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 March 31, 2022

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 May 2, 2022, the registrant had 112,794,203 shares of common stock outstanding.

AVALO THERAPEUTICS, INC.

FORM 10-Q

For the Quarter Ended March 31, 2022

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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)

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 38,469	$ 54,585
Accounts receivable, net	938	1,060
Other receivables	1,445	3,739
Inventory, net	25	38
Prepaid expenses and other current assets	2,682	2,372
Restricted cash, current portion	100	51
Total current assets	43,659	61,845
Property and equipment, net	2,604	2,695
Other long-term asset	1,000	1,000
Intangible assets, net	—	38
Goodwill	14,409	14,409
Restricted cash, net of current portion	227	227
Total assets	$ 61,899	$ 80,214
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,757	$ 3,369
Accrued expenses and other current liabilities	14,136	16,519
Total current liabilities	17,893	19,888
Notes payable	33,183	32,833
Royalty obligation	2,000	2,000
Deferred tax liability, net	122	113
Other long-term liabilities	2,358	2,298
Total liabilities	55,556	57,132
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 112,794,203 shares issued and outstanding at March 31, 2022 and December 31, 2021	113	113
Additional paid-in capital	290,447	285,135
Accumulated deficit	(284,217)	(262,166)
Total stockholders' equity	6,343	23,082
Total liabilities and stockholders' equity	$ 61,899	$ 80,214

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Product revenue, net	$ 1,173	$ 473
Total revenues, net	1,173	473
Operating expenses:		
Cost of product sales	720	77
Research and development	9,584	25,206
General and administrative	9,756	4,911
Sales and marketing	1,928	435
Amortization expense	38	424
Total operating expenses	22,026	31,053
	(20,853)	(30,580)
Other (expense) income:		
Other expense, net	(20)	—
Interest (expense) income, net	(1,169)	17
Total other (expense) income, net from continuing operations	(1,189)	17
Loss from continuing operations before taxes	(22,042)	(30,563)
Income tax expense	9	11
Loss from continuing operations	$ (22,051)	$ (30,574)
Loss from discontinued operations	—	(106)
Net loss	$ (22,051)	$ (30,680)
Net loss per share of common stock, basic and diluted:		
Continuing operations	$ (0.20)	$ (0.32)
Discontinued operations	0.00	0.00
Net loss per share of common stock, basic and diluted	$ (0.20)	$ (0.32)
Net loss per share of preferred stock, basic and diluted:		
Continuing operations		$ (1.61)
Discontinued operations		(0.01)
Net loss per share of preferred stock, basic and diluted		$ (1.62)

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)
(In thousands, except share amounts)

	Common stock		Preferred Stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity
Three Months Ended March 31, 2022							
Balance, December 31, 2021	112,794,203	$ 113	—	$ —	$ 285,135	$ (262,166)	$ 23,082
Stock-based compensation	—	—	—	—	5,312	—	5,312
Net loss	—	—	—	—	—	$ (22,051)	(22,051)
Balance, March 31, 2022	112,794,203	$ 113	—	$ —	$ 290,447	$ (284,217)	$ 6,343

	Common stock		Preferred Stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	equity
Three Months Ended March 31, 2021							
Balance, December 31, 2020	75,004,127	$ 75	1,257,143	$ 1	$ 202,276	$ (177,790)	$ 24,562
Issuance of shares of common stock and pre-funded warrants in underwritten public offering, net	13,971,889	14	—	—	37,639	—	37,653
Exercise of stock options and warrants	128,800	—	—	—	172	—	172
Stock-based compensation	—	—	—	—	1,448	—	1,448
Net loss	—	—	—	—	—	(30,680)	(30,680)
Balance, March 31, 2021	89,104,816	$ 89	1,257,143	$ 1	$ 241,535	$ (208,470)	$ 33,155

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)

