UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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, 2024

OR

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

COMMISSION FILE NUMBER: 001-37590

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0705648**
(State of incorporation)	(I.R.S. Employer Identification No.)
540 Gaither Road, Suite 400 **Rockville, Maryland 20850**	**(410) 522-8707**
(Address of principal executive offices)	(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	AVTX	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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions 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 ☑

As of November 6, 2024, the registrant had 10,393,954 shares of common stock outstanding.

AVALO THERAPEUTICS, INC.

FORM 10-Q

For the Quarter Ended September 30, 2024

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 81,858	$ 7,415
Other receivables	998	136
Prepaid expenses and other current assets	3,251	843
Restricted cash, current portion	41	1
Total current assets	86,148	8,395
Property and equipment, net	1,674	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 98,455	$ 20,993
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,811	$ 446
Accrued expenses and other current liabilities	7,033	4,172
Warrant liability	46,830	—
Contingent consideration	5,000	—
Total current liabilities	60,674	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	154	155
Derivative liability	11,810	5,550
Other long-term liabilities	1,083	1,366
Total liabilities	75,721	13,689
Mezzanine equity:		
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at September 30, 2024 and December 31, 2023, respectively; 13,710 and 0 shares of Series C Preferred Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1,658	—
Series D Preferred Stock—$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at September 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Series E Preferred Stock—$0.001 par value; 1 and 0 shares of Series E Preferred Stock authorized at September 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023;9,682,374 and 801,746 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	10	1
Additional paid-in capital	355,990	342,437
Accumulated deficit	(334,924)	(335,134)
Total stockholders' equity	21,076	7,304
Total liabilities, mezzanine equity and stockholders' equity	$ 98,455	$ 20,993

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 249	$ 236	$ 249	$ 1,353
Total revenues, net	249	236	249	1,353
Operating expenses:				
Cost of product sales	(714)	247	(453)	1,505
Research and development	9,538	1,249	16,254	11,917
Acquired in-process research and development	—	—	27,641	—
General and administrative	4,286	2,490	12,008	7,624
Total operating expenses	13,110	3,986	55,450	21,046
Loss from operations	(12,861)	(3,750)	(55,201)	(19,693)
Other income (expense):				
Excess of initial warrant fair value over private placement proceeds	—	—	(79,276)	—
Change in fair value of warrant liability	36,025	—	148,071	—
Private placement transaction costs	—	—	(9,220)	—
Change in fair value of derivative liability	(1,100)	100	(6,260)	(120)
Interest income (expense), net	964	(1,553)	2,101	(3,498)
Other expense, net	(5)	(17)	(5)	(42)
Total other income (expense), net	35,884	(1,470)	55,411	(3,660)
Income (loss) before taxes	23,023	(5,220)	210	(23,353)
Income tax (benefit) expense	(14)	8	—	23
Net income (loss)	$ 23,037	$ (5,228)	$ 210	$ (23,376)
Net income (loss) per share of common stock[1]:				
Basic	$ 0.98	$ (26.83)	$ 0.01	$ (231.05)
Diluted	$ (2.83)	$ (26.83)	$ (22.63)	$ (231.05)

[1] *Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-240 reverse stock split effected on December 28, 2023. See Note 1 for details.*

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Preferred Stock and Changes in Stockholders' Equity (Unaudited)

(In thousands, except share amounts)

	Preferred Stock		Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity
Three Months Ended September 30, 2024							
Balance, June 30, 2024	**22,360**	**$ 11,457**	**1,034,130**	**$ 1**	**$ 344,352**	**$ (357,961)**	**$ (13,608)**
Retirement of Series C Preferred Stock in exchange for issuance of common stock	(8,648)	(9,799)	—	—	—	—	—
Issuance of common stock in exchange for retirement of Series C Preferred Stock	—	—	8,648,244	9	9,790	—	9,799
Stock-based compensation	—	—	—	—	1,848	—	1,848
Net income	—	—	—	—	—	23,037	23,037
Balance, September 30, 2024	**13,712**	**$ 1,658**	**9,682,374**	**$ 10**	**$ 355,990**	**$ (334,924)**	**$ 21,076**

	Preferred Stock		Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity
Nine Months Ended September 30, 2024							
Balance, December 31, 2023	**— $**	**—**	**801,746**	**$ 1**	**$ 342,437**	**$ (335,134)**	**$ 7,304**
Impact of reverse split fractional share round-up	—	—	60,779	—	—	—	—
Issuance of common stock pursuant to Almata Transaction	—	—	171,605	—	815	—	815
Issuance of Series C Preferred Stock pursuant to Almata Transaction	2,412	11,457	—	—	—	—	—
Issuance of Series C Preferred Stock in private placement	19,946	—	—	—	—	—	—
Issuance of Series D Preferred Stock in private placement	1	—	—	—	—	—	—
Issuance of Series E Preferred Stock in private placement	1	—	—	—	—	—	—
Retirement of Series C Preferred Stock in exchange for issuance of common stock	(8,648)	(9,799)	—	—	—	—	—
Issuance of common stock in exchange for retirement of Series C Preferred Stock	—	—	8,648,244	9	9,790	—	9,799
Stock-based compensation	—	—	—	—	2,948	—	2,948
Net income	—	—	—	—	—	210	210
Balance, September 30, 2024	**13,712**	**$ 1,658**	**9,682,374**	**$ 10**	**$ 355,990**	**$ (334,924)**	**$ 21,076**

	Preferred Stock		Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares[1]	Amount[1]	capital[1]	deficit	equity
Three Months Ended September 30, 2023							
Balance, June 30, 2023	**—**	**$ —**	**58,489**	**$ —**	**$ 314,769**	**$ (321,738)**	**$ (6,969)**
Issuance of common shares pursuant to ATM Program, net	—	—	737,557	1	25,938	—	25,939
Exercise of pre-funded warrants for common shares	—	—	5,549	—	—	—	—
Stock-based compensation	—	—	—	—	953	—	953
Net loss	—	—	—	—	—	(5,228)	(5,228)
Balance, September 30, 2023	**—**	**$ —**	**801,595**	**$ 1**	**$ 341,660**	**$ (326,966)**	**$ 14,695**

	Preferred Stock		Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares[1]	Amount[1]	capital[1]	deficit	equity
Nine Months Ended September 30, 2023							
Balance, December 31, 2022	**—**	**$ —**	**39,294**	**$ —**	**$ 292,909**	**$ (303,824)**	**$ (10,915)**
Issuance of common stock and warrants in underwritten public offering, net	—	—	15,709	—	13,748	—	13,748
Issuance of common shares pursuant to ATM Program, net	—	—	746,077	1	32,469	—	32,470
Retirement of common shares in exchange for pre-funded warrants	—	—	(5,417)	—	(3,874)	234	(3,640)
Issuance of pre-funded warrants in exchange for retirement of common shares	—	—	—	—	3,640	—	3,640
Exercise of pre-funded warrants for common shares	—	—	5,850	—	—	—	—
Shares purchased through employee stock purchase plan	—	—	82	—	67	—	67
Stock-based compensation	—	—	—	—	2,701	—	2,701
Net loss	—	—	—	—	—	(23,376)	(23,376)
Balance, September 30, 2023	**—**	**$ —**	**801,595**	**$ 1**	**$ 341,660**	**$ (326,966)**	**$ 14,695**

[1] Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-240 reverse stock split effected on December 28, 2023. See Note 1 for details.

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows (Unaudited)

(Amounts in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities		
Net income (loss)	$ 210	$ (23,376)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	101	115
Stock-based compensation	2,948	2,701
Acquired in-process research and development	27,641	—
Excess of initial warrant fair value over private placement proceeds	79,276	—
Change in fair value of warrant liability	(148,071)	—
Transaction costs paid pursuant to private placement	7,485	—
Contingent consideration paid pursuant to Almata Transaction	(7,500)	—
Transaction costs payable upon exercise of warrants issued in private placement	1,734	—
Change in fair value of derivative liability	6,260	120
Accretion of debt discount	—	1,828
Deferred taxes	—	23
Changes in assets and liabilities:		
Other receivables	(862)	381
Inventory, net	—	20
Prepaid expenses and other assets	(2,408)	350
Lease incentive	—	158
Accounts payable	1,365	(2,094)
Accrued expenses and other liabilities	(2,110)	(8,088)
Lease liability, net	(81)	(52)
Net cash used in operating activities	(34,012)	(27,914)
Investing activities		
Cash assumed from Almata Transaction	356	—
Leasehold improvements	—	(158)
Disposal of property and equipment	—	25
Net cash provided by (used in) investing activities	356	(133)
Financing activities		
Proceeds from private placement investment, gross	115,625	—
Transaction costs paid pursuant to private placement	(7,485)	—
Proceeds from issuance of common stock and pre-funded warrants in underwritten public offering, net	—	13,748
Prepayment on Notes	—	(21,244)
Proceeds from issuance of common stock pursuant to ATM Program, net	—	32,470
Proceeds from issuance of common stock under employee stock purchase plan	—	67
Net cash provided by financing activities	108,140	25,041
Increase in cash, cash equivalents and restricted cash	74,484	(3,006)
Cash, cash equivalents, and restricted cash at beginning of period	7,546	13,318
Cash, cash equivalents, and restricted cash at end of period	$ 82,030	$ 10,312
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ 1,925
Supplemental disclosures of non-cash activities		
Issuance of common stock and Series C Preferred Stock pursuant to Almata Transaction	$ 12,272	$ —
Fair value of common stock retired in exchange for issuance of pre-funded warrants	$ —	$ 3,640

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30,	
	2024	2023
Cash and cash equivalents	$ 81,858	$ 10,180
Restricted cash, current	41	1
Restricted cash, non-current	131	131
Total cash, cash equivalents and restricted cash	$ 82,030	10,312

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial Statements

1. Business

Avalo Therapeutics, Inc. (the "Company," "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β monoclonal antibody ("mAb"), targeting inflammatory diseases. Avalo also has two additional drug candidates, which include quisovalimab (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein).

Avalo was incorporated in Delaware and commenced operation in 2011, and completed its initial public offering in October 2015.

Liquidity

Since inception, we have incurred significant operating and cash losses from operations. We have primarily funded our operations to date through sales of equity securities, out-licensing transactions and sales of assets.

For the nine months ended September 30, 2024, Avalo generated net income of $0.2 million and negative cash flows from operations of $34.0 million. As of September 30, 2024, Avalo had $81.9 million in cash and cash equivalents. In the first quarter of 2024, the Company closed a private placement investment consisting of an initial upfront gross investment of $15.6 million (net proceeds were $108.1 million after deducting transaction costs) and up to an additional $69.4 million of gross proceeds upon the exercise of 11,967,526 warrants issued in the financing, which expire on November 8, 2024. Subsequent to September 30, 2024 and through November 6, 2024, the Company received gross proceeds of $58.1 million from the exercise of the warrants issued in the private placement.

Based on our current operating plans, we expect that our existing cash and cash equivalents are sufficient to fund operations for at least twelve months from the filing date of this Quarterly Report on Form 10-Q and we expect current cash on hand to fund operations into at least 2027. The Company closely monitors its cash and cash equivalents and seeks to balance the level of cash and cash equivalents with our projected needs to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. We may satisfy any future cash needs through sales of equity securities under the Company's at-the-market program or other equity financings, out-licensing transactions, strategic alliances/collaborations, sale of programs, and/or mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by the Company, or if realized, what the terms may be. To the extent that we raise capital through the sale of equity, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Further, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated balance sheet at December 31, 2023 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC").

The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the December 31, 2023 audited consolidated financial statements.

