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DELTA REPORT

10-Q

ATXI - AVENUE THERAPEUTICS, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	3032
CHANGES	140
DELETIONS	678
ADDITIONS	2214

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

FORM 10-Q

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

For the quarterly period ended September 30, 2023 March 31, 2024

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 November 8, 2023 May 13, 2024
Common Stock, $0.0001 par value	13,247,622 940,986

AVENUE THERAPEUTICS, INC.

Form 10-Q

For the Quarter Ended September 30, 2023 March 31, 2024

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AVENUE THERAPEUTICS, INC.

Unaudited Condensed Consolidated Balance Sheets

($ in thousands, except share and per share amounts)

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023

ASSETS				
Current assets:				
Cash and cash equivalents	$ 161	$ 6,708	$ 3,194	$ 1,783
Other receivables - related party	13	—		
Deferred financing costs	310	—		
Prepaid expenses and other current assets	18	137	116	67
Total assets	$ 502	$ 6,845	$ 3,310	$ 1,850
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable and accrued expenses	$ 1,460	$ 949	$ 647	$ 287
Accounts payable and accrued expenses - related party	264	21	352	323
Warrant liability	3,300	2,609	413	586
Total current liabilities	5,024	3,579	1,412	1,196
Total liabilities	5,024	3,579	1,412	1,196
Commitments and contingencies				
Stockholders' equity (deficit)				
Preferred stock ($0.0001 par value), 2,000,000 shares authorized				
Class A Preferred Stock, 250,000 shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—		
Common stock ($0.0001 par value), 75,000,000 shares authorized				
Common shares, 8,964,222 and 4,773,841 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	—		
Class A Preferred Stock, 250,000 shares issued and outstanding as of March 31, 2024 and December 31, 2023			—	—
Common stock ($0.0001 par value), 200,000,000 and 75,000,000 shares authorized as of March 31, 2024 and December 31, 2023, respectively				
Common shares, 590,188 and 341,324 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			—	3
Additional paid-in capital	87,917	84,456	98,104	92,507
Accumulated deficit	(91,568)	(80,551)	(95,268)	(90,928)
Total stockholders' equity attributed to the Company	(3,650)	3,905	2,836	1,582
Non-controlling interests	(872)	(639)	(938)	(928)
Total stockholders' equity (deficit)	(4,522)	3,266		
Total stockholders' equity			1,898	654
Total liabilities and stockholders' equity	$ 502	$ 6,845	$ 3,310	$ 1,850

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

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AVENUE THERAPEUTICS, INC.

Unaudited Condensed Consolidated Statements of Operations

($ in thousands, except share and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		For the Three Months Ended March 31,	
	2023	**2022**	**2023**	**2022**	**2024**	**2023**
Operating expenses:						
Research and development	$ 907	$ 194	$ 5,149	$ 2,153	$ 2,392	$ 1,215
Research and development – licenses acquired	—	—	4,230	—	—	4,230
General and administrative	1,161	469	3,042	1,978	1,316	984
Loss from operations	(2,068)	(663)	(12,421)	(4,131)	(3,708)	(6,429)
Other income (expense):						
Interest income	9	1	104	4	49	37
Financing costs – warrant liabilities	—	—	(332)	—	—	(332)
Loss on settlement of common stock warrant liabilities					(574)	—
Change in fair value of warrant liabilities	2,572	—	1,544	—	(116)	(878)
Total other income (expense)	2,581	1	1,316	4	(641)	(1,173)
Net income (loss)	$ 513	$ (662)	$ (11,105)	$ (4,127)		
Net loss					$ (4,349)	$ (7,602)
Net income (loss) attributable to non-controlling interests	(13)	—	(88)	—		
Net income (loss) attributable to common stockholders	$ 526	$ (662)	$ (11,017)	$ (4,127)		
Net loss attributable to non-controlling interests					(9)	(66)
Net loss attributable to common stockholders					$ (4,340)	$ (7,536)
Net income (loss) per common share attributable to common stockholders:						
Basic	$ 0.06	$ (0.45)	$ (1.54)	$ (2.86)		
Diluted	$ 0.06	$ (0.45)	$ (1.54)	$ (2.86)		
Net loss per common share attributable to common stockholders, basic and diluted					$ (15.40)	$ (101.57)
Weighted average number of common shares outstanding:						

Basic	8,114,155	1,465,691	7,155,050	1,441,542		
Diluted	8,200,069	1,465,691	7,155,050	1,441,542		
Weighted average number of common shares outstanding, basic and diluted					562,031	74,198

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 September 30, 2023								
	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	
Balance at June 30, 2023	250,000	$ —	7,920,485	$ 1	$ 86,757	$ (92,094)	$ (810)	$ (6,146)
Share based compensation	—	—	—	—	561	—	—	561
Shares issued in a private placement offering	—	—	767,085	—	550	—	—	550
Issuance of common stock for license expense	—	—	276,652	—	—	—	—	—
Non-controlling interest in subsidiaries	—	—	—	—	49	—	(49)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(13)	(13)
Net income attributable to common stockholders	—	—	—	—	—	526	—	526
Balance at September 30, 2023	250,000	$ —	8,964,222	$ 1	$ 87,917	$ (91,568)	$ (872)	$ (4,522)

Three months ended March 31, 2024								
	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders'

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

Nine Months Ended September 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	—	—	—	—	599	—	—	599
Issuance of common stock to Fortress	—	—	374,644	—	72	—	—	72

	Class A Preferred Shares - Shares	Class A Preferred Shares - Amount	Common Shares - Shares	Common Shares - Amount	Additional Paid-in Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity (Deficit)
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	—	—	1,108,270	—	1,230	—	—	1,230
Exercise of warrants	—	—	1,492,382	—	—	—	—	—
Shares issued in a private placement offering	—	—	767,085	—	550	—	—	550
Non-controlling interest in subsidiaries	—	—	—	—	145	—	(145)	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(88)	(88)
Net loss attributable to common stockholders	—	—	—	—	—	(11,017)	—	(11,017)
Balance at September 30, 2023	250,000	$ —	8,964,222	$ 1	$ 87,917	$ (91,568)	$ (872)	$ (4,522)

Three months ended September 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 June 30, 2022	250,000	$ —	1,475,608	$ 2	$ 81,060	$ (80,464)	$ —	$ 598
Reverse stock split adjustment	—	—	—	(2)	2	—	—	—
Share based compensation	—	—	5,831	—	25	—	—	25
Net loss	—	—	—	—	—	(662)	—	(662)
Balance at September 30, 2022	250,000	$ —	1,481,439	$ —	$ 81,087	$ (81,126)	$ —	$ (39)

Nine Months Ended September 30, 2022

	Class A Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Non-Controlling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	(Deficit)
Balance at December 31, 2021	250,000	$ —	1,405,934	$ 2	$ 80,448	$ (76,999)	$ —	$ 3,451

Reverse stock split adjustment	—	—	—	(2)	2	—	—	—
Share based compensation	—	—	75,505	—	637	—	—	637
Net loss	—	—	—	—	—	(4,127)	—	(4,127)
Balance at September 30, 2022	250,000	$ —	1,481,439	$ —	$ 81,087	$ (81,126)	$ —	$ (39)

Three months ended March 31, 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	$ —	63,671	$ —	$ 84,456	$ (80,551)	$ (639)	$ 3,266
Share based compensation	—	—	—	—	11	—	—	11
Issuance of common stock to Fortress	—	—	4,997	—	72	—	—	72
Issuance of common stock and pre-funded warrants, net of offering costs - registered direct offering and private placement	—	—	5,974	—	865	—	—	865
Issuance of common stock for license acquisition	—	—	11,089	—	1,231	—	—	1,231
Exercise of warrants	—	—	5,335	—	—	—	—	—
Net loss attributable to non-controlling interest	—	—	—	—	—	—	(66)	(66)
Net loss attributable to common stockholders	—	—	—	—	—	(7,536)	—	(7,536)
Balance at March 31, 2023	250,000	$ —	91,066	$ —	$ 86,635	$ (88,087)	$ (705)	$ (2,157)

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 Nine Months Ended		For the Three Months Ended	
	September 30, 2023	September 30, 2022	March 31, 2024	March 31, 2023
Cash flows from operating activities:				
Net loss	$ (11,105)	$ (4,127)	$ (4,349)	$ (7,602)
Reconciliation of net loss to net cash used in operating activities:				
Share based compensation	599	637	191	11
Change in fair value of warrant liability	(1,544)	—		
Loss on settlement of common stock warrant liabilities			574	—
Change in fair value of warrant liabilities			116	878
Issuance of common stock for licenses acquired	1,230	—	—	1,230
Research and development - licenses acquired	3,000			
Issuance of common stock to Fortress	72	—	371	72
Common shares issuable - Founders Agreement			(363)	—
Changes in operating assets and liabilities:				
Other receivables - related party	(13)	90	—	(13)
Prepaid expenses and other current assets	119	87	(49)	(61)
Accounts payable and accrued expenses	511	(97)	360	889
Deferred financing costs	(239)	—		
Accrued licenses acquired			—	3,000
Accounts payable and accrued expenses - related party	243	(17)	29	23
Net cash used in operating activities	(7,127)	(3,427)	(3,120)	(1,573)
Cash flows from investing activities:				
Purchase of research and development licenses	(3,000)	—		
Net cash used in investing activities	(3,000)	—		
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	—		
Shares issued in a private placement offering	550	—		
Deferred financing costs	(71)	(119)		
Net cash provided by (used in) financing activities	3,580	(119)		
Issuance of common stock and pre-funded warrants, net of offering costs - registered direct offering and private placement			—	3,101
Exercise of warrants			4,973	—
Warrant transaction costs			(442)	—
Net cash provided by financing activities			4,531	3,101

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Net change in cash and cash equivalents	(6,547)	(3,546)	1,411	1,528
Cash and cash equivalents, beginning of period	6,708	3,763	1,783	6,708
Cash and cash equivalents, end of period	$ 161	$ 217	$ 3,194	$ 8,236
Supplemental cash flow information:				
Unpaid financing costs	$ 239	$ 219		
Unpaid research and development licenses acquired			$ —	$ 3,000
Issuance of common shares - Founders Agreement			$ 371	$ —

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

AVENUE THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Organization, Plan of Business Operations

Avenue Therapeutics, Inc. (the “Company” or “Avenue”) was incorporated in Delaware on February 9, 2015, as a wholly-owned subsidiary of Fortress Biotech, Inc. (“Fortress”). Avenue is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Avenue's current product candidates include AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA", also known as Kennedy's Disease), intravenous tramadol ("IV tramadol") for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders.

Authorized Share Increase

On January 9, 2024, stockholders holding a majority of the outstanding voting power of the Company executed and delivered to the Board of Directors of the Company a written consent approving, among other items, an increase in the number of shares of common stock, par value $0.0001 per share ("common stock"), authorized under the Company’s Third Amended and Restated Certificate of Incorporation, as amended (the “Certificate of Incorporation”), from 75,000,000 to 200,000,000 (the “Authorized Shares Increase”). On February 20, 2024, the Company filed a Certificate of Amendment to its Certificate of Incorporation (the “Certificate of Amendment”) with the Secretary of State for the State of Delaware effectuating the Authorized Shares Increase.