	Three Months Ended March 31,	
	2022	2021
Operating activities		
Net loss	$ (22,051)	$ (30,680)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	67	451
Stock-based compensation	5,312	1,448
Accretion of debt discount	350	—
Deferred taxes	9	21
Changes in assets and liabilities:		
Accounts receivable, net	123	(953)
Other receivables	2,294	152
Inventory, net	13	3
Prepaid expenses and other assets	(310)	195
Accounts payable	388	9,339
Accrued expenses and other liabilities	(2,287)	1,724
Lease liability, net	25	(16)
Net cash used in operating activities	(16,067)	(18,316)
Investing activities		
Purchase of property and equipment	—	(21)
Net cash used in investing activities	—	(21)
Financing activities		
Proceeds from issuance of common stock and pre-funded warrants in underwritten public offering, net	—	37,653
Proceeds from exercise of stock options and warrants	—	172
Net cash provided by financing activities	—	37,825
(Decrease) increase in cash, cash equivalents and restricted cash	(16,067)	19,488
Cash, cash equivalents, and restricted cash at beginning of period	54,863	19,106
Cash, cash equivalents, and restricted cash at end of period	$ 38,796	$ 38,594
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 831	$ —

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):

	March 31,	
	2022	2021
Cash and cash equivalents	$ 38,469	$ 38,292
Restricted cash, current	100	153
Restricted cash, non-current	227	149
Total cash, cash equivalents and restricted cash	$ 38,796	38,594

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" or "Avalo") is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. Avalo's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

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

Liquidity

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. As of March 31, 2022, Avalo had $ 38.5 million in cash and cash equivalents. For the three months ended March 31, 2022, Avalo generated a net loss of $ 22.1 million and negative cash flows from operations of $16.1 million. As of March 31, 2022, Avalo had an accumulated deficit of $284.2 million.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, losses are expected to continue as the Company continues to invest in its research and development pipeline assets. The Company will require additional financing to fund its operations and to continue to execute its business strategy at least one year after the date the condensed consolidated financial statements included herein were issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) dilutive and/or non-dilutive financings, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. 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. Subject to limited exceptions, our venture debt financing agreement prohibits us from incurring certain additional indebtedness, making certain asset dispositions, and entering into certain mergers, acquisitions or other business combination transactions without prior consent of the Lenders. Additionally, our venture debt financing agreement contains certain covenants and certain other specified events that could result in an event of default, which if not cured or waived, could result in the immediate acceleration of all or a substantial portion of the Notes (as defined in Note 9). As of the filing date of this Quarterly Report on Form 10-Q, the Company was not aware of any breach of covenants or occurrence of material adverse change, nor had it received any notice of event of default from the Lenders (refer to Note 9 for more information).

If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financing and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report on Form 10-Q were issued.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will depend on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential receipt and sale of any priority review vouchers it receives.

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, 2021 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, 2021 audited consolidated financial statements.

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 March 31, 2022, 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, 2021, as filed with the SEC on March 2, 2022.

3. Revenue

The Company generates substantially all of its revenue from sales of Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, which is considered a prescription drug. The Company sells its prescription drug in the United States primarily through wholesale distributors. Wholesale distributors account for substantially all of the Company's net product revenues and trade receivables. For the three months ended March 31, 2022, the Company's two largest customers accounted for approximately 75% and 25% of the Company's total net product revenues. Net revenue from sales of prescription drugs was $1.2 million and $0.5 million for the three months ended March 31, 2022 and 2021, respectively.

The Company has a license and supply agreement for the Millipred® product with a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which expires on September 30, 2023. Beginning July 1, 2021, Avalo is required to pay Teva fifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a $0.5 million quarterly minimum payment. For the three months ended March 31, 2022, the Company recognized $0.6 million in cost of product sales related to the royalty. Dr. Sol Barer served as the Chairman of the Company's board of directors until June 2021 and currently serves as the Chairman of Teva's board of directors.

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 transition service agreements, which included managing the third-party logistics provider and providing accounting reporting services. 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 and is obligated to transfer cash generated by such sales to Avalo. In the third quarter of 2021, Avalo finalized its trade and distribution channel to allow it to control the third-party distribution and began managing Millipred® commercial operations at that time. The current transition services agreement allows Aytu to withhold cash of $2.0 million until September 30, 2022 and $1.0 million until December 2024. The Company received $2.2 million from Aytu in the first quarter of 2022. As of March 31, 2022, the total receivable balance was approximately $2.0 million, $1.0 million of which was recognized in other long-term assets and the remainder recognized in other receivables.

4. Net Loss Per Share

The Company computes earnings per share ("EPS") using the two-class method. The two-class method of computing EPS is an earnings allocation formula that determines EPS for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings.