On December 28, 2023, Avalo effected a 1-for-240 reverse stock split of the outstanding shares of the Company's common stock and began trading on a split-adjusted basis on December 29, 2023. The Company retroactively applied the reverse stock split to common share and per share amounts for periods prior to December 28, 2023, including the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2023. Additionally, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company's outstanding options and warrants, and the number of shares authorized for issuance pursuant to the Company's equity incentive plans have been reduced proportionately. Avalo retroactively applied such adjustments in the notes to consolidated financial statements for periods presented prior to December 28, 2023, including the three and nine months ended September 30, 2023. The reverse stock split did not reduce the number of authorized shares of common and preferred stock and did not alter the par value.

Unless otherwise indicated, all amounts in the following tables are in thousands except share and per share amounts.

Significant Accounting Policies

During the three months ended September 30, 2024, there were no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 29, 2024, and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, as filed with the SEC on May 13, 2024 (as amended on July 11, 2024).

3. Asset Acquisition

Almata Transaction

On March 27, 2024, the Company acquired AVTX-009, an anti-IL-1β mAb, through a merger with AlmataBio, Inc. ("AlmataBio") with and into its wholly owned subsidiary (the "Almata Transaction"). The Company's acquisition of AlmataBio was structured as a stock-for-stock transaction whereby all outstanding equity interests in AlmataBio were exchanged in a merger for a combination of the Company's common stock and shares of the Company's non-voting convertible preferred stock (the "Series C Preferred Stock"), resulting in the issuance of 171,605 shares of Company common stock and 2,412 shares of Series C Preferred Stock. Upon Company stockholder approval on August 13, 2024 and subject to beneficial ownership limitations,2,063 shares of Series C Preferred Stock issued to former AlmataBio stockholders automatically converted into 2,062,930 shares of common stock.

In addition to the shares issued, a cash payment of $7.5 million was due to the former AlmataBio stockholders upon the closing of a private placement investment. The private placement closed on March 28, 2024 and the Company paid the $7.5 million in April 2024. The Company is also required to pay potential development milestone payments to the former AlmataBio stockholders, including $5.0 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa ("HS") for AVTX-009, and $15.0 million due upon the first patient dosed in a Phase 3 trial for AVTX-009, both of which are payable in cash or Avalo stock at the election of the former AlmataBio stockholders, subject to the terms and conditions of the definitive merger agreement. In October 2024, the first development milestone was met and the Company paid the $5.0 million cash payment, which was accrued at the transaction closing date and as of September 30, 2024.

The Company has been determined to be the acquiring company for accounting purposes. In connection with the Almata Transaction, substantially all of the consideration paid is allocable to the fair value of acquired in-process research and development ("IPR&D"), specifically AVTX-009, and as such the acquisition is treated as an asset acquisition. The Company initially recognized AlmataBio's assets and liabilities by allocating the accumulated cost of the acquisition based on their relative fair values, as estimated by management. The net assets acquired as of the transaction date have been combined with the assets, liabilities, and results of operations of the Company on consummation of the Almata Transaction. In accordance with ASC 730, *Research and Development*, the portion of the consideration allocated to the acquired IPR&D, specifically AVTX-009, based on its relative fair value, is included as an operating expense as there is no alternative future use.

Below is a summary of the total consideration, assets acquired and the liabilities assumed in connection with the Almata Transaction (in thousands):

	Nine Months Ended September 30, 2024	
Stock consideration[1]	$	12,272
Milestone payment due upon close of private placement investment[2]		7,500
Milestone payment due upon first patient dosed in a Phase 2 trial[2]		5,000
Transaction costs		2,402
Total GAAP Purchase Price at Close	**$**	**27,174**
Acquired IPR&D	$	27,641
Cash		356
Accrued expenses and other current liabilities		(823)
Total net assets acquired and liabilities assumed	**$**	**27,174**

[1] Equal to the aggregate common shares issued of 171,605 and the aggregate preferred shares issued of 2,412 (as-convertible to 2,412,000 shares of common stock), multiplied by the Company's closing stock price of $4.75 on March 27, 2024. 2,063 *of the 2,412 preferred shares were converted into* 2,062,930 *shares of common stock on August 13, 2024 upon Company stockholder approval and subject to beneficial ownership limitations.*

[2] Avalo deemed these milestones probable and estimable as of the transaction close date and therefore included them as part of the GAAP purchase price at close. The first milestone payment due upon the close of the private placement investment was paid in April 2024. The second milestone payment due upon the first patient dosed in a Phase 2 trial was paid in October 2024.

The cost to acquire the IPR&D asset related to AVTX-009 was expensed on the date of the Almata Transaction as it was determined to have no future alternative use. Accordingly, costs associated with the Almata Transaction to acquire the asset were expensed as incurred in acquired IPR&D.

4. Revenue

The Company's license and supply agreement for Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, ended on September 30, 2023. Avalo considered Millipred® a non-core asset. Historically, the Company sold Millipred® in the United States primarily through wholesale distributors, who accounted for substantially all of the Company's net product revenues and trade receivables. The Company continues to monitor estimates for commercial liabilities for Millipred®, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized.

Pursuant to the Millipred® license and supply agreement, Avalo was required to pay the supplier fifty percent of the net profit of the Millipred® product following each calendar quarter, with a $0.5 million quarterly minimum payment contingent on Avalo achieving certain net profit thresholds as stipulated in the agreement. The profit share commenced on July 1, 2021 and ended on September 30, 2023. Within twenty-five months of September 30, 2023, the net profit share is subject to a reconciliation process where estimated deductions to arrive at net profit will be reconciled to actual results, which might result in Avalo owing additional amounts to the supplier or vice versa, which would be recognized in cost of product sales.

Aytu BioScience, Inc. ("Aytu"), to which the Company sold its rights, title, and interests in assets relating to certain commercialized products in 2019 (the "Aytu Transaction"), managed Millipred® commercial operations until August 31, 2021 pursuant to a transition services agreements, which included managing the third-party logistics provider. As a result, Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred® from the second quarter of 2020 through the third quarter of 2021. The transition services agreement allows Aytu to withhold up to $1.0 million until December of 2024 and requires the retention amount to remain at $1.0 million from June 1, 2024 until December 1, 2024, which resulted in the recognition of $0.4 million as an accrued expense and other current liability as of September 30, 2024. The Company assesses the collectability of the receivable, which was $0.9 million as of September 30, 2024, at each reporting period pursuant to ASC 326: *Current Expected Credit Loss Standard*. In the second quarter of 2022, the Company expected a full credit loss on the receivable and therefore fully reserved the receivable. Avalo considered, amongst other factors, Aytu's conclusion within its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 that substantial doubt existed with respect to its ability to continue as a going concern within one year after the date those financial statements were issued. In September 2024, Aytu publicly disclosed in its Annual Report on Form 10-K for the year ended June 30, 2024, that it had alleviated the previously disclosed substantial doubt about its ability to continue as a going concern. As of September 30, 2024, the Company expects to collect the total receivable balance and therefore recognized the amount within other receivables on the unaudited condensed consolidated balance sheet and reversed the reserve as a benefit to cost of product sales.

5. Net Income (Loss) Per Share

The Company had two classes of stock outstanding during the three and nine months ended September 30, 2024, common stock and preferred stock, and had only common stock outstanding during the three and nine months ended September 30, 2023. The Company computes net income (loss) per share using the two-class method, as the Series C Preferred Stock participates in distributions with the Company's common stock. The two-class method of computing net income (loss) per share is an earnings allocation formula that determines net income (loss) for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. As the Company had net income for the three and nine months ended September 30, 2024, the two-class method of calculating net income per share allocates a portion of the net income to the participating securities.

Basic net income (loss) per share for common stock is computed by dividing the sum of distributed and undistributed earnings by the weighted average number of shares outstanding for the period. The weighted average number of common shares outstanding as of September 30, 2023, includes the weighted average effect of pre-funded warrants, the exercise of which required nominal consideration for the delivery of the shares of common stock. There were no pre-funded warrants outstanding as of September 30, 2024.

Diluted net income (loss) per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive, and (iii) preferred stock under the if-converted method. While the impact of these items are generally anti-dilutive during periods of net loss, the Company will determine whether the common stock equivalents should be included in diluted loss per share pursuant to sequencing rules.

The following tables set forth the computation of basic and diluted net income (loss) per share of common stock for the three and nine months ended September 30, 2024 and September 30, 2023 (in thousands, except share and per share amounts):

	Three Months Ended September 30, 2024	
	Common stock	
Basic income per share:		
Net income	$	23,037
Net income attributed to Series C Preferred Stock		(17,575)
Net income - basic	$	5,462
Weighted average shares		5,546,257
Basic net income per share	$	0.98
Diluted loss per share:		
Numerator:		
Net income - basic	$	5,462
Change in fair value of warrant liability		(36,025)
Net loss - diluted	$	(30,563)
Denominator:		
Effect of dilutive securities:		
Weighted average shares - basic		5,546,257
Common shares issuable for warrants		5,237,780
Weighted average shares - diluted		10,784,037
Diluted net loss per share	$	(2.83)

	Nine Months Ended September 30, 2024	
	Common stock	
Basic income per share:		
Net income	$	210
Net income attributed to Series C Preferred Stock		(177)
Net income - basic	$	33
Weighted average shares		2,491,114
Basic net income per share	$	0.01
Diluted loss per share:		
Numerator:		
Net income - basic	$	33
Change in fair value of warrant liability		(148,071)
Net loss - diluted	$	(148,038)
Denominator:		
Effect of dilutive securities:		
Weighted average shares - basic		2,491,114
Common shares issuable for warrants		4,049,849
Weighted average shares - diluted		6,540,963
Diluted net loss per share	$	(22.63)

	Three Months Ended September 30, 2023	
	Common stock	
Net loss	$	(5,228)
Weighted average shares		194,851
Basic and diluted net loss per share	$	(26.83)

	Nine Months Ended September 30, 2023	
	Common stock	
Net loss	$	(23,376)
Weighted average shares		101,173
Basic and diluted net loss per share	$	(231.05)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three and nine months ended September 30, 2024 and 2023, as they could have been anti-dilutive:

	Three and Nine Months Ended September 30,	
	2024[3]	2023
Stock options	2,000,056	7,706
Warrants on common stock[1]	148	17,237
Series C Preferred Stock (as-convertible to common stock)[2]	13,709,653	—
Restricted Stock Units	632,100	—

[1] *The weighted average number of common shares outstanding for the three and nine months ended September 30, 2023 include the weighted average effect of 281 and 2,677 pre-funded warrants, respectively, because their exercise price was nominal. There were no pre-funded warrants outstanding as of September 30, 2024 and 2023.*

[2] *Each share of the Company's Series C Preferred Stock is convertible to 1,000 shares of common stock, subject to certain beneficial ownership limitations.*

[3] *Pursuant to the Almata Transaction, the Company is required to pay potential development milestone payments to the former AlmataBio stockholders in cash or Avalo stock at the election of the former AlmataBio stockholders; refer to Notes 3 and 13 for more information. In the event of share settlement, the number of Avalo shares delivered will vary based on the Company's stock price. These additional shares are not included in the computation of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2024 pursuant to the guidance on contingently issuable shares.*

6. Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820") defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	September 30, 2024 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 80,935	$ —	$ —
Liabilities			
Warrant liability	$ —	$ —	$ 46,830
Derivative liability	$ —	$ —	$ 11,810

	December 31, 2023 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 7,077	$ —	$ —
Liabilities			
Derivative liability	$ —	$ —	$ 5,550

**Investments in money market funds are reflected in cash and cash equivalents on the accompanying unaudited condensed consolidated balance sheets.*

As of September 30, 2024, the Company's financial instruments included cash and cash equivalents, restricted cash, other receivables, prepaid and other current assets, accounts payable, accrued expenses and other current liabilities, derivative liability, and warrant liability. As of December 31, 2023, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, accrued expenses and other current liabilities, and derivative liability.