Reverse Stock Split

On April 25, 2024, the Company filed an amendment (the “Reverse Split Amendment”) to the Company’s Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the 1-for-75 reverse stock split of the Company's shares of common stock ("Reverse Stock Split"). As a result of the reverse stock split effective on September 23, 2022, Reverse Stock Split, every 15 75 shares of common stock outstanding immediately prior to the effectiveness of the reverse stock split Reverse Stock Split were combined and converted into one share of common stock without any change in the par value per share. The Reverse Stock Split became effective on April 26, 2024, and the common stock was quoted on the Nasdaq Stock Market on a post-split basis at the open of business on April 26, 2024. No fractional shares were issued in connection with the reverse stock split. In connection with the reverse stock split, the holders Reverse Stock Split. Stockholders who would have otherwise been entitled to a fraction of a majority of the voting power of Avenue's capital stock executed a written consent approving the reduction of the number of authorized sharesone share of common stock immediately after as a result of the reverse stock split from 50,000,000 to 20,000,000 shares, which reduction became effective on Reverse Stock Split instead received September 23, 2022. On February 2, 2023, following the approval of Avenue's Board of Directors and Avenue's stockholders at the Company’s 2022 one annual meeting of stockholders, the Avenue filed an amendment to Avenue's Third Amended and Restated Certificate of Incorporation to increase the number of authorized shares whole share of common stock from 20,000,000 to 75,000,000 shares. stock.

All share and per share information has been retroactively adjusted to give effect to the reverse stock split 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 ("U.S. GAAP") assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, as described below, substantial doubt about the Company's ability to continue as a going concern exists.

The Company is not yet generating revenue, has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of September 30, 2023 March 31, 2024, the Company had an accumulated deficit of $91.6 million $95.3 million. Due to uncertainties regarding future operations of the Company for an ongoing Phase 1b/2a trial of AJ201, a study protocol that could form the basis for the submission of a complete response to the potential Phase second 3 Complete Response Letter safety study for IV tramadol, and the expansion of the Company's 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, including through at-the-market ("ATM") 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. subsidiary. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the eliminated.

The accompanying unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement accounts of the balances and results for Company's subsidiary, Baergic. Because the periods presented. Company owns less than 100% of Baergic, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in Baergic by the respective non-controlling parties. The Company continually assesses whether changes to existing relationships or future transactions may result in the consolidation or deconsolidation of its' subsidiary.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These unaudited interim condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Therefore, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2022, 2023, which were included in the Company's Annual Report on Form 10-K (the "2022 2023 Form 10-K") and filed with the U.S. Securities and Exchange Commission ("SEC") on March 31, 2023. 18, 2024.

The Company's unaudited condensed consolidated financial statements include

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the results of the Company's subsidiary for which the Company maintains voting control but does not own 100% of the outstanding equity. chief operating decision maker, or decision-making group, in deciding how to allocate resources and assessing performance. The Company records net loss attributable to non-controlling interests in views its consolidated statements of operations and presents non-controlling interests as a component manages its business in one operating and reportable segment.

Use of stockholders' equity on its consolidated balance sheets. All intercompany income and/or expense items are eliminated entirely in consolidation prior to the allocation of net gain/loss attributable to non-controlling interest, which is based on ownership interests as calculated quarterly for the subsidiary. Estimates

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the 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 Actual results may could differ from these those estimates.

Other Receivables Fair Value Measurements– Related Party

Other receivables consist 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 amounts due from Urica Therapeutics, Inc. ("Urica"), 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 consolidated entity under Fortress, 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 the invoiced amount. amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities.

Non-Controlling Interests

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

Net Loss per Share

Net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends. The Company recorded a deemed dividend of $4.3 million for the modification of certain of its existing warrants and issuance of warrants during the three months ended March 31, 2024 (see Note 7 and 8). Diluted net loss per share excludes unvested restricted stock, preferred shares and the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. Dividends declared are paid and set aside among the holders of shares of common stock and Class A Preferred stock pro-rata on an as-if-converted basis.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the Thre
	Ma
	2024
Unvested restricted stock units/awards	1,028
Warrants	745,139
Options	22,474
Class A Preferred shares	223
Total potential dilutive effect	768,864

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 2023 Form 10-K.

Note 3 — Licenses/Supplier Agreements

IV Tramadol License

Effective as of February 17, 2015, Fortress transferred the Revogenex license and all other rights and obligations under the IV Tramadol License Agreement to the Company, pursuant to the terms of the Founders Agreement. In connection with the terms of the IV Tramadol License Agreement, Fortress purchased an exclusive license to IV tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland. 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 for certain intellectual property rights pertaining to the molecule known as JM17, AJ201. 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, $3.0 million, of which $2.0 million $2.0 million was paid on April 27, 2023 and $1.0 million $1.0 million was paid on September 8, 2023.

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.*

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.

In connection with the signing of the AnnJi License Agreement, the Company issued 831,618 11,089 shares of its common stock to AnnJi ("First Tranche Shares") at a fair value of $0.9 million $0.9 million on March 30, 2023. The Company issued 276,652 3,688 shares of common stock ("Second Tranche Shares"), recorded at a fair value of $0.3 million, $0.3 million, on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. The fair value was calculated based on the closing price of the Company's stock as of February 28, 2023, the date the Company entered into the license agreement. 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. License Agreement. 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 Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

In February 2015, Fortress entered into a Management Services Agreement (the "MSA") with the Company to provide services for the Company pursuant to the terms of the MSA. Expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Condensed Consolidated Statements of Operations. For the three months ended March 31, 2024 and 2023, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively.

In February 2015, Fortress entered into a Founders Agreement with the Company, under which the Company agreed to: (i) issue annually to Fortress, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of the Company at the time of issuance (the "Annual Equity Fee") and (ii) issue shares of the common stock equal to two and one half percent (2.5%) of the gross amount of any equity or debt financing (the "Financing Equity Fee"). Pursuant to the Founders Agreement, for the three months ended March 31, 2024 and 2023, the Company issued common stock to Fortress of 5,543 shares and 1,912 shares, respectively, as a Financing Equity Fee. Additionally, the Company recorded a Financing Equity Fee of 5,513 shares of common stock issuable to Fortress for the three-month period ending March 31, 2024.

Pursuant to the Third Amended and Restated Certificate of Incorporation, the Company issued 22,476 shares of common stock to Fortress for the Annual Equity Fee during the three-month period ending March 31, 2024. The Company recorded an expense of approximately $0.3 million in research and development related to these issuable shares during the year ended December 31, 2023. For the three months ended March 31, 2023, the Company issued 3,085 shares of the Company's common stock as an Annual Equity Fee. The Company recorded an expense of approximately $0.3 million in research and development related to these issuable shares during the year ended December 31, 2022.

Founders Agreement and Management Services Agreement with Baergic

Pursuant to the Share Contribution Agreement between Avenue and Fortress, the Founders Agreement and Management Services Agreement that had previously been existing between Fortress and Baergic were assigned to Avenue, such that they now exist between Avenue and Baergic; those agreements are referred to herein as the Avenue-Baergic Founders Agreement and the Avenue-Baergic MSA, as applicable.

The Annual Stock Dividend payable to the Company is 2.5% of common stock calculated as a percentage of fully diluted outstanding capital and became effective as of November 8, 2022.

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

As additional consideration under the Avenue-Baergic Founders Agreement, Baergic will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Baergic that occurs after the effective date of the Avenue-Baergic Founders Agreement and 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.

Note5 — Accounts Payable and Accrued Expenses

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

	As of March 31, 2024
Accounts payable	$ 310
Accrued employee compensation	94
Accrued contracted services and other	243
Total accounts payable and accrued expenses	$ 647

Note6-Commitments and Contingencies

Leases

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

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company will accrue the most likely amount of such loss, and if such amount is not determinable, then the Company will accrue the minimum of the range of probable loss. As of March 31, 2024, there was no litigation against the Company.

Note 7 - Stockholder's Equity

Class A Preferred Stock

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

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

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

Common Stock

On January 9, 2024, the stockholders holding a majority of the outstanding voting power of the Company executed and delivered to the Board of Directors of the Company a written consent approving, among other items, an increase in the number of shares of common stock authorized under the Certificate of Incorporation, from 75,000,000 to 200,000,000. On February 20, 2024, the Company filed the Certificate of Amendment with the Secretary of State for the State of Delaware effectuating the Authorized Shares Increase.

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

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

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No.333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). Approximately $24.9 million of securities remain available for sale under the 2021 Shelf as of March 31, 2024.

January 2024 Warrant Inducement and Private Placement

On January 5, 2024, the Company entered into (i) an inducement offer letter agreement (the “January 2023 Investor Inducement Letter”) with a certain investor (the “January 2023 Investor”) in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 of the Company’s common stock originally issued to the January 2023 Investor on January 31, 2023 (the “January 2023 Warrants”) and (ii) an inducement offer letter agreement (the “November 2023 Investor Inducement Letter Agreement” and, together with the January 2023 Investor Inducement Letter, the “January 2024 Warrant Inducement”) with certain investors (the “November 2023 Investors” and, together with the January 2023 Investor, the “Holders”) in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the November 2023 Investors on November 2, 2023 (the “November 2023 Warrants” and, together with the January 2023 Warrants, the “Existing Warrants”). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company’s agreement to issue in a private placement (x) new Series A common stock purchase warrants (the “New Series A Warrants”) to purchase up to 220,538 shares of common stock (the “New Series A Warrants Shares”) and (y) new Series B common stock purchase warrants (the “New Series B Warrants” and, together with the New Series A Warrants, the “New Warrants”) to purchase up to 220,538 shares of common stock (the “New Series B Warrants Shares”). The New Series A Warrants will expire five years following the issuance date and the New Series B Warrants will expire eighteen months following the issuance date.

The January 2023 Warrants, which were liability classified, were revalued on January 5, 2024 using the Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $0.1 million was recorded as a change in fair value of warrant liabilities in the Condensed Consolidated Statements of Operations (see Note 8). The issuance of the New Warrants was considered as part of the cost of the inducement and the New Warrants were valued using the Black-Scholes Model and allocated between the January 2023 Warrants and November 2023 Warrants on a weighted basis. The approximately $0.6 million of the New Warrants fair value allocated to the January 2023 warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the New Warrant fair value was allocated to the November 2023 Warrants and deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).

The Company received aggregate net proceeds of approximately $4.5 million from the exercise of the Existing Warrants by the Holders, after deducting placement agent fees and other expenses payable by the Company.

The Company filed a registration statement on Form S-3 (File No.333-276671) with the SEC providing for the resale of the New Warrant Shares (the “Resale Registration Statement”) on January 24, 2024, which was declared effective on February 1, 2024.

The key inputs for the Black-Scholes Model calculations on January 5, 2024 were as follows:

	January 2023 Warrants	New Series A Warrants
Stock price	$ 14.25	$ 14.2
Risk-free interest rate	4.40 %	4.0
Expected dividend yield	—	–
Expected term in years	2.1	5.
Expected volatility	185 %	13

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the "2015 Incentive Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and an amendment to the plan to increase the number of authorized shares issuable to 3,556 shares was approved by the Company's stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 70,223 shares and approved by the Company's 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 70,223 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 44,701 shares at March 31, 2024.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 2024:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested balance at December 31, 2023	1,311	$ 196.21
Granted	—	—
Forfeited	—	—
Vested	(283)	85.50
Unvested balance at March 31, 2024	1,028	$ 226.69

At March 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years. This amount does not include, as of March 31, 2024, 45 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2024:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	22,474	$ 85.50	9.5	$ —
Granted	—	$ —		$ —
Exercised	—	$ —		$ —
Cancelled/forfeited	—	$ —		$ —
Expired	—	$ —		$ —
Outstanding at Balance at March 31, 2024	22,474	$ 85.50	9.2	$ —

Expected to vest	*16,304*	*$*	*85.50*	*9.2*	*$*	*—*
Exercisable	*6,170*	*$*	*85.50*	*9.2*	*$*	*—*

There were no options granted in the three-month period ending March 31, 2024. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2024, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.7 million with a weighted average remaining vesting period of 1.6 years.

