connection with the execution of the AnnJi License Agreement, we entered into a registration rights agreement pursuant to which the Company agreed to file a registration statement to register the resale of the Consideration Shares. The Company filed such registration statement on Form S-3 on June 16, 2023, and the registration statement was subsequently declared effective by the SEC on June 27, 2023

In July 2023, we announced the first patient was dosed in the Phase 1b/2a trial of AJ201 for the treatment of SBMA. The 12-week, multicenter, randomized, double-blind trial is expected to enroll approximately 24 patients, randomly assigned to AJ201 (600mg/day) or placebo. The primary endpoint of the study is to assess safety and tolerability of AJ201 in subjects with clinically and genetically defined SBMA. Secondary endpoints include pharmacodynamic data measuring change from baseline in mutant androgen receptor protein levels in skeletal muscle and changes in the fat and muscle composition as seen on MRI scans. Further details on the study can be found using the ClinicalTrials.gov identifier NCT05517603. Information on clinicaltrials.gov does not constitute part of this Quarterly Report on Form 10-Q.

IV Tramadol

In February 2022, we had our Advisory Committee meeting with the U.S. Food and Drug Administration ("FDA") regarding IV tramadol. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. In March 2022, we received an Appeal Denied Letter from the OND in response to the FDRR. In August 2022, the Company participated in a Type A Meeting with the FDA Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") regarding a briefing document submitted that presented a study design the Company believed would have the potential to address the comments and deficiencies noted in the Letter. The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. We incorporated the FDA's suggestions from the meeting minutes and submitted a detailed study protocol.

The Company 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 the Company has received official meeting minutes from the Type C meeting with the FDA. The Type C meeting minutes indicate that the FDA and the Company are in agreement with 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 DAAAP.

In July 2023, the Company announced alignment with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach. The non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine.

The study will randomize post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. 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 expect to submit the revised protocol to the FDA including the statistical plan, which reflects the study design previously discussed, for final review. Pending additional financing, we aim to initiate the Phase 3 safety study as soon as feasible.

BAER-101

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

In August 2023, we reported preclinical data for BAER-101 from an in vivo evaluation in SynapCell's Genetic Absence Epilepsy Rate from Strasbourg ("GAERS") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti-seizure drug development. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg administered orally.

Under the Contribution Agreement, Fortress also agreed to assign to us certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement.

Reverse Stock Split

On September 23, 2022, the Company effected a 1-for-15 reverse stock split of its common stock (the "Reverse Stock Split") without any change in the par value per share of the common stock. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

Resale Registration Statement

In connection with the previously disclosed January 2023 registered direct and private placement transactions, we entered into a registration rights agreement pursuant to which the Company agreed to file a registration statement to register the resale of the shares issuable upon exercise of the private placement warrants. The Company filed such registration statement on Form S-1 on April 11, 2023, and the registration statement was subsequently declared effective by the SEC on May 3, 2023.

Nasdaq Deficiency Letter

On May 19, 2023, we received a deficiency letter (the "Nasdaq Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq"), notifying us that we are not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires us to maintain a minimum of $2,500,000 in stockholders' equity for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"), nor in compliance with either of the alternative listing standards, market value of listed securities of at least $35 million or net income of $500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. Our failure to comply with the Stockholders' Equity Requirement was based on the filing of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, reporting the stockholders' equity of negative $2,157,000. Pursuant to the Nasdaq Letter, we had 45 calendar days from the date of the Nasdaq Letter to submit a plan to regain compliance. On July 3, 2023, we submitted a compliance plan (the "Compliance Plan") to Nasdaq.

Increase in Authorized Shares

On February 2, 2023, following the approval of our Board and our stockholders at the Company's 2022 annual meeting of stockholders, we filed an amendment to our Third Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock from 20,000,000 to 75,000,000 shares.

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 GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the Management's Discussion and Analysis of the Results of Operations in the 2022 Form 10- K.

There were no material changes in our critical accounting estimates or accounting policies from December 31, 2022.