The carrying amounts reported in the accompanying unaudited condensed consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts.

Level 3 Valuation

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability and derivative liability for the three and nine months ended September 30, 2024 and September 30, 2023:

	Warrant liability	Derivative liability	Total
Balance at June 30, 2024	$ 82,855	$ 10,710	$ 93,565
Change in fair value	(36,025)	1,100	(34,925)
Balance at September 30, 2024	$ 46,830	$ 11,810	$ 58,640

	Warrant liability	Derivative liability	Total
Balance at December 31, 2023	$ —	$ 5,550	$ 5,550
Initial valuation of warrant liability	194,901	—	194,901
Change in fair value	(148,071)	6,260	(141,811)
Balance at September 30, 2024	$ 46,830	$ 11,810	$ 58,640

	Derivative liability	Total
Balance at June 30, 2023	$ 5,050	$ 5,050
Change in fair value	(100)	(100)
Balance at September 30, 2023	$ 4,950	$ 4,950

	Derivative liability	Total
Balance at December 31, 2022	$ 4,830	$ 4,830
Change in fair value	120	120
Balance at September 30, 2023	$ 4,950	$ 4,950

Warrant liability

On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received (i)19,946 shares of Series C Preferred Stock and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into). Refer to Note 10 - Capital Structure and sub-header "March 2024 Financing" for more information.

The Company determined that the warrants do not satisfy the conditions to be accounted for as equity instruments. As the warrants do not meet the equity contract scope exception, the Company classified the warrants as a derivative liability upon issuance.

The Company's warrant liability was measured at fair value on the issuance date and is measured at fair value each reporting period thereafter until the warrants are either exercised or expire. As of September 30, 2024, there were 11,967,526 warrants outstanding. Subsequent to September 30, 2024 and through November 6, 2024,10,026,847 warrants were exercised for gross proceeds of $58.1 million. The warrants expire on November 8, 2024, which is the thirty-first day following the public announcement of the first patient dosed in a Phase 2 trial of AVTX-009 in hidradenitis suppurativa (the "Dosing Date"). Avalo expects no warrant liability as of December 31, 2024 given the expiration on November 8, 2024. Avalo will evaluate the impact of the warrant exercises and/or expirations in the fourth quarter of 2024.

The Company utilizes the Black-Scholes option pricing model to measure fair value of the warrants, which requires assumptions including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, are subjective and require judgment to develop. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our warrant liability could be materially different. The warrant liability was classified as a Level 3 instrument as its value was based on unobservable market inputs. The inputs utilized in the valuation as of September 30, 2024 include the following:

	As of September 30, 2024	
Common stock price	$	9.50
Term (in years)		0.1
Expected volatility		127 %
Risk-free rate		4.93 %
Exercise price	$	5.796933
Dividend yield rate		— %

The common stock price utilized is the closing stock price of Avalo's common stock on the last trading day of the reporting period. This input is the main driver of the fair value of the warrant liability as of September 30, 2024. The closing stock price on the last day of the third quarter of 2024 was $9.50 per share compared to the closing stock price on the last day of the second quarter and first quarter of 2024 of $12.47 per share and $21.75 per share, respectively.

The term utilized as of September 30, 2024 represents the contractual expiration date of November 8, 2024, which is the thirty-first day following the Dosing Date.

The other inputs include expected volatility, which, given the short-term of the warrants, is the Company's historical volatility, and the risk-free interest rate, which is based on the implied yield available on U.S. treasury securities with a maturity equivalent to the term.

Derivative liability

In the fourth quarter of 2022, Avalo sold its economic rights to future milestone and royalty payments for previously out-licensed assets AVTX-501, AVTX-007, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice Capital LLC ("Armistice"), in exchange for $5.0 million (the "ES Transaction"). At the time of the transaction, Armistice was a significant stockholder of the Company and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The ES Transaction was approved in accordance with Avalo's related party transaction policy.

The economic rights sold include (a) rights to a milestone payment of $20.0 million upon the filing and acceptance of an NDA for AVTX-501 pursuant to an agreement with Janssen Pharmaceutics, Inc. (the "AVTX-501 Milestone") and (b) rights to any future milestone payments and royalties relating to AVTX-007 under a license agreement with Apollo AP43 Limited ("Apollo"), including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments over a ten year period of a low single digit percentage of annual net sales (which percentage increases to another low single digit percentage if annual net sales exceed a specified threshold) (the "AVTX-007 Milestones and Royalties"). In addition, Avalo waived all its rights to AVTX-611 sales-based payments of up to $20.0 million that were payable by ES.

The exchange of the economic rights of the AVTX-501 Milestone and AVTX-007 Milestones and Royalties for cash met the definition of a derivative instrument. The fair value of the derivative liability is determined using a combination of a scenario-based method and an option pricing method (implemented using a Monte Carlo simulation). The significant inputs including probabilities of success, expected timing, and forecasted sales as well as market-based inputs for volatility, risk-adjusted discount rates and allowance for counterparty credit risk are unobservable and based on the best information available to Avalo. Certain information used in the valuation is inherently limited in nature and could differ from Janssen and Apollo's internal estimates.

The fair value of the derivative liability as of the transaction date was approximately $4.8 million, of which $3.5 million was attributable to the AVTX-501 Milestone and $1.3 million was attributable to the AVTX-007 Milestones and Royalties. Subsequent to the transaction date, at each reporting period, the derivative liability is remeasured at fair value. As of September 30, 2024, the fair value of the derivative liability was $11.8 million, of which $7.8 million was attributable to the AVTX-007 Milestones and Royalties and $4.0 million was attributable to the AVTX-501 Milestone. For the nine months ended September 30, 2024, the $6.3 million change in fair value was recognized in other income (expense), net in the accompanying unaudited condensed consolidated statements of operations and comprehensive income (loss).

The fair value of the AVTX-501 Milestone was primarily driven by an approximate 23% probability of success to reach the milestone in approximately 3.1 years. The fair value of AVTX-007 Milestones and Royalties was primarily driven by sales forecasts with peak annual net sales reaching $1.8 billion in atopic dermatitis, which is a much larger market opportunity than adult-onset Still's disease, the previous indication being pursued that was contemplated in valuations through the first quarter of 2024, an approximate 17% probability of success, as well as time to commercialization of approximately 6.3 years. As discussed above, these unobservable inputs were estimated by Avalo based on limited publicly available information and therefore could differ from Janssen and Apollo's internal development plans. Any changes to these inputs may result in significant changes to the fair value measurement. Notably, the peak annual net sales forecast (for the AVTX-007 Milestones and Royalties) and probability of successes (for both the AVTX-501 Milestone and the AVTX-007 Milestone and Royalties) are the largest drivers of the fair value and therefore changes to such inputs would likely result in significant changes to such fair value.

In the event that Janssen and/or Apollo are required to make payment(s) to ES Therapeutics pursuant to the underlying agreements, Avalo will recognize revenue under its existing contracts with those customers for that amount when it is no longer probable there would be a significant revenue reversal with any differences between the fair value of the derivative liability related to that payment immediately prior to the revenue recognition and revenue recognized to be recorded as other expense. However, given Avalo is no longer entitled to collect these payments, the potential ultimate settlement of the payments in the future from Janssen and/or Apollo to ES Therapeutics (and the future mark-to-market activity each reporting period) will not impact Avalo's future cash flows.

No changes in valuation techniques occurred during the nine months ended September 30, 2024 and 2023. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2024 and 2023.

7. Leases

Avalo currently occupies two leased properties, both of which serve as administrative office space. The Company determined that both of these leases are operating leases based on the lease classification test performed at lease commencement.

The annual base rent for the Company's office located in Rockville, Maryland is $0.2 million, subject to annual 2.5% increases over the term of the lease. The applicable lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company made its first annual fixed rent payment, which occurred in January 2020. The Company has the option to extend the lease two times, each for a period of five years, and may terminate the lease as of the sixth anniversary of the first annual fixed rent payment, upon the payment of a termination fee.

The initial annual base rent for the Company's office located in Chesterbrook, Pennsylvania is $0.2 million and the annual operating expenses are approximately $0.1 million. The annual base rent is subject to periodic increases of approximately 2.4% over the term of the lease. The lease has an initial term of 5.25 years from the lease commencement on December 1, 2021.

The weighted average remaining term of the operating leases at September 30, 2024 was 3.9 years.

Supplemental balance sheet information related to the leased properties include (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Property and equipment, net	$ 1,139	$ 1,329
Accrued expenses and other current liabilities	$ 550	$ 537
Other long-term liabilities	1,083	1,366
Total operating lease liabilities	$ 1,633	$ 1,903

The operating lease right-of-use ("ROU") assets are included in property and equipment, net and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our unaudited condensed consolidated balance sheets. The Company utilized a weighted average discount rate of 9.0% to determine the present value of the lease payments.

The components of lease expense for the three and nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost*	$ 104	$ 97	$ 326	$ 350

**Includes short-term leases, which are immaterial.*

The following table shows a maturity analysis of the operating lease liabilities as of September 30, 2024 (in thousands):

	Undiscounted Cash Flows
October 1, 2024 through December 31, 2024	$ 136
2025	553
2026	563
2027	259
2028	201
2029	207
Thereafter	17
Total lease payments	$ 1,936
Less implied interest	(303)
Total	$ 1,633

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	As of	
	September 30, 2024	December 31, 2023
Research and development	$ 775	$ 352
Compensation and benefits	2,192	580
General and administrative	386	830
Private placement investment transaction costs	1,734	—
Commercial operations	1,155	1,873
Royalty payment	241	—
Lease liability, current	550	537
Total accrued expenses and other current liabilities	$ 7,033	$ 4,172

9. Notes Payable

On June 4, 2021, the Company entered into a $35.0 million venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments XXV, LP ("Powerscourt", and together with Horizon, the "Lenders"). Between June and September of 2021, the Company borrowed the full $35.0 million (the "Note") available under the Loan Agreement.

In the second quarter of 2022, the Company, as collectively agreed upon with the Lenders, prepaid $15.0 million of principal and accrued interest. In June of 2023, the Company, as collectively agreed upon with the Lenders, prepaid $6.0 million of principal. On September 22, 2023, the Company and the Lenders entered into a Payoff Letter (the "Payoff Letter"), pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement in the aggregate amount of $14.3 million. As a result of the payment, all obligations of the parties under the Loan Agreement were deemed satisfied and terminated.

On June 4, 2021, pursuant to the Loan Agreement, the Company issued warrants to the Lenders to purchase 148 shares of the Company's common stock with an exercise price of $7,488.00 per share (the "Loan Warrants"). The Loan Warrants are exercisable for ten years from the date of issuance. Pursuant to the Payoff Letter, Avalo's obligations under the Loan Warrants shall survive pursuant to the original terms at issuance. The Loan Warrants, which met equity classification, were recognized as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Company recognized debt issuance costs and the amount allocated to the Loan Warrants as a debt discount on the date of issuance and amortized these costs to interest expense using the effective interest method over the original term of the loan. As a result of the payoff in the third quarter of 2023, the Company accelerated the remaining $0.9 million amortization of the debt discount, which was recognized as interest expense in the third quarter of 2023.

No Loan Warrants were exercised for the three and nine months ended September 30, 2024.

10. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock, common stock and preferred stock. At September 30, 2024, the total number of shares of capital stock the Company was authorized to issue was 205,000,000, of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share.

Almata Transaction

On March 27, 2024, the Company acquired AlmataBio in which the former AlmataBio stockholders received (i) 171,605 shares of the Company's common stock and (ii) 2,412 shares of the Company's Series C Preferred Stock. Upon Company stockholder approval, which was obtained on August 13, 2024 and subject to beneficial ownership limitations, 2,063 shares of the Series C Preferred Stock issued to the former AlmataBio stockholders automatically converted into 2,062,930 shares of common stock. Refer to Note 3 - Asset Acquisition for more information regarding the acquisition and refer to sub-header *"Series C Preferred Stock"* within the *"March 2024 Financing"* section below for more information regarding the Series C Preferred Stock.