The Company did not grant any stock options in the three months ended March 31, 2024 and 2023.

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

	For the three months ended	
	March 31, 2024	March 31, 2023
Research and development	$ 45	$ —
General and administrative	146	11
Total stock-based compensation expense	$ 191	$ 11

Stock Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2024 and 2023:

	Warrants	Weighted Average Exercise Price
Outstanding, December 31, 2023	524,601	$ 32.42
Granted	441,076	22.55
Exercised	(220,538)	22.55
Outstanding, March 31, 2024	745,139	$ 29.50

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

InvaGen Share Repurchase

Under the Share Repurchase Agreement, the Company agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4.0 million. In connection with the closing of the January 2024 Warrant Inducement in January 2024, the Company made a payment of $0.3 million to InvaGen. In connection with the May 2024 Warrant Inducement (see Note 9), the Company made a payment of $0.3 million to InvaGen in May 2024. Payments to InvaGen are recorded in general and administrative expense on the condensed consolidated statements of operations.

Note 8 - Common Stock Warrant Liabilities

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

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

Warrant Liability

The accounting guidance requires fair value measurements be Company has previously issued freestanding warrants to purchase shares of its common stock in connection with financing activities. The outstanding October 2022 Warrants and the fully exercised January 2023 Warrants are classified and disclosed in oneas liabilities on the balance sheet as they contain terms for redemption 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 underlying security that are directly or indirectly observable in outside the marketplace.*
- *Level 3: Unobservable Company's control. The Black-Scholes Model is used to value the warrants classified as liabilities and the approach required management to estimate inputs which including expected volatility and expected term and is most significantly impacted by the volatility of the Company's common stock price. These inputs are supported by little or no market activity inherently subjective 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 require significant analysis and judgment or estimation. to develop.*

The fair value hierarchy also requires an entity to maximize of the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities warrants was measured at the time of issuance and is re-measured at each financial reporting date with any changes in fair value are classified being recognized in their entirety based on change in fair value of warrant liabilities, a component of other income (expense), in the lowest level consolidated statements of input that is significant operations and comprehensive income (loss). The Company will continue to re-measure the fair value measurement. The Company's assessment of the significance October 2022 Warrant liabilities until exercise or expiration of the warrants on October 10, 2027.

In January 2024, the Company entered into an inducement letter with the investor from the January 2023 Registered Direct Offering which provided for the immediate exercise of certain of its existing outstanding warrants to exercise for cash an aggregate of 25,871 shares of the Company's common stock at a particular input to reduced exercise price of $22.545 per share. Included in the exercise were the entirety of the January 2023 Warrants. The Company revalued the January 2023 Warrants on January 5, 2024, resulting in a fair value of $0.3 million. The $0.1 million increase in the fair value measurement of the common stock warrant liability resulted in its entirety requires management to make judgments and consider factors specific to an offsetting change in fair value of warrant liabilities in the asset or liability. Unaudited Condensed Consolidated Statements of Operations (see Note 7).

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 Accounts Payable and Accrued Expenses

Warrant Accounts payable, accrued expenses, and other liabilities are categorized within Level 3consisted of the fair value hierarchy and are measured at fair value on a recurring basis as follows following (in thousands):

	October 2022	January 2023

		Warrants		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		(291)		(1,253)		(1,544)
Fair value of warrants outstanding as of September 30, 2023	$	2,318	$	982	$	3,300

		As of March 31, 2024
Accounts payable	$	310
Accrued employee compensation		94
Accrued contracted services and other		243
Total accounts payable and accrued expenses	$	647

Note6-Commitments and Contingencies

Leases

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

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company will accrue the most likely amount of such loss, and if such amount is not determinable, then the Company will accrue the minimum of the range of probable loss. As of March 31, 2024, there was no litigation against the Company.

Note 7 - Stockholder's Equity

Class A Preferred Stock

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

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

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

Common Stock

On January 9, 2024, the stockholders holding a majority of the outstanding voting power of the Company executed and delivered to the Board of Directors of the Company a written consent approving, among other items, an increase in the number of shares of common stock authorized under the Certificate of Incorporation, from 75,000,000 to 200,000,000. On February 20, 2024, the Company filed the Certificate of Amendment with the Secretary of State for the State of Delaware effectuating the Authorized Shares Increase.

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

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

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No.333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). Approximately $24.9 million of securities remain available for sale under the 2021 Shelf as of March 31, 2024.

January 2024 Warrant Liability Inducement and Private Placement

On January 5, 2024, the Company entered into (i) an inducement offer letter agreement (the “January 2023 Investor Inducement Letter”) with a certain investor (the “January 2023 Investor”) in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 of the Company’s common stock originally issued to the January 2023 Investor on January 31, 2023 (the “January 2023 Warrants”) and (ii) an inducement offer letter agreement (the “November 2023 Investor Inducement Letter Agreement” and, together with the January 2023 Investor Inducement Letter, the “January 2024 Warrant Inducement”) with certain investors (the “November 2023 Investors” and, together with the January 2023 Investor, the “Holders”) in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the November 2023 Investors on November 2, 2023 (the “November 2023 Warrants” and, together with the January 2023 Warrants, the “Existing Warrants”). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company’s agreement to issue in a private placement (x) new Series A common stock purchase warrants (the “New Series A Warrants”) to purchase up to 220,538 shares of common stock (the “New Series A Warrants Shares”) and (y) new Series B common stock purchase warrants (the “New Series B Warrants” and, together with the New Series A Warrants, the “New Warrants”) to purchase up to 220,538 shares of common stock (the “New Series B Warrants Shares”). The New Series A Warrants will expire five years following the issuance date and the New Series B Warrants will expire eighteen months following the issuance date.

The January 2023 Warrants, which were liability classified, were revalued on January 5, 2024 using the Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $0.1 million was recorded as a change in fair value of warrant liabilities in the Condensed Consolidated Statements of Operations (see Note 8). The issuance of the New Warrants was considered as part of the cost of the inducement and the New Warrants were valued using the Black-Scholes Model and allocated between the January 2023 Warrants and November 2023 Warrants on a weighted basis. The approximately $0.6 million of the New Warrants fair value allocated to the January 2023 warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the New Warrant fair value was allocated to the November 2023 Warrants and deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).

The Company received aggregate net proceeds of approximately $4.5 million from the exercise of the Existing Warrants by the Holders, after deducting placement agent fees and other expenses payable by the Company.

The Company filed a registration statement on Form S-3 (File No.333-276671) with the SEC providing for the resale of the New Warrant Shares (the "Resale Registration Statement") on January 24, 2024, which was declared effective on February 1, 2024.

The key inputs for the Black-Scholes Model calculations on January 5, 2024 were as follows:

	January 2023 Warrants	New Series A Warrants
Stock price	$ 14.25	$ 14.2
Risk-free interest rate	4.40 %	4.0
Expected dividend yield	—	–
Expected term in years	2.1	5.
Expected volatility	185 %	13

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the "2015 Incentive Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and an amendment to the plan to increase the number of authorized shares issuable to 3,556 shares was approved by the Company's stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 70,223 shares and approved by the Company's 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 70,223 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 44,701 shares at March 31, 2024.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 2024:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested balance at December 31, 2023	1,311	$ 196.21
Granted	—	—
Forfeited	—	—
Vested	(283)	85.50

Unvested balance at March 31, 2024	1,028	$	226.69

At March 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years. This amount does not include, as of March 31, 2024, 45 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2024:

	Number of Options (in thousands)	Weighted Average Exercise Price		Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)	
Outstanding at December 31, 2023	22,474	$	85.50	9.5	$	—
Granted	—	$	—		$	—
Exercised	—	$	—		$	—
Cancelled/forfeited	—	$	—		$	—
Expired	—	$	—		$	—
Outstanding at Balance at March 31, 2024	22,474	$	85.50	9.2	$	—
Expected to vest	16,304	$	85.50	9.2	$	—
Exercisable	6,170	$	85.50	9.2	$	—

There were no options granted in the three-month period ending March 31, 2024. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2024, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.7 million with a weighted average remaining vesting period of 1.6 years.

The Company did not grant any stock options in the three months ended March 31, 2024 and 2023.

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

	For the three months ended March 31, 2024		March 31, 2023	
Research and development	$	45	$	—
General and administrative		146		11
Total stock-based compensation expense	$	191	$	11

Stock Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2024 and 2023:

	Weighted Average

	Warrants	Exercise Price
Outstanding, December 31, 2023	524,601	$ 32.42
Granted	441,076	22.55
Exercised	(220,538)	22.55
Outstanding, March 31, 2024	745,139	$ 29.50

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

InvaGen Share Repurchase

Under the Share Repurchase Agreement, the Company agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4.0 million. In connection with the closing of the January 2024 Warrant Inducement in January 2024, the Company made a payment of $0.3 million to InvaGen. In connection with the May 2024 Warrant Inducement (see Note 9), the Company made a payment of $0.3 million to InvaGen in May 2024. Payments to InvaGen are recorded in general and administrative expense on the condensed consolidated statements of operations.

Note 8 - Common Stock Warrant Liabilities

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

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

Warrant Liability

The Company has previously issued freestanding warrants to purchase shares of its common stock in connection with financing activities (Warrants as described in Note 8). activities. The Company's outstanding common stock warrants issued in connection with the equity offering completed in October 2022 ("October 2022 Warrants") Warrants and the fully exercised January 2023 ("January 2023 Warrants") Warrants are classified as liabilities in on the balance sheet as they contain terms for redemption of the underlying security that are outside the Company's 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 Model is used to value the January 2023 Warrants at warrants classified as liabilities and 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 the Company's common stock price. These inputs are inherently subjective and require significant analysis and judgment to develop.

The fair value of the warrants was measured at the time of issuance and is re-measured at each financial reporting date with any changes in fair value being recognized in change in fair value of warrant liabilities, a component of other income (expense), in the 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 2027.and

In January 2024, the January 2023 Warrants until exercise or expiration of Company entered into an inducement letter with the warrants on January 31, 2026. The October 2022 Warrants originally contained a one-time down-round price protection feature. In connection with investor from the January 2023 Registered Direct and Private Placement, Offering which provided for the down-round immediate exercise of certain of its existing outstanding warrants to exercise for cash an aggregate of 25,871 shares of the Company's common stock at a reduced exercise price protection feature was triggered and of $22.545 per share. Included in the exercise price for were the October 2022 Warrants was permanently adjusted to $1.55, which was the offering price for entirety of the January 2023 Registered Direct and Private Placement. Warrants. The Black-Scholes model was used to value the October 2022 Warrants and January 2023 Warrants as of September 30, 2023.