Results of Operations

General

At June 30, 2023, we had an accumulated deficit of $92.1 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate are still in development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Comparison of the Three Months Ended June 30, 2023 and 2022

	For The Three Months Ended June 30,		Change	
($ in thousands)	**2023**	**2022**	**$**	**%**
Operating expenses:				
Research and development	$ 3,027	$ 151	$ 2,876	1905%
General and administrative	896	454	442	97%
Loss from operations	(3,923)	(605)	(3,318)	548%
Other income (expense)				
Interest income	57	1	56	5600%
Change in fair value of warrant liabilities	(150)	—	(150)	—%
Total other income (expense)	(93)	1	(94)	(9400)%
Net Loss	$ (4,016)	$ (604)	$ (3,412)	565%
Net loss attributable to non-controlling interests	9	—	9	—%
Net loss attributable to common stockholders	(4,007)	(604)	(3,403)	563%

Research and Development Expenses

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

For the three months ended June 30, 2023 and 2022, research and development expenses were $3.0 million and $0.2 million, respectively. The increase of $2.8 million is primarily associated with a $2.6 million increase in AJ201 clinical study expenses, $0.1 million increase in BAER-101 pre-clinical study expense and $0.1 million Fortress-Avenue MSA fee.

We expect our research and development activities to continue as we attempt to gain regulatory approval for our existing product candidate, reflecting costs associated with the following:

- employee-related expenses;
- license fees and milestone payments related to in-licensed product and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory 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 June 30, 2023 and 2022, general and administrative expenses were $0.9 million and $0.5 million, respectively. The increase of $0.4 million is primarily related to $0.2 million of professional fees, $0.1 million in salary expense and $0.1 million Fortress-Avenue MSA fee.

Interest Income

Interest income was $57,000 and $1,000 for the three months ended June 30, 2023 and 2022, respectively. The increase in interest income was due to the increase in cash and higher interest rates.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a loss of $0.2 million and $0 for the three months ended June 30, 2023 and June 30, 2022, respectively. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The change in the fair value of warrant liabilities was primarily due to the fluctuation in our stock price.

Comparison of the Six Months Ended June 30, 2023 and 2022

	For the Six Months Ended June 30,		Change	
($ in thousands)	**2023**	**2022**	**$**	**%**
Operating expenses:				
Research and development	$ 4,242	$ 1,959	$ 2,283	117%
Research and development – licenses acquired	4,230	—	4,230	—%
General and administrative	1,880	1,509	371	25%
Loss from operations	(10,352)	(3,468)	(6,884)	199%
Interest income	94	3	91	3033%
Financing costs – warrant liabilities	(332)	—	(332)	—%
Change in fair value of warrant liabilities	(1,028)	—	(1,028)	—%
Net Loss	$ (11,618)	$ (3,465)	$ (8,153)	235%
Net loss attributable to non-controlling interests	75	—	75	—%
Net loss attributable to common stockholders	(11,543)	(3,465)	(8,078)	233%

Research and Development Expenses

For the six months ended June 30, 2023 and 2022, research and development expenses were $4.2 million and $2.0 million, respectively. The increase of $2.2 million is primarily associated with an increase of $3.5 million in AJ201 clinical study expenses offset by a decrease of $0.9 million in IV tramadol advisory committee preparation and costs, $0.2 million in bonus costs and $0.2 million in non-cash stock compensation costs.

For the six months ended June 30, 2023 and 2022, research and development - licenses acquired expenses were $4.2 million and $0, respectively. The increase of $4.2 million is primarily associated with the AnnJi License Agreement which includes a $3.0 million cash license expense and $1.2 million expense for the fair value of the First Tranche Shares and Second Tranche Shares.

We expect our research and development activities to continue as we attempt to gain regulatory approval for our existing product candidate, reflecting costs associated with the following:

- employee-related expenses;
- license fees and milestone payments related to in-licensed product and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory interactions, submissions, and approvals.