March 2024 Financing

On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received (i) 19,946 shares of non-voting convertible Series C Preferred Stock, and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into), resulting in upfront gross proceeds of $115.6 million. Net proceeds were $108.1 million after deducting transaction costs. Upon the closing of financing, the Company could receive up to an additional $69.4 million of gross proceeds upon the exercise of the warrants, which expire on November 8, 2024. Subsequent to September 30, 2024 and through November 6, 2024, the Company received gross proceeds of $58.1 million pursuant to the exercise of 10,026,847 warrants. Upon Company stockholder approval, which was obtained on August 13, 2024 and subject to beneficial ownership limitations, 6,585 shares of Series C Preferred Stock issued pursuant to the financing automatically converted into 6,585,314 shares of common stock.

Warrants on common stock or Series C Preferred Stock issued in March 2024 Financing

The warrants are exercisable via gross physical settlement for $5.796933 per underlying share of common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into). The warrants expire on November 8, 2024, which is the thirty-first day following the public announcement of the first patient dosed in a Phase 2 trial of AVTX-009 in hidradenitis suppurativa. The warrants include anti-dilution protection provisions.

The Company determined that the warrants do not satisfy the conditions to be accounted for as equity instruments. As the warrants do not meet the equity contract scope exception, the Company classified the warrants as a derivative liability upon issuance. The initial measurement of the warrant at fair value exceeded the proceeds received such that the difference between the initial fair value of the warrants and net upfront cash proceeds is recognized in the income statement as a loss. Subsequently, the warrants are carried at fair value with changes in fair value recognized in the Company's unaudited condensed consolidated statements of operations and comprehensive income (loss) until either exercised or expired. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. See Note 6 - Fair Value Measurement for a description of the warrant's valuation methodology.

No warrants were exercised for the nine months ended September 30, 2024. Subsequent to September 30, 2024 and through November 6, 2024, 10,026,847 warrants were exercised resulting in the issuance of 711,580 shares of common stock and 9,315.267 shares of Series C Preferred Stock. Each share of Series C Preferred Stock is convertible into 1,000 shares of common stock, subject to beneficial ownership limitations. Remaining unexercised warrants, if any, will expire on November 8, 2024.

Upon exercise of the warrants, the Company will pay an additional amount of transaction costs to a third-party financial institution, based on 2.5% gross proceeds received from the exercise. As the warrants are in the money as of September 30, 2024, the Company has recognized $1.7 million for transaction costs within other income (expense), net for the nine months ended September 30, 2024. Based on warrant exercises through November 6, 2024, the Company will pay approximately $1.5 million of transaction costs in the fourth quarter of 2024 and will monitor additional fees due for any subsequent exercises. The Company also incurred an additional $7.5 million of transaction costs related to the private placement investment which were expensed within other income (expense), net for the nine months ended September 30, 2024.

Series C Preferred Stock issued in the Almata Transaction and March 2024 Financing

As of September 30, 2024, the Company had 5,000,000 shares of Preferred Stock authorized, of which 34,326 have been designated as Series C Preferred Stock. Of the 22,358 shares of Series C Preferred Stock that were issued pursuant to the March 2024 Financing and the Almata Transaction, 8,648 shares of Series C Preferred Stock were converted into 8,648,244 shares of common stock on August 13, 2024 upon Company stockholder approval and subject to beneficial ownership limitations, leaving 13,710 shares of Series C Preferred Stock outstanding as of September 30, 2024. The Series C Preferred Stock has a par value of $0.001 per share. The Series C Preferred Stock has no voting rights, no liquidation preference, and are not redeemable. In the event of any liquidation, dissolution or winding up of the Company, holders of Series C Preferred Stock are entitled to be paid out of the assets with the Company legally available for distribution to its stockholders on an as-converted and pari-passu basis with common stock. The Series C Preferred Stock is subject to broad-based weighted average anti-dilution protection for certain issuances of common stock and securities convertible into common stock. The Series C Preferred Stock is entitled to receive dividends equal to and in the same form, and in the same manner, based on the then-current conversion ratio as dividends actually paid on shares of the common stock, when, as and if such dividends are paid on shares of the common stock.

The Series C Preferred Stock is contingently redeemable outside the control of the Company such that the Series C Preferred Stock is recognized outside of permanent equity. The $11.5 million carrying value of the 2,412 shares of Series C Preferred Stock issued to the former AlmataBio stockholders pursuant to the Almata Transaction was recognized outside of stockholders' equity on the Company's unaudited condensed consolidated balance sheet upon issuance. Following the automatic conversion of 2,063 of the shares of Series C Preferred Stock on August 13, 2024, the remaining 349 shares of Series C Preferred Stock held by the former AlmataBio stockholders, with a carrying value of $1.7 million, remains recognized outside of stockholders' equity on the Company's unaudited condensed consolidated balance sheet as of September 30, 2024. Upon converting to common stock, the corresponding carrying value of the shares of Series C Preferred Stock of $9.8 million, was classified as a component of permanent stockholders' equity within additional paid-in capital in the Company's unaudited condensed consolidated balance sheet as of September 30, 2024. No amounts were allocated to the Series C Preferred Stock issued pursuant to the March 2024 Financing because the initial fair value of the warrants exceeded gross proceeds received for the issuance of the private placement bundle that included both Series C Preferred Stock and warrants. The Series C Preferred Stock is not remeasured to redemption value until the shares are probable of becoming redeemable for cash. As of September 30, 2024, the Company expects to have sufficient authorized and unissued shares to settle the Series C Preferred Stock, and therefore it is not probable that the Series C Preferred Stock would be redeemable for cash as of the balance sheet date.

Series D and Series E Preferred Stock issued in the March 2024 Financing

As a condition to the March 2024 Financing, a single share of Series D Preferred Stock and a single Series E Preferred Stock were issued to two institutional investors that participated in the private placement. Both the Series D and the Series E Preferred Stock have a par value and liquidation preference of $0.001 per share. The Series D and Series E Preferred Stock do not have voting rights, are not entitled to dividends, and are not convertible into common stock. The holders of the Series D and Series E Preferred Stock have the option to require the Company to redeem their shares at a price equal to the par value at any time. The Company retains the right to redeem the Series D and Series E Preferred Stock at a price equal to the par value if the holder owns less than a certain threshold of the Company's outstanding common stock. While the Series D and Series E Preferred Stock do not provide the holders with substantive economics, the Series D and Series E Preferred Stock were issued solely to allow for the institutional investors to appoint a director to the Company's board of directors.

Common Stock Warrants

At September 30, 2024, the following common stock warrants were outstanding:

Number of common shares underlying warrants			Exercise price per share	Expiration date
148			$ 7,488	June 2031
11,967,526	(1)	(2)	$ 5.796933	November 8, 2024
11,967,674				

(1) The warrants are exercisable for shares of common stock or an equivalent amount (as converted to common stock) of Series C Preferred Stock.
(2) Subsequent to September 30, 2024 and through November 6, 2024,10,026,847 warrants were exercised resulting in the issuance of711,580 shares of common stock and9,315.267 shares of Series C Preferred Stock. Each share of Series C Preferred Stock is convertible into 1,000 shares of common stock, subject to certain beneficial ownership limitations.

11. Stock-Based Compensation

2016 Equity Incentive Plan

In April 2016, our board of directors adopted the 2016 Equity Incentive Plan, which was approved by our stockholders in May 2016 and which was subsequently amended and restated in May 2018 and August 2019 with the approval of our board of directors and our stockholders (the "2016 Third Amended Plan"). In June 2024, our board of directors approved a fourth amended and restated equity incentive plan, which was subsequently approved by the Company's stockholders in August 2024 (the "2016 Fourth Amended Plan"). During the term of the 2016 Fourth Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year ending on (and including) January 1, 2034, by an amount equal to 5% of the total number of outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted stock basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any) as of December 31st of the preceding calendar year. On January 1, 2024, pursuant to the terms of the 2016 Third Amended Plan, an additional32,070 shares were made available for issuance. Upon approval of the 2016 Fourth Amended Plan on August 13, 2024, the number of shares available for issuance increased by 3,508,804 shares. As of September 30, 2024, there were 1,300,743 shares available for future issuance under the 2016 Fourth Amended Plan.

Option grants expire after ten years. Employee options typically vest over four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. Options granted to directors typically vest either immediately or over a period of one or three years. Directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. Stock-based compensation expense includes expense related to stock options, restricted stock units and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the three and nine months ended September 30, 2024 and 2023 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 762	$ 371	$ 1,250	$ 1,028
General and administrative	1,086	582	1,698	1,673
Total stock-based compensation	$ 1,848	$ 953	$ 2,948	$ 2,701

Stock options with service-based vesting conditions

The Company has granted options that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periodsA summary of option activity for the nine months ended September 30, 2024 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)
Balance at December 31, 2023	7,211	$ 3,191.97	$ 1,930.00	8.3
Granted	1,993,100	$ 10.47	$ 9.04	
Forfeited	(27)	$ 323.13	$ 232.02	
Expired	(228)	$ 13,926.66	$ 6,649.90	
Balance at September 30, 2024	2,000,056	$ 20.35	$ 15.22	9.8
Exercisable at September 30, 2024	5,588	$ 3,240.47	$ 2,000.64	7.5

On August 13, 2024, as part of its annual stock option award, the Company granted options with service-based vesting conditions to purchase1.4 million shares of common stock to its employees that vest over four years and options with service-based vesting conditions to purchase0.1 million shares of common stock to its non-employee directors that vest overthree years. Additionally, in June and July 2024, the Company granted 0.2 million options to each of its newly appointed Chief Legal Officer and newly appointed Chief Medical Officer. The options were granted as inducement option grants pursuant to Nasdaq Listing Rule 5635(c)(4) and are subject to service-based vesting conditions.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2024, the aggregate intrinsic value of options outstanding was zero. There were 2,300 options that vested during the nine months ended September 30, 2024 with a weighted average exercise price of $1,164.22 per share. The total grant date fair value of shares which vested during the nine months ended September 30, 2024 was $1.9 million.

The Company recognized stock-based compensation expense of $1.4 million and $2.5 million related to stock options with service-based vesting conditions for the three and nine months ended September 30, 2024. At September 30, 2024, there was $18.4 million of total unrecognized compensation cost related to unvested service-based vesting condition awards. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.3 years.

Stock-based compensation assumptions

The following table presents the assumptions used to compute stock-based compensation for stock options with service-based vesting conditions granted under the Black-Scholes valuation model for the nine months ended September 30, 2024.

Service-based options	
Expected term of option (in years)	5.81 - 6.25
Expected stock price volatility	113.1% - 116.9%
Risk-free interest rate	3.70% - 4.26%
Expected annual dividend yield	0%

As of September 30, 2024, there were no outstanding stock options that contained market-based vesting conditions.