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

	September 30, 2023 (Black-Scholes model)		Decembe 2022 (Monte C simulat
Stock price	$	0.71	$
Risk-free interest rate		4.60 %	
Expected dividend yield		—	
Expected term in years		4.0	
Expected volatility		141 %	

The key inputs for Company revalued the January 2023 Warrants using on January 5, 2024, resulting in a fair value of $0.3 million. The $0.1 million increase in the Black-Scholes model were as follows: fair value of the common stock warrant liability resulted in an offsetting change in fair value of warrant liabilities in the Unaudited Condensed Consolidated Statements of Operations (see Note 7).

	September 30, 2023		January 2023 (Initia measurer
Stock price	$	0.71	$
Risk-free interest rate		5.03 %	
Expected dividend yield		—	
Expected term in years		2.4	
Expected volatility		165 %	

Note5 — Accounts Payable Net Loss per Share

Net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends. The Company recorded a deemed dividend of $4.3 million for the modification of certain of its existing warrants and Accrued Expenses issuance of warrants during the three months ended March 31, 2024 (see Note 7 and 8). Diluted net loss per share excludes unvested restricted stock, preferred shares and the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. Dividends declared are paid and set aside among the holders of shares of common stock and Class A Preferred stock pro-rata on an as-if-converted basis.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the Thre Ma

	2024
Unvested restricted stock units/awards	1,028
Warrants	745,139
Options	22,474
Class A Preferred shares	223
Total potential dilutive effect	768,864

Summary of Significant Accounting Policies

Accounts payable There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2023 Form 10-K.

Note3 — Licenses/Supplier Agreements

IV Tramadol License

Effective as of February 17,2015, Fortress transferred the Revogenex license and accrued expenses consisted all other rights and obligations under the IV Tramadol License Agreement to the Company, pursuant to the terms of the following (in thousands): 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.

	As of September 30, 2023	As of Dece 202
Accounts payable	$ 296	$
Accrued employee compensation	230	
InvaGen contingent fee	—	
Accrued contracted services and other	934	
Total accounts payable and accrued expenses	$ 1,460	$

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 for certain intellectual property rights pertaining to AJ201. 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 was paid on September 8, 2023. The Company is also obligated to make additional payments over the course of the AnnJi License Agreement including: reimbursement payments of up to $10.8 million in connection with the product’s Phase 1b/2a clinical trial (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.

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.

In connection with the signing of the AnnJi License Agreement, the Company issued 11,089 shares of its common stock to AnnJi (“First Tranche Shares”) at a fair value of $0.9 million on March 30, 2023. The Company issued 3,688 shares of common stock ("Second Tranche Shares"), recorded at a fair value of $0.3 million, on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. The fair value was calculated based on the closing price of the Company's stock as of February 28, 2023, the date the Company entered into the AnnJi License Agreement. 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, 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 6 4 -— Related Party Transactions Agreements

Founders Agreement and Management Services Agreement with Fortress

In February 2015, Fortress entered into a Management Services Agreement (the "MSA") with the Company to provide services for the Company pursuant to the terms of the MSA. Expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Condensed Consolidated Statements of Operations. For the three months ended March 31, 2024 and 2023, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively.

In February 2015, Fortress entered into a Founders Agreement with Avenue in February 2015 (as amended, the “Fortress-Avenue Founders Agreement”), pursuant to Company, under 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 Company 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; the Company at the time of issuance (the "Annual Equity Fee") and (ii) pay an equity fee in issue shares of Avenue the 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 financing (the "Financing Equity Fee"). Pursuant to the Founders Agreement, for the four three months ended March 31, 2024 and one 2023, half percent (4.5%) the Company issued common stock to Fortress of Avenue's annual net sales, payable on 5,543 shares and 1,912 shares, respectively, as a Financing Equity Fee. Additionally, the Company recorded a Financing Equity Fee of 5,513 shares of common stock issuable to Fortress for the three-month period ending March 31, 2024.

Pursuant to the Third Amended and Restated Certificate of Incorporation, the Company issued 22,476 shares of common stock to Fortress for the Annual Equity Fee during the three-month period ending March 31, 2024. The Company recorded an annual basis, within expense of approximately $0.3 million in research and development related to these issuable shares during the year ended ninety December 31, 2023. For the three (months ended 90 March 31, 2023,) days the Company issued 3,085 shares of the end Company's common stock as an Annual Equity Fee. The Company recorded an expense of each calendar year. In approximately $0.3 million in research and development related to these issuable shares during the event of a change in control (as it is defined in the Founders Agreement), Fortress will be paid a year ended one December 31, 2022.-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 $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 $1.0 million for each calendar year in which Baergic has net assets in excess of $100 million $100 million at the beginning of the calendar year.

Shared Services Agreement with Urica Therapeutics

Effective

February 1, 2023, 6and 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 $13,229 and $79,991 for the three and nine months ended September 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 September 30, 2023 that is related to the shared services agreement is $13,229 and is included in "Other receivables – related party" on the Company's consolidated balance sheets.

Note 75 -— Net Loss per Share

LossNet loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding excludingduring the period. Net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends. The Company recorded a deemed dividend of $4.3 million for the modification of certain of its existing warrants and issuance of warrants during the three months ended March 31, 2024 (see Note 7 and 8). Diluted net loss per share excludes unvested restricted stock, preferred shares and the effect of shares of common stock to be issued upon the exercise of stock options and preferred shares, during the period. warrants, as their inclusion would be anti-dilutive. Dividends declared are paid and set aside among the holders of shares of common stock and Class A Preferred stock pro-rata on an as-if-converted basis.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the Three and Nine Months Ended September 30,		For the Three Months Ended March 31,	
	2023	2022	2024	2023
Unvested restricted stock units/awards	98,137	13,145	1,028	177
Warrants	6,078,132	—	745,139	95,607
Options	1,685,000	—	22,474	—
Class A Preferred shares	16,666	16,666	223	223
Total potential dilutive effect	7,877,935	29,811	768,864	96,007

Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2023 Form 10-K.

Note3 — Licenses/Supplier Agreements

IV Tramadol License

Effective as of February 17,2015, Fortress transferred the Revogenex license and all other rights and obligations under the IV Tramadol License Agreement to the Company, pursuant to the terms of the Founders Agreement. In connection with the terms of the IV Tramadol License Agreement, Fortress purchased an exclusive license to IV tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland. 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 for certain intellectual property rights pertaining to AJ201. 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 was paid on September 8, 2023. The Company is also obligated to make additional payments over the course of the AnnJi License Agreement including: reimbursement payments of up to $10.8 million in connection with the product's Phase 1b/2a clinical trial (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.

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.

In connection with the signing of the AnnJi License Agreement, the Company issued 11,089 shares of its common stock to AnnJi ("First Tranche Shares") at a fair value of $0.9 million on March 30, 2023. The Company issued 3,688 shares of common stock ("Second Tranche Shares"), recorded at a fair value of $0.3 million, on September 26, 2023 upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial. The fair value was calculated based on the closing price of the Company's stock as of February 28, 2023, the date the Company entered into the AnnJi License Agreement. 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, 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.

Note4 — Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

In February 2015, Fortress entered into a Management Services Agreement (the "MSA") with the Company to provide services for the Company pursuant to the terms of the MSA. Expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Condensed Consolidated Statements of Operations. For the three months ended March 31, 2024 and 2023, the Company recorded expense related to the MSA of $0.1 million and $0.1 million, respectively.

In February 2015, Fortress entered into a Founders Agreement with the Company, under which the Company agreed to: (i) issue annually to Fortress, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of the Company at the time of issuance (the "Annual Equity Fee") and (ii) issue shares of the common stock equal to two and one half percent (2.5%) of the gross amount of any equity or debt financing (the "Financing Equity Fee"). Pursuant to the Founders Agreement, for the three months ended March 31, 2024 and 2023, the Company issued common stock to Fortress of 5,543 shares and 1,912 shares, respectively, as a Financing Equity Fee. Additionally, the Company recorded a Financing Equity Fee of 5,513 shares of common stock issuable to Fortress for the three-month period ending March 31, 2024.

Pursuant to the Third Amended and Restated Certificate of Incorporation, the Company issued 22,476 shares of common stock to Fortress for the Annual Equity Fee during the three-month period ending March 31, 2024. The Company recorded an expense of approximately $0.3 million in research and development related to these issuable shares during the year ended December 31, 2023. For the three months ended

March 31, 2023, the Company issued 3,085 shares of the Company's common stock as an Annual Equity Fee. The Company recorded an expense of approximately $0.3 million in research and development related to these issuable shares during the year ended December 31, 2022.

Founders Agreement and Management Services Agreement with Baergic

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

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

As additional consideration under the Avenue-Baergic Founders Agreement, Baergic will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Baergic that occurs after the effective date of the Avenue-Baergic Founders Agreement and 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.

Note5 — Accounts Payable and Accrued Expenses

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

	As of March 31, 2024
Accounts payable	$ 310
Accrued employee compensation	94
Accrued contracted services and other	243
Total accounts payable and accrued expenses	$ 647

Note6-Commitments and Contingencies

Leases

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

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company will accrue the most likely amount of such loss, and if such amount is not determinable, then the Company will accrue the minimum of the range of probable loss. As of March 31, 2024, there was no litigation against the Company.

Note 7 - Stockholder's Equity

Class A Preferred Stock

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

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

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

Common Stock

On January 9, 2024, the stockholders holding a majority of the outstanding voting power of the Company executed and delivered to the Board of Directors of the Company a written consent approving, among other items, an increase in the number of shares of common stock authorized under the Certificate of Incorporation, from 75,000,000 to 200,000,000. On February 20, 2024, the Company filed the Certificate of Amendment with the Secretary of State for the State of Delaware effectuating the Authorized Shares Increase.

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

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

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No.333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). Approximately $24.9 million of securities remain available for sale under the 2021 Shelf as of March 31, 2024.

January 2024 Warrant Inducement and Private Placement

On January 5, 2024, the Company entered into (i) an inducement offer letter agreement (the “January 2023 Investor Inducement Letter”) with a certain investor (the “January 2023 Investor”) in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 of the Company’s common stock originally issued to the January 2023 Investor on January 31, 2023 (the “January 2023 Warrants”) and (ii) an inducement offer letter agreement (the “November 2023 Investor Inducement Letter Agreement” and, together with the January 2023 Investor Inducement Letter, the “January 2024 Warrant Inducement”) with certain investors (the “November 2023 Investors” and, together with the January 2023 Investor, the “Holders”) in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the November 2023 Investors on November 2, 2023 (the “November 2023 Warrants” and, together with the January 2023 Warrants, the “Existing Warrants”). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company’s agreement to issue in a private placement (x) new Series A common stock purchase warrants (the “New Series A Warrants”) to purchase up to 220,538 shares of common stock (the “New Series A Warrants Shares”) and (y) new Series B common stock purchase warrants (the “New Series B Warrants” and, together with the New Series A Warrants, the “New Warrants”) to purchase up to 220,538 shares of common stock (the “New Series B Warrants Shares”). The New Series A Warrants will expire five years following the issuance date and the New Series B Warrants will expire eighteen months following the issuance date.

The January 2023 Warrants, which were liability classified, were revalued on January 5, 2024 using the Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $0.1 million was recorded as a change in fair value of warrant liabilities in the Condensed Consolidated Statements of Operations (see Note 8**). The issuance of the New Warrants was considered as part of the cost of the inducement and the New Warrants were valued using the Black-Scholes Model and allocated between the January 2023 Warrants and November 2023 Warrants on a weighted basis. The approximately $0.6 million of the New Warrants fair value allocated to the January 2023 warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the New Warrant fair value was allocated to the November 2023 Warrants and deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).**

The Company received aggregate net proceeds of approximately $4.5 million from the exercise of the Existing Warrants by the Holders, after deducting placement agent fees and other expenses payable by the Company.