The Company had only common stock outstanding during the three months ended March 31, 2022. The Company had two classes of stock outstanding during the three months ended March 31, 2021; common stock and preferred stock. The preferred stock outstanding

during the prior period converted to shares of common stock on a 1-for-5 ratio and had the same rights, preferences and privileges as the Company's common stock other than it held no voting rights. In April 2021, Armistice Capital, LLC, ("Armistice"), which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, serve on the Board of the Company, converted the then outstanding 1,257,143 shares of convertible preferred stock into6,285,715 shares of Avalo's common stock (refer to Note 10 for more information). Under the two-class method, the convertible preferred stock was considered a separate class of stock until the time it was converted to common shares for EPS purposes. Therefore, basic and diluted EPS is provided below for common stock for the three months ended March 31, 2022, and both common stock and preferred stock for the three months ended March 31, 2021.

EPS for common stock and EPS for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. In applying the two-class method, undistributed earnings are allocated to common stock and preferred stock based on the weighted average shares outstanding during the period, which assumed the convertible preferred stock had been converted to common stock. The weighted average number of common shares outstanding as of March 31, 2022 and 2021 include the weighted average effect of the pre-funded warrants issued in connection with the underwritten public offering that closed in January 2021, the exercise of which requires nominal consideration for the delivery of the shares of common stock (refer to Note 10 for more information).

Diluted net 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; and (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses.

The following tables set forth the computation of basic and diluted net loss per share of common stock for the three months ended March 31, 2022, and common stock and preferred stock for the three months ended March 31, 2021 (in thousands, except share and per share amounts):

	Three Months Ended March 31, 2022	
	Common stock	
	Continuing Operations	Discontinued Operations
Numerator:		
Allocation of undistributed net loss	$ (22,051)	$ —
Denominator:		
Weighted average shares	112,794,203	112,794,203
Basic and diluted net loss per share	$ (0.20)	$ (0.00)

	Three Months Ended March 31, 2021			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net loss	$ (28,548)	$ (99)	$ (2,026)	$ (7)
Denominator:				
Weighted average shares	88,576,559	88,576,559	1,257,143	1,257,143
Basic and diluted net loss per share	$ (0.32)	$ (0.00)	$ (1.61)	$ (0.01)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three months ended March 31, 2022 and 2021, as they could have been anti-dilutive:

	Three Months Ended March 31,	
	2022	2021
Stock options	17,088,040	12,944,891
Warrants on common stock[1]	4,406,224	4,002,380
Restricted Stock Units	11,250	155,833

[1] *The weighted average number of common shares outstanding as of March 31, 2021 includes the weighted average effect of thel,676,923 pre-funded warrants issued in connection with the underwritten public offering that closed in January 2021 because the exercise of such warrants requires only nominal consideration ($0.001 per share exercise price for each pre-funded warrant). During 2021, the holder exercised 308,880 of the pre-funded warrants. As of March 31, 2022, the weighted average number of common shares outstanding includes the weighted average effect of the remaining 1,368,043 pre-funded warrants outstanding. These pre-funded warrants are not included in the table above.*

5. Fair Value Measurements

ASC No. 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):

	March 31, 2022 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*	$ 37,821	$ —	$ —

	December 31, 2021 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*	$ 54,010	$ —	$ —

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

As of March 31, 2022 and December 31, 2021, 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 long-term debt. The carrying amounts reported in the accompanying 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. The estimated fair value of the Company's debt approximates its carrying value as of March 31, 2022 and is in Level Two of the fair value hierarchy (refer to Note 9 for more information).

No changes in valuation techniques or inputs occurred during the three months ended March 31, 2022 and 2021. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three months ended March 31, 2022 and 2021.

6. Leases

The Company 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 provided for a rent abatement period of 3 months following lease commencement. 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 March 31, 2022 was 6.2 years.

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

	As of	
	March 31, 2022	December 31, 2021
Property and equipment, net	$ 1,940	$ 2,001
Accrued expenses and other current liabilities	$ 522	$ 485
Other long-term liabilities	1,945	2,018
Total operating lease liabilities	$ 2,467	$ 2,503

The operating lease 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 condensed consolidated balance sheets. The Company utilized a weighted average discount rate of 9.2% to determine the present value of the lease payments.