Restricted Stock Units

The Company has granted restricted stock units ("RSU") that contain service-based vesting conditions. The Company measures the fair value of the RSUs using the stock price on the date of grant. The compensation cost for RSUs is recognized on a straight-line basis over the vesting period. A summary of RSU activity for the nine months ended September 30, 2024 is as follows:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Balance at Unvested RSUs at December 31, 2023	—	$ —
Granted	632,100	9.88
Unvested RSUs at September 30, 2024	632,100	$ 9.88

The RSUs, which were granted on August 13, 2024, vest annually over a three-year period beginning on March 28, 2025. The Company recognized stock-based compensation expense of $0.4 million related to RSUs for the three and nine months ended September 30, 2024. At September 30, 2024, there was $8 million of total unrecognized compensation cost related to RSUs. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.5 years.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan, which was approved by the Company's stockholders and became effective on May 18, 2016 (the "Initial ESPP"). In June 2024, our board of directors approved an amended and restated employee stock purchase plan, which was subsequently approved by the Company's stockholders in August 2024 (the "ESPP").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

The Company initially reserved and authorized up to 174 shares of common stock for issuance under the Initial ESPP. Pursuant to the ESPP, on January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP automatically increases by a number equal to 1% of the Company's outstanding shares of common stock and Series C Preferred Stock (determined on an as-converted basis) plus all outstanding prefunded warrants to acquire shares of common stock (if any), as of December 31st of the preceding calendar year. On January 1, 2024, pursuant to the Initial ESPP the number of shares available for issuance increased by 174. Upon approval of the ESPP on August 13, 2024, the number of shares available for issuance increased by 233,920 shares. As of September 30, 2024, 234,878 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized minimal stock-based compensation expense for the three and nine months ended September 30, 2024.

12. Income Taxes

The Company recognized minimal income tax expense for the three and nine months ended September 30, 2024 and 2023 due to the significant valuation allowance against the Company's deferred tax assets and the quarter-to-date and year-to-date pre-tax net income.

13. Commitments and Contingencies

Litigation

Litigation - General

The Company may become party to various contractual disputes, litigation, and potential claims arising in the ordinary course of business. Reserves are established in connection with such matters when a loss is probable, and the amount of such loss can be reasonably estimated. The Company currently does not believe that the resolution of such matters will have a material adverse effect on its financial position or results of operations except as otherwise disclosed in this report.

Possible Future Milestone Payments for In-Licensed Compounds

General

Avalo is a party to license and development agreements with various third parties, which contain future payment obligations such as royalties and milestone payments. The Company recognizes a liability (and related expense) for each milestone if and when such milestone is probable and can be reasonably estimated. As typical in the biotechnology industry, each milestone has unique risks that the Company evaluates when determining the probability of achieving each milestone and the probability of success evolves over time as the programs progress and additional information is obtained. The Company considers numerous factors when evaluating whether a given milestone is probable including (but not limited to) the regulatory pathway, development plan, ability to dedicate sufficient funding to reach a given milestone and the probability of success.

AVTX-009 Agreements

On March 27, 2024, Avalo obtained the rights to an anti-IL-1β mAb (AVTX-009), including the world-wide exclusive license from Eli Lilly and Company ("Lilly") (the "Lilly License Agreement"), pursuant to its acquisition of AlmataBio. AlmataBio had previously purchased the rights, title and interest in the asset from Leap Therapeutics, Inc. ("Leap") in 2023, which have since been assumed by Avalo pursuant to its acquisition of AlmataBio (the "Leap Agreement"). Avalo is responsible for the development and commercialization of the program.

Avalo is required to pay up to $70.0 million based on the achievement of specified development and regulatory milestones to Lilly. Upon commercialization, the Company is required to pay sales-based milestones aggregating up to $650.0 million payable to Lilly and $70.0 million payable to Leap. There are no annual or maintenance fees payable under the Lilly License Agreement and Leap Agreement. Additionally, Avalo is required to pay royalties to Lilly during a country-by-country royalty term in which the low end and the high end of the range fall between 5% and 15% of Avalo or its sublicensees' annual net sales. The royalty term due to Lilly commences on the date of first commercial sale of the licensed product in a given territory and expires on a county-by-country basis; on the latest of (a) the tenth (10th) anniversary of the date of the first commercial sale, (b) the expiration of the last-to-expire licensed patent in the given territory, or (c) the expiration of any data exclusivity period for the licensed product in the given territory.

The Lilly License Agreement remains in effect until the expiration of the last-to-expire royalty term of any licensed products. Each party may terminate for cause or by mutual agreement though the Company may terminate at its sole discretion by giving one-hundred twenty (120) days' prior written notice to Lilly. There are no termination or expiration provisions under the Leap Agreement.

Avalo has not paid any milestones, royalties or any other amounts under the Lilly License Agreement or Leap Agreement.

No expense related to the agreements was recognized in the nine months ended September 30, 2024. There has been no cumulative expense recognized as of September 30, 2024 under the agreements. The Company will continue to monitor the milestones and royalties at each reporting period.

Refer to the sub-header below entitled "Acquisition Related and Other Contingent Liabilities" for information regarding future development milestones that are payable to the former AlmataBio stockholders.

Quisovalimab (AVTX-002) Agreements

KKC License Agreement

On March 25, 2021, the Company entered into a license agreement with Kyowa Kirin Co., Ltd. ("KKC") for exclusive worldwide rights to develop, manufacture and commercialize quisovalimab, KKC's first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody for all indications (the "KKC License Agreement"). The KKC License Agreement replaced the Amended and Restated Clinical Development and Option Agreement between the Company and KKC dated May 28, 2020. Avalo is responsible for the development and commercialization of quisovalimab in all indications worldwide (other than the option in the KKC License Agreement that, upon exercise by KKC, allows KKC to develop, manufacture and commercialize quisovalimab in Japan).

Under the KKC License Agreement, the Company paid KKC an upfront license fee of $10.0 million, which we recognized within research and development expenses in 2021. Avalo is also required to pay KKC up to an aggregate of $112.5 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to make milestone payments to KKC aggregating up to $75.0 million tied to the achievement of annual net sales targets. There are no annual or maintenance fees payable under the KKC License Agreement.

Additionally, the Company is required to pay KKC royalties during a country-by-country royalty term equal to a mid-teen percentage of annual net sales. The Company is required to pay KKC a mid-twenties percentage of the payments that the Company receives from sublicensing of its rights under the KKC License Agreement, subject to certain exclusions. The royalty term due to KKC commences on the date of first commercial sale of the licensed product in a given territory and expires on a county-by-country basis, on the latest of (a) the twelfth (12th) anniversary of the date of the first commercial sale, (b) the expiration of the last-to-expire licensed patent in the given territory, or (c) the expiration of any data exclusivity period for the licensed product in the given territory.

The KKC License Agreement remains in effect while the Company and its affiliates and sublicensees develop and commercialize quisovalimab subject to customary termination rights. Each party may terminate for cause though Avalo may terminate for convenience upon six (6) months' prior written notice in the case where regulatory approval has not been obtained for the licensed product or upon twelve (12) months' prior written notice where regulatory approval has been obtained for the licensed product.

As disclosed above, Avalo paid the $10.0 million upfront license fee in 2021. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to the KKC License Agreement was recognized in the nine months ended September 30, 2024. There has been no cumulative expense recognized as of September 30, 2024 related to the milestones, royalties or any other amounts other than the $10.0 million upfront license fee incurred in 2021 as disclosed above. The Company will continue to monitor the milestones and royalties at each reporting period.

CHOP License Agreement

Following its February 3, 2020 merger with Aevi Genomic Medicine, Inc. ("Aevi"), the Company became party to a license agreement with The Children's Hospital of Philadelphia ("CHOP") (as amended, the "CHOP License Agreement"). Quisovalimab became a covered product under this license agreement in 2021 and at that time became subject to the terms therein.

An initial upfront fee of $0.5 million was paid to CHOP by Aevi, which Avalo acquired in 2020. Avalo is required to pay an additional $1.0 million to CHOP based on the achievement of specified regulatory and commercial milestones Avalo is obligated to pay an annual license maintenance fee of $0.2 million to CHOP, of which Avalo has paid an aggregate of $0.9 million as of the filing date of this Quarterly Report on Form 10-Q.

The Company is also obligated to pay tiered royalties to CHOP on a country-to-country basis in which the low end and high end of the range are single-digit royalties based on the Company's net sales of quisovalimab. The royalty term extends to the later of (a) fifteen years following the original date of the CHOP License Agreement, (b) the last-to-expire of the valid claims in the licensed patent rights covering the manufacture, sale, or use of quisovalimab and (c) the expiration of the regulatory exclusivity period for quisovalimab.

CHOP may terminate the CHOP License Agreement for the material default or insolvency of the Company, and the Company may terminate the CHOP License Agreement at will withsix (6) months' written notice.

As disclosed above, Aevi paid the $0.5 million upfront license fee and Avalo has paid $0.9 million of annual license fees. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to the milestones and royalties due under the CHOP Agreement was recognized for the nine months ended September 30, 2024. Avalo has not recognized any cumulative expense under the agreement related to the milestone or royalties as of September 30, 2024. The Company will continue to monitor the milestones and royalties at each reporting period.

AVTX-008 Sanford Burnham Prebys License Agreement

On June 21, 2021, the Company entered into an Exclusive Patent License Agreement with Sanford Burnham Prebys Medical Discovery Institute (the "Sanford Burnham Prebys License Agreement") under which the Company obtained an exclusive license to a portfolio of issued patents and patent applications covering an immune checkpoint program (AVTX-008). Avalo is responsible for the development and commercialization of the program.

Under the terms of the Sanford Burnham Prebys License Agreement, the Company paid an upfront license fee of $0.4 million, as well as patent costs of $0.5 million, which we recognized within research and development expenses and within general and administrative expenses, respectively, in 2021. Additionally, Avalo pays a $ 40 thousand annual maintenance fee payable on the first anniversary of the effective date and each anniversary thereafter until the first commercial sale (of which Avalo has paid $ 0.1 million of annual maintenance fees as of the filing date of this Quarterly Report on Form 10-Q). The Company is required to pay Sanford Burnham Prebys up to approximately $24.2 million based on achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay Sanford Burnham Prebys sales-based milestone payments aggregating up to $50.0 million tied to annual net sales targets.

Additionally, the Company is required to pay Sanford Burnham Prebys royalties during a country-by-country royalty term equal to a tiered low-to-mid single digit percentage of annual net sales. Avalo is also required to pay Sanford Burnham Prebys tiered payments in which the low end and high end of the range fall on or between 10% and 20% of what Avalo receives from sublicensing its rights under the Sanford Burnham Prebys License Agreement, subject to certain exclusions.

The Sanford Burnham Prebys License Agreement remains in effect until the expiration of the royalty term, which with respect to each product and country, continues until the expiration, invalidation or abandonment of the last of the licensed patent rights. Avalo may terminate the Sanford Burnham Prebys License Agreement at any time at its convenience upon providing at least ninety (90) days' prior written notice. Sanford Burnham Medical Discovery Institute may terminate the Sanford Burnham Prebys License Agreement for cause.

As disclosed above, Avalo paid the $0.4 million upfront fee, as well as total patent costs of $0.5 million and $0.1 million of annual maintenance fees. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to milestones or royalties pursuant to the Sanford Burnham Prebys License Agreement was recognized in the nine months ended September 30, 2024. There has been no cumulative expense recognized as of September 30, 2024 related to the milestones or royalties under this license agreement other than the $0.4 million upfront fee incurred in 2021. The Company will continue to monitor the milestones and royalties at each reporting period.

AVTX-006 Astellas License Agreement

On July 15, 2019, the Company entered into an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for the worldwide development and commercialization of the novel, second generation mTORC1/2 inhibitor (AVTX-006). Avalo is fully responsible for the development and commercialization of the program. Avalo considers AVTX-006 a non-core asset and is exploring strategic alternatives.

Under the terms of the license agreement, there was an upfront license fee of $0.5 million. The Company is required to pay Astellas up to an aggregate of $5.5 million based on the achievement of specified development and regulatory milestones. There are no annual maintenance fees payable under the Astellas license agreement. Additionally, the Company is required to pay Astellas a tiered mid-to-high single digit percentage of the payments that Avalo receives from any sublicensing of its rights under the Astellas license agreement, subject to certain exclusions. Upon commercialization, the Company is required to pay Astellas royalties during a country-by-country royalty term equal to a tiered mid-to-high single digit percentage of annual net sales during the period beginning upon the date of the first commercial sale of such licensed product in such country and ending on the later to occur of (a) the expiry of the last valid claim of an OSI product patent covering such licensed product in such country, (b) expiration of regulatory exclusivity in such country, and (c) ten (10) years from the first commercial sale of such licensed product in such country.