The Company filed a registration statement on Form S-3 (File No.333-Stockholders' Equity276671) with the SEC providing for the resale of the New Warrant Shares (the “Resale Registration Statement”) on January 24, 2024, which was declared effective on February 1, 2024.

The key inputs for the Black-Scholes Model calculations on January 5, 2024 were as follows:

	January 2023 Warrants	New Series A Warrants
Stock price	$ 14.25	$ 14.2
Risk-free interest rate	4.40 %	4.0
Expected dividend yield	—	–
Expected term in years	2.1	5.
Expected volatility	185 %	13

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the “2015 Incentive Plan’ Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and an amendment to the plan to increase the number of authorized shares issuable to 266,666 3,556 shares was approved by the Company's stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 5,266,666 70,223 shares and approved by the Company's 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 70,223 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company’s 2015 Incentive Plan was 3,352,489 44,701 shares at September 30, 2023 March 31, 2024.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 2024:

	Number of Units and Awards	**Weighted Average Grant Date Fair Value**
	(in thousands)	
Unvested balance at December 31, 2023	1,311	$ 196.21
Granted	—	—
Forfeited	—	—
Vested	(283)	85.50
Unvested balance at March 31, 2024	1,028	$ 226.69

At March 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years. This amount does not include, as of March 31, 2024, 45 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

Stock Options

The following table summarizes stock option activity during the nine three months ended September 30, 2023 March 31, 2024:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)	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	—	$ —	—	$ —				
Outstanding at December 31, 2023					22,474	$ 85.50	9.5	$ —
Granted	1,685,000	$ 1.14	10.0	$ —	—	$ —		$ —
Exercised	—	$ —	—	$ —	—	$ —		$ —
Cancelled/forfeited	—	$ —	—	$ —	—	$ —		$ —
Expired	—	$ —	—	$ —	—	$ —		$ —
Outstanding at Balance at September 30, 2023	1,685,000	$ 1.14	9.7	$ —				
Outstanding at Balance at March 31, 2024					22,474	$ 85.50	9.2	$ —
Expected to vest	1,422,500	$ 1.14	9.7	$ —	16,304	$ 85.50	9.2	$ —
Exercisable	262,500	$ 1.14	9.7	$ —	6,170	$ 85.50	9.2	$ —

There were no options granted or outstanding in the nine three month -month period ending September 30, 2022. March 31, 2024. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2023 March 31, 2024, the total compensation cost related to non-vested options awards not yet recognized is approximately $1.2 million $0.7 million with a weighted average remaining vesting period of 1.8 1.6 years.

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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:

	Nine Months Ended September 30, 2023		Nine Months Ended September 30, 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 Company did not grant any stock options in the aggregate RSU and RSA activity during the nine three months ended September 30, 2023 March 31, 2024 :

	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
Unvested balance at September 30, 2023	98,137	$ 2.60

At September 30, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.6 years. This amount does not 2023. include, as of September 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		For the nine months ended		For the three months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022	March 31, 2024	March 31, 2023
Research and development	$ 144	$ 8	$ 150	$ 297	$ 45	$ —
General and administrative	417	17	449	340	146	11
Total stock-based compensation expense	$ 561	$ 25	$ 599	$ 637	$ 191	$ 11

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No.333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). Approximately $24.9 million of securities remain available for sale under the 2021 Shelf as of March 31, 2024.

January 2024 Warrant Inducement and Private Placement

On January 5, 2024, the Company entered into (i) an inducement offer letter agreement (the “January 2023 Investor Inducement Letter”) with a certain investor (the “January 2023 Investor”) in connection with certain outstanding warrants to purchase up to an aggregate of 25,871 of the Company’s common stock originally issued to the January 2023 Investor on January 31, 2023 (the “January 2023 Warrants”) and (ii) an inducement offer letter agreement (the “November 2023 Investor Inducement Letter Agreement” and, together with the January 2023 Investor Inducement Letter, the “January 2024 Warrant Inducement”) with certain investors (the “November 2023 Investors” and, together with the January 2023 Investor, the “Holders”) in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the November 2023 Investors on November 2, 2023 (the “November 2023 Warrants” and, together with the January 2023 Warrants, the “Existing Warrants”). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company’s agreement to issue in a private placement (x) new Series A common stock purchase warrants (the “New Series A Warrants”) to purchase up to 220,538 shares of common stock (the “New Series A Warrants Shares”) and (y) new Series B common stock purchase warrants (the “New Series B Warrants” and, together with the New Series A Warrants, the “New Warrants”) to purchase up to 220,538 shares of common stock (the “New Series B Warrants Shares”). The New Series A Warrants will expire five years following the issuance date and the New Series B Warrants will expire eighteen months following the issuance date.

The January 2023 Warrants, which were liability classified, were revalued on January 5, 2024 using the Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $0.1 million was recorded as a change in fair value of warrant liabilities in the Condensed Consolidated Statements of Operations (see Note 8). The issuance of the New Warrants was considered as part of the cost of the inducement and the New Warrants were valued using the Black-Scholes Model and allocated between the January 2023 Warrants and November 2023 Warrants on a weighted basis. The approximately $0.6 million of the New Warrants fair value allocated to the January 2023 warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the New Warrant fair value was allocated to the November 2023 Warrants and deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).

The Company received aggregate net proceeds of approximately $4.5 million from the exercise of the Existing Warrants by the Holders, after deducting placement agent fees and other expenses payable by the Company.

The Company filed a registration statement on Form S-3 (File No.333-276671) with the SEC providing for the resale of the New Warrant Shares (the “Resale Registration Statement”) on January 24, 2024, which was declared effective on February 1, 2024.

The key inputs for the Black-Scholes Model calculations on January 5, 2024 were as follows:

	January 2023 Warrants	New Series A Warrants
Stock price	$ 14.25	$ 14.2
Risk-free interest rate	4.40 %	4.0
Expected dividend yield	—	–
Expected term in years	2.1	5.
Expected volatility	185 %	13

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the “2015 Incentive Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and an amendment to the plan to increase the number of authorized shares issuable to 3,556 shares was approved by the Company's stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 70,223 shares and approved by the Company's 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 70,223 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company’s 2015 Incentive Plan was 44,701 shares at March 31, 2024.

Restricted Stock Warrants Units and Restricted Stock Awards

The following table summarizes the warrant restricted stock unit and award activity for during the nine three months ended September 30, 2023 and 2022 March 31, 2024:

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

	Number of Units and Awards	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested balance at December 31, 2023	1,311	$ 196.21
Granted	—	—
Forfeited	—	—
Vested	(283)	85.50
Unvested balance at March 31, 2024	1,028	$ 226.69

At March 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years. This amount does not include, as of March 31, 2024, 45 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2024:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)

Outstanding at December 31, 2023	22,474	$	85.50	9.5	$	—
Granted	—	$	—		$	—
Exercised	—	$	—		$	—
Cancelled/forfeited	—	$	—		$	—
Expired	—	$	—		$	—
Outstanding at Balance at March 31, 2024	22,474	$	85.50	9.2	$	—
Expected to vest	16,304	$	85.50	9.2	$	—
Exercisable	6,170	$	85.50	9.2	$	—

There were no outstanding warrants during options granted in the nine three-month period ending March 31, 2024. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2024, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.7 million with a weighted average remaining vesting period of 1.6 years.

The Company did not grant any stock options in the three months ended September 30, 2022. March 31, 2024 and 2023.

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

	For the three months ended	
	March 31, 2024	March 31, 2023
Research and development	$ 45	$ —
General and administrative	146	11
Total stock-based compensation expense	$ 191	$ 11

Capital Raises

2021 Shelf

On December 7, 2021, the Company filed a shelf registration statement (File No.333-261520) on Form S-3, which was declared effective on December 10, 2021 (the "Shelf"). Approximately $24.9 million of securities remain available for sale under the 2021 Shelf as of March 31, 2024.

January 2023 2024 Registered Direct Warrant Inducement and Private Placement

On January 27, 2023, 5, 2024, the Company entered into a Securities Purchase Agreement (i) an inducement offer letter agreement (the "Registered Purchase Agreement"“January 2023 Investor Inducement Letter”) with a single institutional accredited certain investor pursuant (the “January 2023 Investor”) in connection with certain outstanding warrants to which the Company agreed purchase up to issue and sell (i) 448,000 shares (the “Shares”) an aggregate of 25,871 of the Companies' Company’s common stock at a price per Share of $1.55, originally issued to the January 2023 Investor on January 31, 2023 (the “January 2023 Warrants”) and (ii) pre-funded an inducement offer letter agreement (the “November 2023 Investor Inducement Letter Agreement” and, together with the January 2023 Investor Inducement Letter, the “January 2024 Warrant Inducement”) with certain investors (the “November 2023 Investors” and, together with the January 2023 Investor, the “Holders”) in connection with certain outstanding warrants (the “Pre-funded Warrants”) to purchase 1,492,299 up to an aggregate of 194,667 shares of common stock, at a price per Pre-funded Warrant equal originally issued to the price per Share, less $0.001 (the “Registered Offering”). The Pre-funded Warrants have an exercise price of $0.001 per shareNovember 2023 Investors on November 2, 2023 (the “November 2023 Warrants” and, 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”) together with the same institutional accredited investor for a private placement offering (“Private Placement”) of the January 2023 Warrants, the “Existing Warrants”). The January 2023 Warrants had an exercise price of $116.25 per share, and the November 2023 Warrants had an exercise price of $22.545 per share.

Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise for cash its January 2023 Warrants at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise for cash their November 2023 Warrants at the existing exercise price of $22.545 in consideration for the Company’s agreement to issue in a private placement (x) new Series A common stock purchase warrants (the “New Series A Warrants”) to purchase 1,940,299 up to 220,538 shares of common stock. Pursuant stock (the “New Series A Warrants Shares”) and (y) new Series B common stock purchase warrants (the “New Series B Warrants” and, together with the New Series A Warrants, the “New Warrants”) to purchase up to 220,538 shares of common stock (the “New Series B Warrants Shares”). The New Series A Warrants will expire five years following the PIPE Purchase Agreement, issuance date and the Company agreed New Series B Warrants will expire eighteen months following the issuance date.

The January 2023 Warrants, which were liability classified, were revalued on January 5, 2024 using the Black-Scholes Model to issue calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $0.1 million was recorded as a change in fair value of warrant liabilities in the Condensed Consolidated Statements of Operations (see Note 8). The issuance of the New Warrants was considered as part of the cost of the inducement and sell the New Warrants were valued using the Black-Scholes Model and allocated between the January 2023 Warrants at an offering price of $0.125 per and January 2023 Warrant to purchase one share of common stock. The January November 2023 Warrants have an exercise price on a weighted basis. The approximately $0.6 million of $1.55 per share (subject the New Warrants fair value allocated to adjustment as set forth in the January 2023 Warrants), are exercisable immediately after issuance warrants was recorded as a loss on common stock warrant liabilities in the Condensed Consolidated Statements of Operations with a corresponding offset to additional paid-in-capital. Approximately $4.3 million of the New Warrant fair value was allocated to the November 2023 Warrants and will expire three years deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations (see Note 2).