General and Administrative Expenses

For the six months ended June 30, 2023 and 2022, general and administrative expenses were $1.9 million and $1.5 million, respectively. The increase of $0.4 million is primarily related to $0.2 million of professional fees, $0.1 million Fortress-Avenue MSA fee and $0.1 million in salary expense.

Interest Income

Interest income was $94,000 and $3,000 for the six months ended June 30, 2023 and 2022, respectively. The increase in interest income was due to the increase in cash and higher interest rates.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a loss of $1.0 million and $0 for the six months ended June 30, 2023 and June 30, 2022, respectively. We issued stock purchase warrants that are required to be classified as a liability and 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

Going Concern

The Company is not yet generating revenue, has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of June 30, 2023, we had a cash and cash equivalents balance of $1.6 million and accumulated deficit of $92.1 million. We do not believe that our cash is sufficient for the next twelve months. As a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including potentially obtaining lines of credit, debt or equity financings or other arrangements. Our future success depends on our ability to raise capital and/or implement the various strategic alternatives discussed above. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities or even terminate our operations.

Recently Adopted and Issued Accounting Pronouncements

As of June 30, 2023, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2022 Form 10-K that would materially affect the Company's present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

Cash Flows for the Six Months Ended June 30, 2023 and 2022

	For the Six Months Ended June 30,	
($ in thousands)	**2023**	**2022**
Total cash and cash equivalents provided by (used in):		
Operating activities	$ (6,238)	$ (2,873)
Investing activities	(2,000)	—
Financing activities	3,101	—
Net increase in cash and cash equivalents	$ (5,137)	$ (2,873)

Operating Activities

Net cash and cash equivalents used in operating activities was $6.2 million for the six months ended June 30, 2023, primarily comprised of our $11.6 million net loss partially offset by an increase in operating assets and liabilities of $1.0 million, $2.0 million in research and development AJ201 license expense, $1.2 million in stock issuance for licenses acquired, $1.0 million change in fair value of warrant liability and $0.1 million in common share issuance to Fortress.

Net cash and cash equivalents used in operating activities was $2.9 million for the six months ended June 30, 2022, primarily comprised of our $3.5 million net loss partially offset by $0.6 million in share based compensation.

Investing Activities

Net cash and cash equivalents used in investing activities was $2.0 million for the six months ended June 30, 2023, primarily comprised of the $2.0 million AJ201 license payment.

Financing Activities

Net cash and cash equivalents provided by financing activities was $3.1 million for the six months ended June 30, 2023, primarily comprised of the $3.1 million Registered Direct and Private Placement on January 31, 2023.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and interim Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2023, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company's Chief Executive Officer and interim Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2023 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 not deemed material are not expected to have a material adverse effect on our financial condition, results of operations, or cash flows. In the ordinary course of business, however, the Company may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's 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 2022 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 2022 Form 10-K, the information below, and the other information set forth elsewhere in this Quarterly Report on Form 10-Q. You should be aware that these risk factors and other information may not describe every risk facing our Company. Additional risks and uncertainties not currently known to us may also materially adversely affect our business, financial condition and/or results of operations.

Item 2. Recent Sales of Unregistered Securities.

N/A.

Item 3. Defaults Upon Senior Securities.

N/A.

Item 4. Mine Safety Disclosures.

N/A.

Item 5. Other Information.

N/A.

Item 6. Financial Statements and Exhibits

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 27, 2017 (File No. 001-38114) and incorporated herein by reference.
3.2	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-Q filed on August 14, 2018 (File No. 001-38114) and incorporated herein by reference.
3.3	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	Second Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 10, 2023 (File No. 000-38114) and incorporated herein by reference.
31.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 11, 2023. *
31.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 11, 2023. *
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 August 11, 2023. **
32.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 11, 2023. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements. *
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). *

* Filed herewith.
** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Avenue Therapeutics, Inc.
(Registrant)

Date: August 11, 2023

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

Date: August 11, 2023

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

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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)
August 11, 2023

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 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)
August 11, 2023

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 June 30, 2023 (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)
August 11, 2023

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 June 30, 2023 (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)
August 11, 2023