The Astellas License Agreement remains in effect on a country-by-country and licensed product-by-licensed product basis (in the territory), unless the license agreement is terminated earlier in accordance with the license agreement. Avalo may terminate the agreement at any time upon providing sixty (60) days' written notice to Astellas and may terminate the agreement in its entirety without cause.

As disclosed above, Avalo paid the $0.5 million upfront license fee. No further amounts have been paid related to the milestones, royalties or any other amounts under the agreement.

No expense related to this license agreement was recognized in the nine months ended September 30, 2024. There has been $0.5 million of cumulative expense recognized as of September 30, 2024 related to the milestones under this license agreement. The Company will continue to monitor the remaining milestones and royalties at each reporting period. The Company will continue to monitor the remaining milestones and royalties at each reporting period.

Possible Future Milestone Proceeds for Out-Licensed Compounds

AVTX-301 Out-License

On May 28, 2021, the Company out-licensed its rights in respect of its non-core asset, AVTX-301, to Alto Neuroscience, Inc. ("Alto"). The Company initially in-licensed the compound from an affiliate of Merck & Co., Inc. in 2013. Alto is fully responsible for the development and commercialization of the program.

Under the out-license agreement, the Company received a mid-six digit upfront payment from Alto, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $18.6 million based on the achievement of specified development, regulatory and commercial sales milestones. Additionally, the Company is entitled to a less than single digit percentage royalty based on annual net sales.

The out-license agreement remains in effect on a licensed product-by-licensed product and country-by-country basis until the later of (i) the expiration of the last to expire valid patent claim covering such licensed product in such country, or (ii) 10 (ten) years after the first commercial sale of such licensed product in such country. Upon expiration of the agreement, the licenses shall become a fully paid-up, royalty-free, irrevocable, perpetual non-exclusive license and sublicense.

The Company had not recognized any milestones as of September 30, 2024 or received any payments other than the upfront payment as disclosed above.

AVTX-406 License Assignment

On June 9, 2021, the Company assigned its rights, title, interest, and obligations under an in-license covering its non-core asset, AVTX-406, to ES, a wholly owned subsidiary of Armistice, who was a significant stockholder of the Company at the time of the transaction and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The transaction with ES was approved in accordance with Avalo's related party transaction policy. ES is fully responsible for the development and commercialization of the program.

Under the assignment agreement, the Company received a low-six digit upfront payment from ES, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $6.0 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is eligible to receive sales-based milestone payments aggregating up to $20.0 million tied to annual net sales targets.

The Company had not recognized any milestones as of September 30, 2024 or received any payments other than the upfront payment as disclosed above.

AVTX-800 Series Asset Sale

On October 27, 2023, the Company sold its rights, title and interests in AVTX-801, AVTX-802 and AVTX-803 (collectively, the "800 Series") to AUG Therapeutics, LLC ("AUG"). AUG is fully responsible for the development and commercialization of the program.

Pursuant to the Purchase Agreement with AUG, the Company received an upfront payment of $0.2 million. Additionally, AUG assumed aggregate liabilities of $ 0.4 million, which included certain liabilities incurred prior to the date of the Purchase Agreement, costs due and payable between the date of the Purchase Agreement and the closing date, and obligations under 800 Series contracts assumed by AUG. Avalo is also entitled to a contingent milestone payment of 20% of certain amounts, if any, granted to AUG upon sale of any priority review voucher related to the 800 Series compounds granted to AUG by the FDA, net of any selling costs, or $ 15.0 million for each compound (for a potential aggregate of $45.0 million) if the first FDA approval is for any indication other than a Rare Pediatric Disease (as defined in the Purchase Agreement).

The Company had not recognized any revenue related to the milestones as of September 30, 2024 or received any payments other than the upfront payment and reimbursement for certain liabilities as disclosed above.

Acquisition Related and Other Contingent Liabilities

Almata Transaction Possible Future Milestone Payments

On March 27, 2024, the Company acquired AVTX-009 through its acquisition of AlmataBio. Pursuant to the Almata Transaction, the Company made a cash payment of $7.5 million in April 2024 to the former AlmataBio stockholders, which was due upon the initial closing of the private placement investment on March 28, 2024 (the "Initial Milestone"). Further, a portion of the consideration for the AlmataBio transaction includes development milestones to the former AlmataBio stockholders including $ 5.0 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa for AVTX-009 (the "Second Milestone"), which was met and paid in October 2024 as discussed below, and $15.0 million due upon the first patient dosed in a Phase 3 trial for AVTX-009 (the "Third Milestone"), both of which are payable in cash or stock of Avalo at the election of the former AlmataBio stockholders. In the absence of timely notice of such election, Avalo may elect to pay the milestones in cash or common stock of Avalo.

The Company paid the Initial Milestone payment in April 2024 and recognized the payment within acquired in-process research and development expense in the condensed consolidated statements of operations and comprehensive income (loss) for the nine months ended September 30, 2024. In addition, the Company concluded the Second Milestone was probable as of the acquisition date and therefore recognized the $5.0 million milestone within acquired in-process research and development expense in the condensed consolidated statements of operations and comprehensive income (loss) for the nine months ended September 30, 2024 and the corresponding liability as contingent consideration as of September 30, 2024. The Company made a cash payment of $5.0 million in October 2024 upon meeting the Second Milestone. The Company will continue to monitor the Third Milestone each reporting period.

Aevi Merger Possible Future Milestone Payments

In the first quarter of 2020, the Company consummated its merger with Aevi, in which Avalo acquired the rights to quisovalimab, AVTX-006 and AVTX-007 (the "Merger" or the "Aevi Merger"). A portion of the consideration for the Aevi Merger included two future contingent development milestones worth up to an additional $6.5 million, payable in either shares of Avalo's common stock or cash, at the election of Avalo.

The first milestone was the enrollment of a patient in a Phase 2 study related to quisovalimab (for treatment of pediatric onset Crohn's disease), AVTX-006 (for treatment of any indication) or AVTX-007 (for treatment of any indication) prior to February 3, 2022, which would have resulted in a milestone payment of $ 2.0 million. The Company did not meet the first milestone prior to February 3, 2022. Therefore, no contingent consideration related to this milestone was recognized as of September 30, 2024 andno future contingent consideration will be recognized.

The second milestone is the receipt of an NDA approval for either AVTX-006 or AVTX-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of $4.5 million. The contingent consideration related to the second development milestone will be recognized if and when such milestone is probable and can be reasonably estimated. No contingent consideration related to the second development milestone had been recognized as of September 30, 2024. The Company will continue to monitor the second milestone each reporting period.

AVTX-006 Royalty Agreement with Certain Related Parties

In July 2019, Aevi entered into a royalty agreement, and liabilities thereunder were assumed by Avalo upon close of the Aevi Merger in February 2020. The royalty agreement provided certain investors, including LeoGroup Private Investment Access, LLC on behalf of Garry Neil, the Company's Chief Executive Officer and Chairman of the Board, and Mike Cola, the Company's former Chief Executive Officer (collectively, the "Investors"), a royalty stream, in exchange for a one-time aggregate payment of $2.0 million (the "Royalty Agreement"). Pursuant to the Royalty Agreement, the Investors will be entitled collectively to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of the Company's second generation mTORC1/2 inhibitor, AVTX-006 for a royalty term consistent with the royalty term disclosed in the AVTX-006 Astellas License Agreement section above. Avalo considers AVTX-006 a non-core asset and is exploring strategic alternatives. At any time beginning three years after the date of the first public launch of AVTX-006, Avalo may exercise, at its sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75% of the net present value of the royalty payments. A majority of the independent members of the board of directors and the audit committee of Aevi approved the Royalty Agreement.

Avalo assumed this Royalty Agreement upon closing of the Aevi Merger and it is recorded as a royalty obligation within the Company's accompanying unaudited condensed consolidated balance sheet as of September 30, 2024 and December 31, 2023. Because there is a significant related party relationship between the Company and the Investors, the Company has treated its obligation to make royalty payments under the Royalty Agreement as an implicit obligation to repay the funds advanced by the Investors. As the Company makes royalty payments in accordance with the Royalty Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which will result in a corresponding increase in the liability balance.

Karbinal Royalty Make-Whole Provision

In 2018, in connection with the acquisition of certain commercialized products, the Company entered into a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc. ("TRIS"). As part of the Karbinal Agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2025. The Company was required to pay TRIS a royalty make whole payment ("Make-Whole Payments") of $30 for each unit under the 70,000 units annual minimum sales commitment through 2025.

As a part of the Aytu Transaction, the Company assigned all its payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the "TRIS Obligations") to Aytu. However, under the original license agreement, the Company could ultimately be liable for the TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

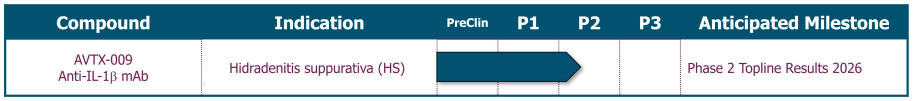
This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "pro forma" or other similar words (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates; and other statements that are not historical. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those set out in our Quarterly Report on Form 10-Q, Part II – Item 1A, "Risk Factors," filed with the Securities and Exchange Commission, or SEC, on August 12, 2024, as well as in our Annual Report on Form 10-K filed with the SEC on March 29, 2024, and in our other filings with the SEC. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2023 appearing in our Annual Report on Form 10-K filed with the SEC on March 29, 2024.

Overview

Avalo Therapeutics, Inc. (the "Company," "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β monoclonal antibody ("mAb"), targeting inflammatory diseases. Avalo has two additional drug candidates which include quisovalimab (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein).

Management's primary evaluation of the success of the Company is the ability to progress its pipeline forward toward commercialization or opportunistically out-licensing rights to indications or geographies. We believe the ability to achieve the anticipated milestone as presented in the following chart represents our most immediate evaluation point as to the progress of our goal to move the pipeline forward.



Recent Developments

In October 2024, Avalo announced that its first patient had been dosed in the Company's Phase 2 ("LOTUS") trial of AVTX-009, an anti-IL-1β (mAb), in hidradenitis suppurativa ("HS"). The LOTUS Trial is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two AVTX-009 dose regimens to evaluate the efficacy and safety of AVTX-009 in approximately 180 adults with moderate to severe HS. Subjects will be randomized (1:1:1) to receive either one of two doses of AVTX-009 or placebo. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Avalo is the study sponsor and the current proposed trial locations include the United States, Canada, France, Germany, Italy, Spain, Bulgaria, Czech Republic, Greece, Poland, Australia and Turkey.

Subsequent to September 30, 2024 and through November 6, 2024, Avalo received $58.1 million in additional proceeds from the exercise of the warrants issued in the private placement financing that closed in March 2024.

Liquidity

Since inception, we have incurred significant operating and cash losses from operations. We have primarily funded our operations to date through sales of equity securities, out-licensing transactions and sales of assets.

For the nine months ended September 30, 2024, Avalo generated net income of $0.2 million and negative cash flows from operations of $34.0 million. As of September 30, 2024, Avalo had $81.9 million in cash and cash equivalents. In the first quarter of 2024, the Company closed a private placement investment consisting of an initial upfront gross investment of $115.6 million (net proceeds were $108.1 million after deducting transaction costs) and up to an additional $69.4 million of gross proceeds upon the exercise of 11,967,526 warrants issued in the financing, which expire on November 8, 2024. Subsequent to September 30, 2024 and through November 6, 2024, the Company received gross proceeds of $58.1 million from the exercise of the warrants issued in the private placement.