The Company received aggregate net proceeds of approximately $4.5 million from the date on which exercise of the January 2023 Existing Warrants become exercisable. The January 2023 Warrants contain standard anti-dilution adjustments to by 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 the Company from the Private Placement, before Holders, after deducting placement agent fees and other estimated offering expenses payable by the Company, were approximately $0.24 million. Company.

September 2023 Private Placement

On September 8, 2023, the Company entered into an unwritten agreement with Fortress and Dr. Lindsay A. Rosenwald, a director on the board of directors of the Company (Dr. Rosenwald and Fortress, together, the “Private Placement Investors”), pursuant to which the Company agreed to issue and sell 767,085 shares (the “September 2023 Private Placement Shares”) of common stock of the Company, par value $0.0001 per share, for an aggregate purchase price of approximately $550,000 in a private placement transaction (the “September 2023 Private Placement”) exempt from the registration requirements of the Securities Act of 1933, as amended (the “Securities Act”), and the rules and regulations of the SEC thereunder. The shares were purchased by the Private Placement Investors at a price per September 2023 Private Placement Share of $0.717, which was the “consolidated closing bid price” of the Common Stock on the Nasdaq Capital Market as of September 7, 2023, in compliance with Nasdaq Listing Rule 5365(c). The gross proceeds to the Company from the September 2023 Private Placement, before deducting estimated offering expenses payable by the Company, were approximately $550,000. The Company did not incur any underwriting or placement agent fees associated with the September 2023 Private Placement. The Company intends to use the net proceeds from the September 2023 Private Placement for working capital and other general corporate purposes.

In connection with the September 2023 Private Placement, the Company entered into filed a registration rights letter agreement (the “Registration Rights Letter Agreement”) with the Private Placement Investors. Pursuant to the Registration Rights Letter Agreement, the Company will be required to file, statement on or prior to Form S-September 8, 2024 (3the “Private Placement Filing Date”), a resale registration statement (the “Private Placement Resale Registration Statement” (File No.333-276671) with the SEC to register providing for the resale of the New Warrant Shares (the “Resale Registration Statement”) on September January 24, 2024, which was declared effective on February 1, 2024.

The key inputs for the Black-Scholes Model calculations on January 5, 2024 were as follows:

	January 2023 Warrants		New Series A Warrants	
Stock price	$	14.25	$	14.2
Risk-free interest rate		4.40 %		4.0
Expected dividend yield		—		–
Expected term in years		2.1		5.
Expected volatility		185 %		13

Equity Incentive Plan

The Company has in effect the Avenue Therapeutics, Inc. 2015 Incentive Plan (as amended, the “2015 Incentive Plan"). The 2015 Incentive Plan was adopted in January 2015 by the Company's stockholders and an amendment to the plan to increase the number of authorized shares issuable to 3,556 shares was approved by the Company's stockholders in December 2021. The 2015 Incentive Plan was amended again to increase the number of authorized shares issuable to 70,223 shares and approved by the Company's 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 70,223 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company’s 2015 Incentive Plan was 44,701 shares at March 31, 2024.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes the restricted stock unit and award activity during the three months ended March 31, 2024:

	Number of Units and Awards		**Weighted Average Grant Date Fair Value**
	(in thousands)		
Unvested balance at December 31, 2023	1,311	$	196.21
Granted	—		—
Forfeited	—		—
Vested	(283)		85.50
Unvested balance at March 31, 2024	1,028	$	226.69

At March 31, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.4 years. This amount does not include, as of March 31, 2024, 45 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. The expense is recognized over the vesting period of the award. Stock-based compensation for awards containing performance conditions will be measured as of the grant date and recorded if and when it is probable that the performance condition will be achieved.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2024:

	Weighted Average

	Number of Options (in thousands)	Weighted Average Exercise Price	Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	22,474	$ 85.50	9.5	$ —
Granted	—	$ —		$ —
Exercised	—	$ —		$ —
Cancelled/forfeited	—	$ —		$ —
Expired	—	$ —		$ —
Outstanding at Balance at March 31, 2024	22,474	$ 85.50	9.2	$ —
Expected to vest	16,304	$ 85.50	9.2	$ —
Exercisable	6,170	$ 85.50	9.2	$ —

There were no options granted in the three-month period ending March 31, 2024. The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2024, the total compensation cost related to non-vested options awards not yet recognized is approximately $0.7 million with a weighted average remaining vesting period of 1.6 years.

The Company did not grant any stock options in the three months ended March 31, 2024 and 2023.

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

	For the three months ended	
	March 31, 2024	March 31, 2023
Research and development	$ 45	$ —
General and administrative	146	11
Total stock-based compensation expense	$ 191	$ 11

Stock Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2024 and 2023Private Placement Shares. :

	Warrants	Weighted Average Exercise Price
Outstanding, December 31, 2023	524,601	$ 32.42
Granted	441,076	22.55
Exercised	(220,538)	22.55
Outstanding, March 31, 2024	745,139	$ 29.50

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

InvaGen Share Repurchase

Under the Share Repurchase Agreement, the Company agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4.0 million. $4.0 million. In connection with the closing of the January 2023 2024 Registered Direct and Private Placement, Warrant Inducement in January 2024, the Company made a payment of $0.2 million $0.3 million to InvaGen. In connection with the May 2024 Warrant Inducement (see Note 9), the Company made a payment of $0.3 million to InvaGen in May 2024. Payments to InvaGen are recorded in general and administrative expense on the condensed consolidated statements of operations.

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Note 8 - Common Stock Warrant Liabilities

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

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

Warrant Liability

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

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

In January 2024, the Company entered into an inducement letter with the investor from the January 2023 Registered Direct Offering which provided for the immediate exercise of certain of its existing outstanding warrants to exercise for cash an aggregate of 25,871 shares of the Company's common stock at a reduced exercise price of $22.545 per share. Included in the exercise were the entirety of the January 2023 Warrants. The Company revalued the January 2023 Warrants on January 5, 2024, resulting in a fair value of $0.3 million. The $0.1 million increase in the fair value of the common stock warrant liability resulted in an offsetting change in fair value of warrant liabilities in the Unaudited Condensed Consolidated Statements of Operations (see Note 7).

Fair Value of Warrant Liabilities

Warrant liabilities are categorized within Level 3 2023. 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, 2023	$ 426	$ 160	$ 586
Change in fair value of warrants	(13)	129	116
Exercise of warrants	—	(289)	(289)
Fair value of warrants outstanding as of March 31, 2024	$ 413	$ —	$ 413

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

		March 31, 2024
Stock price	$	11.10
Risk-free interest rate		4.21
Expected dividend yield		—
Expected term in years		3.5
Expected volatility		162

Note 9 - Subsequent Events

November 2023 Public Offering Reverse Stock Split

In On April 25, 2024, the Company filed the Reverse Split Amendment to effect the Reverse Stock Split. As a result of the Reverse Stock Split, every 75 shares of the Company's pre-reverse split common stock was combined and reclassified as one share of common stock. Proportionate voting rights and other rights of common stockholders were not affected by the reverse. Instead, stockholders who were otherwise entitled to receive fractional shares because they held a number of shares of common stock that was not evenly divided by the reverse split ratio had their fractional shares rounded up to the next whole share in lieu of such fractional shares. No fractional shares were issued in connection with the Reverse Stock Split and no cash payments were made for fractional shares. The Reverse Stock Split became effective on April 26, 2024, and the common stock was quoted on the Nasdaq Stock Market on a post-split basis at market open on April 26, 2024. The par value and other terms of the common stock were not affected by the Reverse Stock Split.

May 2024 Warrant Inducement

On April 28, 2024, the Company entered into inducement offer letter agreements (the "May 2024 Warrant Inducement") with (i) certain investors (the "October 2022 Investors") that held certain outstanding October 2022 Warrants to purchase up to an aggregate of 27,271 shares of the Company's common stock; (ii) certain investors (the "November 2023 Investors") that hold November 2023 Avenue closed on a public offering of the issuance and sale of Warrants to purchase up to an aggregate of 16,633,400 units at a 221,333 shares of Common Stock; and (iii) certain investors (the "January 2024 Investors" and, collectively with the October 2022 Investors and November 2023 Investors, the "Holders") that hold New Warrants to purchase up to an aggregate of 441,076 shares of Common Stock. We refer to the New Warrants collectively with the October 2022 Warrants and November 2023 Warrants as the Existing Warrants. The October 2022 Warrants had an exercise price of $0.3006 $116.25 per unit. Each unit consists of (i) one share, of common stock (or pre-funded warrant in lieu of), and (ii) one Series A warrant to purchase one share of commons stock, exercisable immediately upon issuance at a the November 2023 Warrants had an exercise price of $0.3006 $22.545 per share, and expiring five years following the issuance date, and (iii) one New Warrants had an exercise price of $22.545 per share. Pursuant to the May 2024 Warrant Inducement, the Holders agreed to exercise for cash the Existing Warrants at a reduced exercise price of $6.20 per share in partial consideration for the Company's agreement to issue in a private placement (x) new Series B warrant C Common Stock purchase warrants (the "New Series C Warrants") to purchase one share up to 689,680 shares of common stock, exercisable immediately upon issuance at Common Stock (the "New Series C Warrant Shares") and (y) new Series D Common Stock Purchase Warrants (the "New Series D Warrants" and, together with the New Series C Warrants, the "May 2024 Warrants") to purchase up to 689,680 shares of Common Stock (the "New Series D Warrant Shares" and, together with the New Series C Warrant Shares, the "May 2024 Warrant Shares"). The Holders also agreed to make a price payment of $0.3006 $0.125 per share and expiring eighteen months following May 2024 Warrant Share (the "Additional Warrant Consideration"). The closing of the issuance date. transactions contemplated pursuant to the May 2024 Warrant Inducement occurred on May 1, 2024 (the "Closing Date"). The total Company received aggregate gross proceeds from the offering were approximately $5.0 million with net proceeds of approximately $3.9 million after $4.4 million from the exercise of the Existing Warrants by the Holders and the payment of the Additional Warrant

Consideration, before deducting placement agent fees and other transaction costs. expenses payable by the Company. The Company intends to use the net proceeds for general corporate purposes.

At-the-Market Facility

In connectionMay 2024, the Company entered into an At-the-Market Offering Agreement (the "Offering Agreement") with H.C. Wainwright & Co. LLC ("Wainwright") under which the Company may offer and sell, from time to time at its sole discretion, up to $3,850,000 of shares of its common stock, par value $0.0001 per share (the "Shares"), through or to Wainwright. The offer and sale of the Shares will be made pursuant to the base prospectus forming a part of the Shelf, and the related prospectus supplement dated May 10, 2024 (the "Registration Statement") filed with the closing SEC on such date pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act").

Under current SEC regulations and General Instruction I.B.6 of Form S-3, if on or after specified measurement periods the Company's public float is less than $75.0 million, and for so long as the Company's public float remains less than $75.0 million, the amount the Company can raise through primary public offerings of securities in any 12-month period using offerings registered under shelf registration statements is limited to an aggregate of one-third of the November 2023 Company's public offering, float, which is referred to as the baby shelf rules. As of March 31, 2024, the Company's calculated public float was less than $75.0 million.

As a result of the warrant inducement transaction, and as of the date of this filing, the Company owes a fee believes it has stockholders' equity of approximately $0.3 million to InvaGen. at least $2.5 million as required by Nasdaq Listing Rule 5550(b)(1).