Based on our current operating plans, we expect that our existing cash and cash equivalents are sufficient to fund operations for at least twelve months from the filing date of this Quarterly Report on Form 10-Q and we expect current cash on hand to fund operations into at least 2027. The Company closely monitors its cash and cash equivalents and seeks to balance the level of cash and cash equivalents with our projected needs to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. We may satisfy any future cash needs through sales of equity securities under the Company's at-the-market program or other equity financings, out-licensing transactions, strategic alliances/collaborations, sale of programs, and/or mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by the Company, or if realized, what the terms may be. To the extent that we raise capital through the sale of equity, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Further, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates.

Our Strategy

Our strategy for increasing stockholder value includes:

- Advancing our pipeline of compounds through development and to regulatory approval;
- Developing the go-to-market strategy to quickly and effectively market, launch, and distribute each of our compounds that receive regulatory approval;
- Opportunistically out-licensing rights to indications or geographies; and
- Acquiring or licensing rights to targeted, complementary differentiated preclinical and clinical stage compounds.

There is no guarantee that our products will obtain regulatory approval by the United States Food and Drug Administration (the "FDA") or comparable foreign regulatory authorities. The FDA approval process is complex, time-consuming, and expensive. It typically involves the following prior to submitting a new drug application (NDA) or biologics license application (BLA): preclinical laboratory and animal testing, submission of an IND application, and human clinical trials to establish safety and efficacy. Human clinical trials typically include: Phase 1 studies to evaluate the safety and tolerability of the drug, generally in normal, healthy volunteers; Phase 2 studies to evaluate safety and efficacy, as well as appropriate doses; these studies are typically conducted in patient volunteers who suffer from the particular disease condition that the drug is designed to treat; and Phase 3 studies to evaluate safety and efficacy of the product at specific doses in one or more larger pivotal trials. Upon submission of an NDA or BLA, the FDA reviews the application including potentially an FDA advisory committee review and typically inspects manufacturing facilities and clinical study sites prior to FDA approval or rejection of the application. Even if a product receives FDA approval, the agency may impose post-approval requirements or withdraw approval if safety or efficacy issues arise. The processes for obtaining marketing approvals in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

Results of Operations

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

Product Revenue, Net

The Company's license and supply agreement for Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions expired, as planned, on September 30, 2023. The Company continues to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or benefit) for differences between actuals or updated estimates to the reserves previously recognized. As such, the Company recognized minimal revenue for both the three months ended September 30, 2024 and 2023 and we expect minimal to no revenue going forward.

Cost of Product Sales

We recognized a benefit of $0.7 million to cost of product sales for the three months ended September 30, 2024, compared to $0.2 million for the same period in 2023. The benefit recognized in the current period was mainly driven by the reversal of a $1.0 million reserve against the receivable due from Aytu BioScience, Inc. ("Aytu") in December 2024 given that Avalo expects the receivable to be collectible as of September 30, 2024, partially offset by additional royalty on the profit share as a result of a change in estimate for commercial liabilities. The cost of product sales incurred in the prior period was driven by units sold.

The Company will continue to monitor estimates for commercial liabilities, such as sales returns, profit share with the supplier pursuant to the reconciliation process, and commercial activity with Aytu, who previously managed Millipred® commercial operations on our behalf. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized, which could be recognized in cost of product sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,	
	2024	2023
Nonclinical expenses	$ 154	$ 269
Clinical expenses	5,078	915
CMC expenses	1,978	(1,191)
Internal expenses:		
Salaries, benefits and related costs	1,511	826
Stock-based compensation expense	761	371
Other	56	59
	$ 9,538	$ 1,249

Research and development expenses increased $8.3 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This increase was mainly driven by a $4.2 million increase in clinical expenses and a $3.2 million increase in chemistry, manufacturing, and controls ("CMC") expenses.

Clinical expenses increased due to LOTUS Trial initiation activities, which culminated with the dosing of the first patient in early October 2024. Additionally, CMC expenses increased as a result of raw material purchases for an upcoming manufacturing run for AVTX-009 compared to a reversal of CMC expense in the prior year due to a reduced cancellation fee on a cancelled manufacturing run of AVTX-002.

Salaries, benefits and related costs increased $0.7 million compared to the three months ended September 30, 2023 due to increased non-equity incentive plan compensation expense and headcount additions.

We expect future research and development expenses to increase as a result of our development plans for AVTX-009, including the execution of the Phase 2 LOTUS Trial which commenced in October 2024.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,	
	2024	2023
Salaries, benefits and related costs	$ 1,171	$ 582
Legal, consulting and other professional expenses	1,603	1,146
Stock-based compensation expense	1,086	582
Other	426	180
	$ 4,286	$ 2,490

General and administrative expenses increased $1.8 million for the three months ended September 30, 2024 compared to the prior period. The increase was driven by a $0.6 million increase in salaries benefits and related costs due to increased non-equity incentive plan compensation expense and headcount additions, as well as a $0.5 million increase to stock compensation expense due to option and restricted stock unit grants during the period, including the annual grant in August 2024. In addition, legal, consulting and other professional expenses increased by $0.5 million for reporting, compliance and transition work incurred following the Almata Transaction and March 2024 private placement financing, as well as increased consulting services to support market research.

While we expect the majority of operating expense increases will be focused on research and development activities to progress AVTX-009, we also expect moderate increases to general and administrative expenses to support the AVTX-009 program.

Other Income (Expense), Net

The following table summarizes our other income (expense), net for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,	
	2024	2023
Change in fair value of warrant liability	36,025	—
Change in fair value of derivative liability	(1,100)	100
Interest income (expense), net	964	(1,553)
Other expense, net	(5)	(17)
	$ 35,884	$ (1,470)

Other income, net increased $37.4 million for the three months ended September 30, 2024 compared to the prior period. The increase was primarily driven by a $36.0 million gain recognized on the change of fair value of the warrant liability associated with the warrants issued in the March 2024 financing. The warrant liability fair value was $46.8 million as of September 30, 2024, as compared to $82.9 million as of June 30, 2024. The decrease in the fair value was mainly driven by the decrease in the closing stock price on the last trading day of the third quarter of 2024 of $9.50 per share compared to the closing stock price on the last trading day of the second quarter of 2024 of $12.47 per share, paired with a shorter term as the warrants approach expiration on November 8, 2024. Avalo expects no warrant liability as of December 31, 2024 following the exercise and/or expiration of the warrants during the fourth quarter of 2024. Refer to Note 6 - Fair Value Measurements of the unaudited condensed and consolidated financial statements for more information.

Interest income increased by $2.5 million given the Company's increased cash position compared to the prior period, paired with no interest expense incurred in the current period given the Company's full payoff of its former loan in the prior year.

Finally, the increase to other income, net was partially offset by a $1.1 million increase in fair value of the derivative liability (representing a loss on the change in fair value), primarily driven by the passage of time and declines in market credit spreads and risk-free rates. Refer to Note 6 - Fair Value Measurements of the unaudited condensed consolidated financial statements for more information.

Income Tax Expense

The Company recognized minimal income tax expense for both the three months ended September 30, 2024 and 2023.

Comparison of the Nine Months Ended September 30, 2024 and 2023

Product Revenue, Net

The Company's license and supply agreement for Millipred® expired, as planned, on September 30, 2023. The Company continues to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or benefit) for differences between actuals or updated estimates to the reserves previously recognized. For the nine months ended September 30, 2024, the Company recognized minimal net product revenue of $0.2 million compared to $1.4 million for the nine months ended September 30, 2023 for sales of Millipred® during the period. We do not expect future gross product revenue for Millipred®.

Cost of Product Sales

We recognized a benefit of $0.5 million to cost of product sales for the nine months ended September 30, 2024, compared to $1.5 million for the same period in 2023. The benefit recognized in the current period was mainly driven by the reversal of a reserve against the receivable due from Aytu in December 2024 given that Avalo expects the receivable to be collectible as of September 30, 2024, partially offset by an additional royalty on the profit share due as a result of a change in estimate for commercial liabilities. The cost of product sales in the prior period was driven by units sold.

The Company will continue to monitor estimates for commercial liabilities, such as sales returns, profit share with the supplier pursuant to the reconciliation process, and commercial activity with Aytu, who previously managed Millipred® commercial operations on our behalf for an interim period. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized, which could be recognized in cost of product sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Nonclinical expenses	$ 501	$ 844
Clinical expenses	6,719	5,388
CMC expenses	2,971	1,787
Internal expenses:		
Salaries, benefits and related costs	4,644	2,699
Stock-based compensation expense	1,250	1,028
Other	169	171
	$ 16,254	$ 11,917

Research and development expenses increased $4.3 million for the nine months ended September 30, 2024. The increase was driven a $1.9 million increase in salaries, benefits and related costs due primarily to increased non-equity incentive plan compensation expense incurred in the current period and increases in clinical and CMC expenses by $1.3 million and $1.2 million, respectively. Clinical expenses increased due to LOTUS Trial initiation activities including preparation of the investigational new drug application, which was active in early July 2024, and trial start-up activities, which culminated with the first patient being dosed in October 2024. CMC expenses increased as a result of raw material purchases for an upcoming manufacturing run for AVTX-009. These increases were partially offset by development and manufacturing activity ongoing in the prior year for quisovalimab that did not repeat in the current year given the PEAK trial concluded in June 2023.

We expect future research and development expenses to increase as a result of our development plans for AVTX-009, including the execution of the Phase 2 LOTUS Trial which commenced in October 2024.

Acquired in-process research and development

In the first quarter of 2024, we acquired AVTX-009 pursuant to the Almata Transaction, resulting in us acquiring $27.6 million of acquired IPR&D. The fair value of the IPR&D, substantially all of which is related to AVTX-009, was recognized as acquired IPR&D expense for the nine months ended September 30, 2024 as there is no alternative future use. There was no acquired IPR&D for the nine months ended September 30, 2023.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Salaries, benefits and related costs	$ 3,457	$ 1,768
Legal, consulting and other professional expenses	5,601	3,399
Stock-based compensation expense	1,698	1,673
Other	1,252	784
	$ 12,008	$ 7,624

General and administrative expenses increased $4.4 million for the nine months ended September 30, 2024 compared to the prior period. The increase was driven by a $2.2 million increase in legal, consulting and other professional expenses incurred for accounting and reporting work incurred as well as increased consulting services following the Almata Transaction and March 2024 private placement financing. Additionally, salaries, benefits and related costs increased $1.7 million primarily due to increased non-equity incentive plan compensation expense incurred in the current period.

While we expect the majority of operating expense increases will be focused on research and development activities to progress AVTX-009, we also expect moderate increases to general and administrative expenses to support the AVTX-009 program.

Other Income (Expense), Net

The following table summarizes our other income (expense), net for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Excess of initial warrant fair value over private placement proceeds	(79,276)	—
Change in fair value of warrant liability	148,071	—
Private placement transaction costs	(9,220)	—
Change in fair value of derivative liability	(6,260)	(120)
Interest income (expense), net	2,101	(3,498)
Other expense, net	(5)	(42)
	$ 55,411	$ (3,660)

Other income, net increased $59.1 million for the nine months ended September 30, 2024 as compared to the prior period primarily driven by the impact of the warrant liability associated with the warrants issued in the March 2024 financing. For the nine months ended September 30, 2024, we recognized a $79.3 million loss at issuance on the excess of initial warrant liability fair value ($194.9 million) over the private placement proceeds ($115.6 million). The loss was more than offset by a $148.1 million gain recognized on the change of fair value of the warrant liability from March 31, 2024 to September 30, 2024. The decrease in the fair value was mainly driven by the decrease in the closing stock price on the last trading day of the third quarter of $9.50 per share compared to the closing stock price on the last trading day of the first quarter of $21.75 per share, paired with a shorter term as the warrants approach expiration on November 8, 2024. Avalo expects no warrant liability as of December 31, 2024 following the exercise and/or expiration of the warrants during the fourth quarter of 2024. Refer to Note 6 - Fair Value Measurements of the unaudited condensed and consolidated financial statements for more information.