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. All statements other factors than statements of current or historical fact contained in this report, including statements that may cause express our actual results, performance intentions, plans, objectives, beliefs, expectations, strategies, predictions or achievements any other statements relating to be materially different from the our future results, performance activities or achievements expressed other future events or implied by such conditions are forward-looking statements. The words "anticipate," "believe," "continue,""could,""estimate,""expect,""intend," "may," "expect, plan,""predict,""should,""project," "will," "could,""project,""should,""intend would," and similar expressions are generally intended to identify forward-looking statements. Our These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from the results anticipated what is expressed or forecasted in, or implied by, these the forward-looking statements due to a variety of factors, including, without limitation: numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from:

- *the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized;*
- *the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates;*

- *our ability to successfully integrate Baergic Bio, Inc. develop, partner, or develop BAER-101 commercialize any of our current or AJ201; future product candidates including AJ201, IV tramadol, and BAER-101;*

- *the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing;*

- *the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future;*

- *our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability could force us to delay, reduce or eliminate our product development programs or commercialization efforts;*

- *our reliance on third parties for several aspects of our operations;*

- *our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate, unreliable, or unreliable; unacceptable to regulatory authorities;*

- *the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons;*

- *the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny;*

- *the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations;*

- *the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications;*

- *the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products;*

- *our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates;*

- *our exposure to potential product liability claims;*

- *related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;*

- *our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business;*

- *the fact that Fortress Biotech, Inc. ("Fortress") controls a voting majority of the voting power of our common outstanding capital 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 December 31, 2023 (the "2022 2023 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. statements to reflect events or circumstances that may arise after the date of this report, except as required by applicable law.

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

Overview

Avenue Therapeutics, Inc. ("Avenue" or the "Company") is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Our product candidates include AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA", also known as Kennedy's Disease), an intravenous formulation of tramadol ("IV tramadol"), a schedule IV opioid for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders. We may in the future acquire additional product candidates.

Our net loss for the nine three months ended September 30, 2023 March 31, 2024 and 2022 2023 was approximately $11.1 million $4.3 million and $4.1 million $7.6 million, respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of approximately $91.6 million $95.3 million. Substantially all our net losses resulted from costs incurred in connection with the ongoing AJ201 Phase 1b/2a clinical trial, our for research and development, program of IV tramadol, and from general and administrative costs associated with our operations. purposes.

We expect to continue to incur research and development costs increased and general and administrative related costs and incur 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 securities 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 or securities convertible into or exercisable for equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding shares of our common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to stockholders. We may also seek financing through strategic partnerships for some or all of our portfolio assets. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

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

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

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 paid an initial cash license fee of $3.0 million, of which $2.0 million was paid on April 27, 2023 and $1.0 million was paid on September 8, 2023. The Company is also obligated to issue issued shares of its common stock, par value $0.0001 per share (the "common stock") under the Subscription Agreement (described below) and is obligated to make additional payments over the course of the AnnJi License Agreement including reimbursement payments of up to $10.8 million in connection with the product’s Phase 1b/2a clinical trial.

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. 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 enrolled 25 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.

In September 2023, January 2024, we announced the eighth patient was enrolled completion of enrollment for the Phase 1b/2a trial and pursuant to the License Agreement, we issued the Second Tranche Shares to AnnJi. currently expect topline data midyear 2024.

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 we received official meeting minutes from the Type C meeting with the FDA. The Type C meeting minutes indicate that the FDA and the Company we are in agreement with the FDA on a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the DAAAP.

In July 2023, the Company January 2024, we announced alignment that we reached final agreement with the FDA on key elements of the Phase 3 safety study protocol and statistical analysis approach, including the primary endpoint and statistical analysis approach. endpoint. The final 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 approximately 300 post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Patients Of note, this study design was used in the first of two Phase 3 trials. In a Phase 3 safety study to be conducted, patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression.

We have submitted 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. possible, subject to having the necessary financing.

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

Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of neurologic disorders. Baergic was acquired by the Company pursuant to a stock contribution agreement (the "Contribution Agreement") with Fortress, in order to strategically align with Avenue's goals of building a rare and neurologic pipeline. Baergic's pipeline currently consists of a single compound, BAER-101, a novel α2/3–subtype-selective GABA A positive allosteric modulator. BAER-101 (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 the Strasbourg ("GAERS") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti-seizure drug development. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg administered orally. The data were subsequently presented at the American Epilepsy Society ("AES") 2023 Annual Meeting in December 2023 and at the American Society for Experimental Neurotherapeutics ("ASENT") 2024 Annual Meeting in March 2024. The data were also published in *Drug Development Research* in February 2024.

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 April 26, 2024, the Company effected a 1-for-15 1-for-75 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.

Nasdaq Deficiency Letter

On May 19, 2023, we received a deficiency letter (the "Nasdaq "First Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq" (the "Nasdaq"), notifying us that we are were not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires us to maintain a the minimum of $2,500,000 in stockholders' equity requirement for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"), nor in compliance. In accordance 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, rules, we had were provided 45 calendar days, from the date of the Nasdaq Letter or until July 3, 2023, to submit a plan to regain compliance. On July 3, 2023, we submitted a compliance plan (the "Compliance Plan"). We submitted our Compliance Plan and, on July 17, 2023, the Staff granted our request for an extension through November 15, 2023 to Nasdaq. regain compliance with the Stockholders' Equity Requirement. We were unable to demonstrate compliance with the Stockholders' Equity Requirement by that date, and, on November 20, 2023, the Staff formally notified us that it would move to delist our securities from Nasdaq unless we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). We submitted the request for a hearing before the Panel (the "Hearing"), which request stayed any further action by Nasdaq pending completion of the Hearing and the expiration of any extension that may be granted by the Panel to the Company.

On Also as previously disclosed, on September 27, 2023, we received a second deficiency letter (the "Second Letter") from the Staff of the Listing Qualifications Department (the "Staff") of Nasdaq stating that the bid price of the Company's our common stock had closed below $1.00 per share for 30 consecutive business days and, that, therefore, as such, we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum-Bid Price Requirement"), which sets forth the minimum bid price requirement for continued listing on The Nasdaq Capital Market.

Nasdaq's notice has no immediate effect on the listing of the common stock on The Nasdaq Capital Market. Market (the "Bid Price Requirement"). Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we are were afforded a 180-calendar day grace period, through March 25, 2024, to regain compliance with the bid price requirement. Compliance can be achieved Bid Price Requirement.

The Hearing before the Panel was held on February 15, 2024 and, by evidencing decision dated March 11, 2024, the Panel granted the Company's request for an extension through May 20, 2024 to demonstrate compliance with the Stockholders' Equity Requirement and Bid Price Requirement. In order to timely evidence compliance with the Bid Price Requirement in particular, we must evidence a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days, although the Staff may, in its discretion, require compliance for a longer period of time (generally no 10, though generally not more than 20, consecutive business days) during the 180-calendar day grace period.

If we do not days by May 20, 2024. The Company is considering all options available to it to regain compliance with the bid price requirement by March 25, 2024, we may be eligible for an additional 180-calendar day compliance period so long as it satisfies the criteria for initial listing on The Nasdaq Stock Market, other than the market value of publicly held shares requirement, Stockholders' Equity Requirement and the continued listing requirement for market value of publicly held shares and the Company provides written notice Bid Price Requirement; however, there can be no assurance that we will be able to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. We are closely monitoring the closing bid price of the common stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made. do so.

September 2023 January 2024 Warrant Inducement and Private Placement

On September 8, 2023 January 5, 2024, we entered into (i) an inducement offer letter agreement (the "January 2023 Investor Inducement Letter") with Fortress Biotech, Inc., the holder a certain investor (the "January 2023 Investor") in connection with certain outstanding warrants to purchase up to an aggregate of a majority of the voting power of the Company's capital stock ("Fortress"), and Dr. Lindsay A. Rosenwald, a director on the board of directors of the Company, pursuant to which the Company agreed to issue and sell 767,085 25,871 shares of common stock, originally issued to the January 2023 Investor on January 31, 2023 (the "January 2023 Warrants") and (ii) an inducement offer letter agreement (the "November 2023 Investor Inducement Letter Agreement" and, together with the January 2023 Investor Inducement Letter, the "January 2024 Warrant Inducement") with certain investors (the "November 2023 Investors" and, together with the January 2023 Investor, the "Holders") in connection with certain outstanding warrants to purchase up to an aggregate of 194,667 shares of common stock, originally issued to the Company, par value $0.0001 November 2023 Investors on November 2, 2023 (the "November 2023 Warrants" and, together with the January 2023 Warrants, the "Existing Warrants"). The January 2023 Warrants had an exercise price of $116.25 per share, for and the November 2023 Warrants had an aggregate purchase exercise price of approximately $550,000 $22.545 per share. Pursuant to the January 2024 Warrant Inducement, (i) the January 2023 Investor agreed to exercise its January 2023 Warrants for cash at a reduced exercise price of $22.545 per share and (ii) the November 2023 Investors agreed to exercise their November 2023 Warrants for cash at the existing exercise price of $22.545, in each case in consideration for the Company's agreement to issue in a private placement transaction (the "Private Placement" (x) Series A Warrants to purchase up to 220,538 shares of common stock ("Series A Warrants") exempt and (y) Series B Warrants to purchase up to 220,538 shares of common stock ("Series B Warrants"). The net proceeds to Avenue from the registration requirements exercise of the Securities Act of 1933. The shares were purchased by Fortress and Dr. Lindsay A. Rosenwald at a price per share of $0.717, which warrants was the "consolidated closing bid price" of the common stock on the Nasdaq Capital Market as of September 7, 2023 approximately $4.5 million, in compliance with Nasdaq Listing Rule 5365(c). The gross proceeds from the Private Placement, before after deducting estimated offering expenses payable by us, were approximately $550,000. We did not incur any underwriting or placement agent fees associated with and offering costs.

As a result of the Private Placement. January 2024 Warrant Inducement, the Company presents a deemed dividend for the issuance of the Series A Warrants and Series B Warrants of $4.3 million for the 3 months ending March 31, 2024. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the condensed consolidated statements of operations.

Critical Accounting Policies and Use of Estimates

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

For a discussion of our critical accounting estimates, see the Management's Discussion and Analysis of the Results of Operations in the 2022 2023 Form 10- K. 10-K.

There were no material changes in our critical accounting estimates or accounting policies from December 31, 2022 December 31, 2023.

Results of Operations

General

At September 30, 2023 March 31, 2024, we had an accumulated deficit of $91.6 million $95.3 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate are still in development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Comparison of the Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

	For The Three Months Ended September 30,		Change		For The Three Months Ended March 31,		Change	
($ in thousands)	2023	2022	$	%	2024	2023	$	%
Operating expenses:								
Research and development	$ 907	$ 194	$ 713	368%	$ 2,392	$ 1,215	$ 1,177	97%
Research and development – licenses acquired					—	4,230	(4,230)	(100)%
General and administrative	1,161	469	692	148%	1,316	984	332	34%
Loss from operations	(2,068)	(663)	(1,405)	212%	(3,708)	(6,429)	2,721	(42)%
Other income (expense):								
Interest income	9	1	8	800%	49	37	12	32%
Financing costs – warrant liabilities					—	(332)	332	(100)%
Loss on settlement of common stock warrant liabilities					(574)	—	(574)	—%
Change in fair value of warrant liabilities	2,572	—	2,572	—%	(116)	(878)	762	(87)%
Total other income	2,581	1	2,580	258000%				
Net income (loss)	$ 513	$ (662)	$ 1,175	(177)%				
Total other income (expense)					(641)	(1,173)	532	(45)%
Net loss					$ (4,349)	$ (7,602)	$ 3,253	(43)%
Net loss attributable to non-controlling interests	(13)	—	(13)	—%	(9)	(66)	57	(86)%
Net income (loss) attributable to common stockholders	526	(662)	1,188	(179)%	(4,340)	(7,536)	3,196	(42)%

Research and Development Expenses

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

For the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, research and development expenses were $0.9 million $2.4 million and $0.2 million $1.2 million, respectively. The increase of $0.7 million $1.2 million is primarily associated with a $0.5 million $1.1 million increase in AJ201 clinical study expenses, $0.1 million Fortress-Avenue MSA fee and $0.1 million in non-cash stock compensation costs.

For the three months ended March 31, 2024 and 2023, research and development - licenses acquired expenses were $0 and $4.2 million, respectively. The decrease of $4.2 million is related to the AJ201 license acquisition in 2023.

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 September 30, 2023 March 31, 2024 and 2022, 2023, general and administrative expenses were $1.2 million $1.3 million and $0.5 million $1.0 million, respectively. The increase of $0.7 million $0.3 million is primarily related to $0.4 million an increase of $0.2 million in professional fees and $0.1 million in non-cash stock compensation costs, $0.1 million of professional fees, $0.1 million in salary expense and $0.1 million Fortress-Avenue MSA fee. costs.

Interest Income

Interest income was $9,000 $49,000 and $1,000 $37,000 for the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. The increase in interest income was due to a larger cash and cash equivalent balance.

Loss on Settlement of Common Stock Warrant Liabilities

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

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a gain loss of $2.6 million $0.1 million and $0 $0.9 for the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. We issued warrants Warrants to purchase common stock that are required to be classified as a liability and are valued at fair market value at each reporting period. The change in the fair value of warrant liabilities was primarily due to the fluctuation in our stock price.

Comparison modification of the Nine Months Ended September 30, 2023 and 2022

($ in thousands)	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022	Change $	Change %
Operating expenses:				
Research and development	$ 5,149	$ 2,153	$ 2,996	139 %
Research and development – licenses acquired	4,230	—	4,230	— %
General and administrative	3,042	1,978	1,064	54 %
Loss from operations	(12,421)	(4,131)	(8,290)	201 %
Other income (expense):				
Interest income	104	4	100	2500 %
Financing costs – warrant liabilities	(332)	—	(332)	— %
Change in fair value of warrant liabilities	1,544	—	1,544	— %
Total other income (expense)	1,316	4	1,312	25
Net loss	$ (11,105)	$ (4,127)	$ (6,978)	$ 27
Net loss attributable to non-controlling interests	(88)	—	(88)	— %
Net loss attributable to common stockholders	(11,017)	(4,127)	(6,890)	167 %

Research and Development Expenses

For exercise price as part of a warrant inducement, the nine months ended September 30, 2023 and 2022, research and development expenses were $5.1 million and $2.2 million, respectively. The increase exercise of $2.9 million is primarily associated with an increase of $4.0 million in AJ201 clinical study expenses and $0.2 million in BAER-101 costs offset by a decrease of $0.9 million in IV tramadol regulatory and consulting costs, $0.2 million in bonus costs and $0.2 million in non-cash stock compensation costs.

For the nine months ended September 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 nine months ended September 30, 2023 and 2022, general and administrative expenses were $3.0 million and $2.0 million, respectively. The increase of $0.9 million is primarily related to $0.6 million of professional fees, $0.2 million Fortress-Avenue MSA fee, $0.1 million in non-cash stock compensation costs and $0.1 million in salary expense.

Interest Income

Interest income was $104,000 and $4,000 for the nine months ended September 30, 2023 and 2022, respectively. The increase in interest income was due to higher cash balances and interest rates.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a gain of $1.5 million and $0 for the nine months ended September 30, 2023 and 2022, respectively. We issued stock purchase warrants that are required to be classified as a liability liabilities, 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 At March 31, 2024, we had $3.2 million in cash and expects to continue to incur significant operating losses cash equivalents. To date, we have funded our operations primarily with proceeds from various public and private offerings of our common and preferred stock. We expect that our expenses will increase substantially for the foreseeable future as it executes we continue to execute on its our product development plan and may never become profitable. As of September 30, 2023, we had a cash seek opportunities to license or acquire additional products. We will require additional financing to carry out our business plan and cash equivalents balance of $0.2 million implement our strategy, and accumulated deficit of $91.6 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, including through at-the-market program ("ATM") offerings, 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 sure that these initiatives or raising any additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, funding, if needed, will be available on terms favorable to us or if available, will be on terms acceptable to us. at all. If we issue additional securities to raise funds, these securities may have rights, preferences, obtain funding through a strategic collaboration 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, licensing arrangement, we may be required to curtail relinquish our current development programs, cut rights to our product candidates or marketing territories. Without additional capital, we do not expect our cash will be sufficient to fund our projected operating costs, forego future development requirements or allow us to fund our operating plan past the third quarter of 2024. We regularly evaluate market conditions, our liquidity profile, and other various financing alternatives for opportunities or even terminate to enhance our operations. capital structure.

Recently Adopted and Issued Accounting Pronouncements

As of September 30, 2023 March 31, 2024, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2022 2023 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 Nine Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

($ in thousands)	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022	For the Three Months Ended March 31, 2024	For the Three Months Ended March 31, 2023
Total cash and cash equivalents provided by (used in):				
Operating activities	$ (7,127)	$ (3,427)	$ (3,120)	$ (1,573)
Investing activities	(3,000)	—		
Financing activities	3,580	(119)	4,531	3,101
Net increase in cash and cash equivalents	$ (6,547)	$ (3,546)	$ 1,411	$ 1,528

Operating Activities

Net cash and cash equivalents used in operating activities was $7.1 million $3.1 million for the nine three months ended September 30, 2023 March 31, 2024, primarily comprised of our $11.1 million $4.3 million net loss and $1.5 million $0.4 million reduction in common share issuable to Fortress, partially offset by a $0.6 million loss on settlement of common stock warrant liabilities, an increase of $0.3 million in operating assets and liabilities, $0.4 million for shares issued to Fortress, $0.1 million change in fair value of warrant liability, partially offset by the $3.0 million AJ201 license payment, an increase in operating assets liabilities and liabilities of $0.6 million, $0.6 million $0.2 million in share-based compensation, $1.2 million in stock issuance for licenses acquired and $0.1 million in common share issuance to Fortress. compensation.

Net cash and cash equivalents used in operating activities was $3.4 million $1.6 million for the nine three months ended September 30, 2022 March 31, 2023, primarily comprised of our $4.1 million $7.6 million net loss partially offset by $0.6 million an increase in share-based compensation.

Investing Activities

Net cash operating assets and cash equivalents used liabilities of $3.8 million, $1.2 million in investing activities was $3.0 million stock issuance for the nine months ended September 30, 2023, comprised licenses acquired, $0.9 million change in fair value of the $3.0 million AJ201 license payment. warrant liability and $0.1 million in common share issuance to Fortress.

Financing Activities

Net cash and cash equivalents provided by financing activities was $3.6 million $4.5 million for the nine three months ended September 30, 2023 March 31, 2024, primarily comprised of $3.1 million $4.5 million in net proceeds from the January 2023 Registered Direct and Private Placement, $0.6 million from the September 2023 Private Placement, partially offset by $0.1 million of amounts paid due to expenses related to the November 2023 public offering. 2024 Warrant Inducement.

Net cash and cash equivalents used in provided by financing activities was $0.1 million $3.1 million for the nine three months ended September 30, 2022 March 31, 2023, primarily comprised of amounts payable due the $3.1 million Registered Direct and Private Placement on January 31, 2023.

Subsequent to expenses related end of the first quarter, we received net proceeds of $3.9 million, after deducting placement agent fees and offering costs, pursuant to the October 2022 public offering. May 2024 Warrant Inducement. See Note 9 - Subsequent Events to our unaudited condensed consolidated financial statements included herein.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

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

With respect to the quarter ended September 30, 2023 March 31, 2024, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company's Chief Executive Officer and interim Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective.

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

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2023 March 31, 2024 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 2023 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 2023 Form 10-K, the information below, and the other information set forth elsewhere in this Quarterly Report on Form 10-Q. 10-Q, including under "Forward-looking Statements." 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. During the three months ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified, or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act of 1933).

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	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., as filed on February 20, 2024, filed as Exhibit 3.1 to Form 8-K filed on February 23, 2024 (File No. 001-38114) and incorporated herein by reference.
3.6	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc. as filed on April 25, 2024, filed as exhibit 3.1 to Form 8-K filed on April 26, 2024 (File No. 001-38114) and incorporated herein by reference.
3.7	Second Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 10, 2023 (File No. 000-38114) and incorporated herein by reference.
10.1 4.1	Form of Avenue Therapeutics, Inc. Stock Option Agreement, New Series A Warrant (January 2024), filed as Exhibit 10.1 4.1 to Form 8-K filed on July 5, 2023 January 8, 2024 (File No. 001-38114) and incorporated herein by reference.
4.2	Form of New Series B Warrant (January 2024), filed as Exhibit 4.2 to Form 8-K filed on January 8, 2024 (File No. 001-38114) and incorporated herein by reference.
10.1	Registration Rights Form of January 2023 Investor Inducement Letter, Agreement, dated September 8, 2023, by and among the Company and the purchaser parties thereto, filed as Exhibit 10.1 to Form 8-K filed on September 8, 2023 January 8, 2024 (File No. 001-38114) and incorporated herein by reference.
10.2	Form of November 2023 Investor Inducement Letter, filed as Exhibit 10.2 to Form 8-K filed on January 8, 2024 (File No. 001-38114) and incorporated herein by reference.
31.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 13, 2023 May 15, 2024. *
31.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 13, 2023 May 15, 2024. *
32.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 13, 2023 May 15, 2024. **
32.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 13, 2023 May 15, 2024. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 March 31, 2024, 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: November 13, 2023 May 15, 2024

By: /s/ Alexandra MacLean, M.D.

Alexandra MacLean, M.D.

Chief Executive Officer and Director

Date: November 13, 2023 May 15, 2024

By: /s/ David Jin

David Jin

Interim Chief Financial Officer and Chief Operating Officer

(Duly Authorized Officer, Principal Financial and Accounting Officer)

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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 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)
November 13, 2023 May 15, 2024

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 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)

November 13, 2023 May 15, 2024

Exhibit 32.1

Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Alexandra MacLean, M.D., Chief Executive Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to my knowledge:

- The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 March 31, 2024 (the "Report") filed with the Securities and Exchange Commission fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Alexandra MacLean, M.D.

Alexandra MacLean, M.D.

Chief Executive Officer

(Principal Executive Officer)

November 13, 2023 May 15, 2024

Exhibit 32.2

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

I, David Jin, Interim Chief Financial Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to my knowledge:

- The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 March 31, 2024 (the "Report") filed with the Securities and Exchange Commission fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ David Jin

David Jin

Interim Chief Financial Officer

(Principal Financial Officer)

November 13, 2023 May 15, 2024

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