The increase to other income, net was partially offset by $9.2 million of private placement transaction costs, largely consisting of the placement agent fee of $7.0 million due on the transaction close date in March 2024, and $1.7 million fee payable upon exercise of the warrants issued in the private placement investment.

Additionally, other income, net was partially offset by a $6.3 million increase in fair value of the derivative liability (representing a loss on the change in fair value) driven primarily by changes in assumptions utilized in the valuation of the AVTX-007 Milestones and Royalties (as defined in Note 6 of the unaudited condensed consolidated financial statements) due to updated publicly available information of the indication and status of trial activities pursued for the asset by Apollo. The main driver of this increase was a significant increase to the peak annual net sales forecast as a result of Apollo developing the asset in atopic dermatitis, which is a much larger market opportunity than adult-onset Still's disease, the previous indication being pursued. Refer to Note 6 - Fair Value Measurements of the unaudited condensed consolidated financial statements for more information.

Finally, interest income increased by $5.6 million given the Company's increased cash position compared to the prior period, paired with no interest expense incurred in the current period given the Company's full payoff of its former loan in the prior year.

Income Tax Expense

The Company recognized minimal income tax expense for both the nine months ended September 30, 2024 and 2023.

Liquidity and Capital Resources

Uses of Liquidity

The Company uses cash to primarily fund the ongoing development of its research and development pipeline assets, mainly AVTX-009, and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (34,012)	$ (27,914)
Investing activities	356	(133)
Financing activities	108,140	25,041
Net increase (decrease) in cash and cash equivalents	$ 74,484	$ (3,006)

Net cash used in operating activities

Net cash used in operating activities was $34.0 million for the nine months ended September 30, 2024 and consisted primarily of net income of $0.2 million and adjustments to reconcile net income to net cash used in operating activities including the change in fair value of the warrant liability of $148.1 million, excess of initial warrant fair value over private placement investment proceeds of $79.3 million, acquired IPR&D of $27.6 million, $7.5 million milestone payment made to the former AlmataBio stockholders upon the closing of a private placement investment, change in fair value of the derivative liability of $6.3 million and stock-based compensation of $2.9 million. Prepaid expense increased $2.4 million primarily due to advances paid for AVTX-009 contracts and the timing of insurance prepayments. Accrued expenses and other liabilities increased $2.1 million primarily related to non-equity incentive compensation and increased research and development and general and administrative activities to support the development of AVTX-009.

Net cash used in operating activities was $27.9 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of $23.4 million and non-cash adjustments to reconcile cash used in operating activities including stock-based compensation expense of $2.7 million and accretion of the debt discount of $1.8 million. Accrued expenses and other current liabilities and accounts payable decreased $8.1 million and $2.1 million, respectively, from December 31, 2022.

We expect future cash used in operating activities, excluding the milestone payment made to the former AlmataBio stockholders, to increase in future periods as a result of our development plans for AVTX-009, including the execution of the Phase 2 LOTUS Trial which commenced in October 2024.

Net cash provided by (used in) investing activities

Net cash provided by investing activities for the nine months ended September 30, 2024 consisted of the cash acquired as part of the Almata Transaction. Net cash used in investing activities was minimal for the nine months ended September 30, 2023.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2024 consisted of gross proceeds of $115.6 million from the private placement investment that closed on March 28, 2024, partially offset by $7.5 million of transaction costs paid related to the private placement investment.

Subsequent to September 30, 2024 and through November 6, 2024, Avalo received $58.1 million in additional proceeds from the exercise of the warrants issued in the private placement financing that closed in March 2024 and could receive up to $11.3 million upon the exercise of the remaining warrants prior to expiry on November 8, 2024.

Net cash provided by financing activities for the nine months ended September 30, 2023 consisted of net proceeds of $32.5 million from the sale of common stock pursuant to the Company's at-the-market program and net proceeds of $13.7 million from an underwritten public offering that closed in February 2023, partially offset by debt principal payments of $21.2 million. In September of 2023, the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under its loan agreement.

Critical Accounting Policies, Estimates, and Assumptions

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared in accordance with GAAP. In preparing the financial statements in conformity with GAAP, the Company makes estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements, the valuation of warrant liabilities, the valuation of derivative liabilities, cash flows used in management's going concern assessment, income taxes, goodwill, and clinical trial accruals. The Company believes, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise. Our most critical accounting estimates and assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 29, 2024 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the SEC on May 13, 2024 (as amended on July 11, 2024). There have been no significant changes to our critical accounting policies during the three months ended September 30, 2024.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

The information set forth in Note 13 - Commitments and Contingencies, under the heading “Litigation” to our Unaudited Condensed Consolidated Financial Statements, included in Part I, Item 1 of this Quarterly Report on Form 10-Q, is incorporated herein by reference.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 29, 2024 (the “2023 10-K”) and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 12, 2024 (the “Q2 2024 10-Q”), which could materially affect our business, financial condition, or future results. Our risk factors as of the date of this Quarterly Report on Form 10-Q have not changed materially from those described in the 2023 10-K and Q2 2024 10-Q referenced above. The risks described in the 2023 10-K and Q2 2024 10-Q referenced above, however, are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, or future results of operations and the trading price of our common stock.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1	Employment Agreement, dated June 1, 2024, by and between Avalo Therapeutics, Inc. and Mittie Doyle (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on July 16, 2024).
10.2	Avalo Therapeutics, Inc. Fourth Amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 14, 2024).
10.3	Avalo Therapeutics, Inc. Amended and Restated 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 14, 2024).
10.4+	Non-Employee Director Compensation Policy, Amended June 6, 2024 with an effective date of July 1, 2024.
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets as of September 30, 2024 (Unaudited) and December 31, 2023; (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) (Unaudited) for the Three and Nine Months Ended September 30, 2024 and 2023; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2024 and 2023; (iv) Condensed Consolidated Statements of Preferred Stock and Changes in Stockholders' Equity (Unaudited) for the Three and Nine Months Ended September 30, 2024 and 2023; and (v) Notes to Unaudited Financial Statements.
104	Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

+ Filed herewith.

† This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Avalo Therapeutics, Inc.

Date: November 7, 2024

/s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer
(on behalf of the registrant and as the registrant's principal financial officer)

Avalo Therapeutics, Inc.

Non-Employee Director Compensation Policy Amended Effective July 1, 2024

Each member of the Board of Directors (the "Board") who is not also serving as an employee of Avalo Therapeutics, Inc. (the "Company") or any of its subsidiaries (each such member, an "Eligible Director") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service on and following July 1, 2024 (the "Effective Date"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each calendar quarter in which service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a calendar quarter, each retainer set forth below for such quarter will be pro-rated based on days served in the applicable calendar quarter, with regular full quarterly payments thereafter. Likewise, if an Eligible Director ceases to serve on the Board or a committee of the Board at a time other than effective as of the last day of a calendar quarter, each retainer set forth below for such quarter will be pro-rated based on days served in the applicable calendar quarter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000
2. Annual Committee Member Service Retainer:
    a. Member of the Audit Committee: $10,000
    b. Member of the Compensation Committee: $6,500
    c. Member of the Nominating and Corporate Governance Committee: $5,000
    d. Member of the Science and Technology Advisory Committee: $7,500
3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
    a. Chair of the Audit Committee: $10,000
    b. Chair of the Compensation Committee: $6,500
    c. Chair of the Nominating and Corporate Governance Committee: $5,000
    d. Chair of the Science and Technology Advisory Committee: $7,500

Election to Receive Stock Options in Lieu of Cash

An Eligible Director may make an election to receive all or a portion of his or her annual cash compensation described above in the form of stock options to purchase shares of the Company's common stock (the "Common Stock"). Elections must be made in multiples of 5% of an Eligible Director's aggregate cash retainer.

1. Timing of Elections:
   a. *Current Eligible Directors*: Elections must be made prior to the beginning of each quarter.
   b. *New Eligible Directors*: Elections for the first quarter of service must be made within 30 days of becoming an Eligible Director, provided that such election shall be applicable only to the portion of the cash retainers earned after the date of the election.
   c. *New committee member or committee chair*: Elections for the first quarter of service must be made prior to the date that the Eligible Director becomes a committee member or committee chair (or, if a new Eligible Director, within 30 days of becoming a committee member or committee chair, provided that such election shall be applicable only to the portion of the cash retainer earned after the date of the election).

2. Description of Stock Options: The stock options will be granted under the Company's Fourth Amended and Restated 2016 Equity Incentive Plan, as further amended from time to time (the "Plan"). The stock options will be granted on the date on which the cash would otherwise have been paid (i.e. on the last day of each calendar quarter). All stock options granted will be nonqualified stock options using the Company's standard form of Nonqualified Stock Option Grant Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Common Stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan). The actual number of shares subject to the stock options will be determined so that the options have a "fair value" on the date of grant, using a Black-Scholes or binominal valuation model consistent with the methodology used by the Company in preparing its financial statements, equal to the amount of cash fees forgone. The stock options will immediately vest and become exercisable in full upon grant.

Equity Compensation

The equity compensation set forth below will be granted under the Plan. All stock options granted under this policy will be nonqualified stock options using the Company's standard form of Nonqualified Stock Option Grant Agreement under the Plan, with an exercise price per share equal to the last reported sale price of the Common Stock on the NASDAQ Capital Market on the date of grant or, if such grant date is not a trading date, on the last trading date prior to the grant date, and with a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant for New Eligible Directors: For each Eligible Director who is first appointed or elected to the Board following the Effective Date, on the date of such election or appointment (or, if such date is not a market trading day, the first market trading day thereafter), such Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 34,100 shares of Common Stock. The stock options will vest and become exercisable in three substantially equal annual installments on the first, second and third anniversary of the date of grant, subject to the Eligible Director's continued service on each such vesting date.
2. Annual Grant for 2024 Only: On the date of the first annual stockholders meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted equity awards totaling 34,100 shares of Common Stock, which total will be divided, as determined by the Board in its sole discretion, between stock options and restricted stock units. All such restricted stock units will vest, and all such stock options will vest and become exercisable, in three substantially equal annual installments on March 28, 2025, March 28, 2026, and March 28, 2027, subject to the Eligible Director's continued service on such applicable vesting date.
3. Annual Grant for 2025 and Beyond: On the date of each annual stockholders meeting of the Company held beginning in 2025, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, be granted a stock option for 17,050 shares of Common Stock. The stock options will vest and become exercisable in full on the first anniversary of the grant date, subject to the Eligible Director's continued service on such vesting date.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garry Neil, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avalo Therapeutics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

/s/ Garry Neil, M.D.

Garry Neil, M.D.
Chief Executive Officer
(Registrant's Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avalo Therapeutics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

/s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer
(Registrant's Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Avalo Therapeutics, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garry Neil, Chief Executive Officer (principal executive officer) of the Registrant, and I, Christopher Sullivan, Chief Financial Officer (principal financial officer) of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition at the end of the period covered by the Report and the results of operations of the Registrant for the periods covered by the Report.

Date: November 7, 2024	By:	/s/ Garry Neil, M.D.
	Name:	**Garry Neil, M.D.**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: November 7, 2024	By:	/s/ Christopher Sullivan
	Name:	**Christopher Sullivan**
	Title:	**Chief Financial Officer** **(Registrant's Principal Financial Officer)**

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Avalo Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.