The components of lease expense for the three months ended March 31, 2022 and 2021 were as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating lease cost*	$ 116	$ 95

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

The following table shows a maturity analysis of the operating lease liabilities as of March 31, 2022 (in thousands):

	Undiscounted Cash Flows
April 1, 2022 through December 31, 2022	$ 391
2023	528
2024	537
2025	547
2026	557
2027	258
Thereafter	426
Total lease payments	$ 3,244
Less implied interest	(777)
Total	$ 2,467

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of March 31, 2022 and December 31, 2021 consisted of the following (in thousands):

	As of	
	March 31, 2022	December 31, 2021
Research and development	$ 5,280	$ 8,221
Compensation and benefits	4,780	4,310
General and administrative	1,108	1,275
Sales and marketing	92	111
Commercial operations	1,910	1,733
Royalty payment	440	375
Lease liability, current	522	485
Other	4	9
Total accrued expenses and other current liabilities	$ 14,136	$ 16,519

8. Cost Reduction Plan

On March 2, 2022, the Board approved a cost reduction plan to enable the Company to execute its strategy of prioritizing the development of its most promising programs (the "Plan"). As part of the Plan, the Company is winding down internal development efforts of AVTX-006 and is pausing current development efforts of AVTX-802. Additionally, the Company previously announced that it is winding down internal development efforts of AVTX-007 in multiple myeloma. Accordingly, a reduction in workforce plan was approved to reduce headcount and related expenses. The reduction in workforce plan, which is considered a one-time termination benefit, is expected to be completed in the second quarter of 2022.

The one-time termination benefits mainly relate to severance payments to be made to separated employees. As a result, the Company recognized $1.5 million of expense during the three months ended March 31, 2022, of which $0.7 million was recognized in research and development expense, $0.5 million was recognized in sales and marketing expense and $0.3 million was recognized in general and administrative expense.

Of the $1.5 million initial liability recognized in the first quarter of 2022, $40.6 thousand was paid in the first quarter. The remaining severance liability will be paid over the next two to twelve months as dictated in each separation agreement. Additionally, $0.4 million of stock-based compensation expense was recognized in the first quarter of 2022 related to the Plan, which was mainly related to accelerated vesting of certain separated employees' stock options.

In addition, previously and separately, during the three months ended March 31, 2022, the Company separated from certain section 16 executive officers. Each of the former executives are entitled to the benefits provided in their respective separation agreements, which include severance payments to be paid over twelve to eighteen months. As a result, the Company recognized expense of $1.7 million for the three months ended March 31, 2022. Of the total expense, $1.3 million was recognized in general and administrative expense

and $0.4 million was recognized in sales and marketing expense. Additionally, the Company accelerated the vesting of certain outstanding stock options and extended the exercisability periods resulting in the recognition of $3.9 million of compensation cost for the three months ended March 31, 2022. Refer to Note 11 for information regarding stock compensation expense related to separations entered into in the first quarter of 2022.

9. Notes Payable

On June 4, 2021, the Company entered into a $35.0 million Loan Agreement with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments XXV, LP ("Powerscourt", together with Horizon, the "Lenders"). In accordance with the Loan Agreement, $20.0 million was funded on the closing date (the "Initial Note"), with the remaining $15.0 million fundable upon the Company achieving certain predetermined milestones, which the Company met in the third quarter of 2021. On July 30, 2021, after achieving a predetermined milestone, the Company borrowed an additional $10.0 million, which was evidenced by a second note payable (the "Second Note"). On September 29, 2021, after achieving a second predetermined milestone, the Company borrowed the remaining $5.0 million, which was evidenced by a third note payable (the "Third Note", and collectively with the Initial and Second Notes, the "Notes").

Each advance under the Loan Agreement will mature 42 months from the first day of the month following the funding of the advance. Each advance accrues interest at a per annum rate of interest equal to 6.25% plus the prime rate, as reported in the Wall Street Journal (subject to a floor of3.25%). The Loan Agreement provides for interest-only payments for each advance for the first 18 months, however the interest-only period was extended to 24 months as a result of the Company satisfying the Interest Only Extension Milestone (as defined in the Loan Agreement) in the third quarter of 2021. Thereafter, amortization payments will be payable in monthly installments of principal and interest through each advance's maturity date. Upon ten business days' prior written notice, the Company may prepay all of the outstanding advances by paying the entire principal balance and all accrued and unpaid interest, subject to prepayment charges of up to 3% of the then outstanding principal balance. Upon the earlier of (i) payment in full of the principal balance, (ii) an event of default, or (iii) the maturity date, the Company will pay an additional final payment of 3% of the principal loan amount to the Lenders.

Each advance of the loan is secured by a lien on substantially all of the assets of the Company, other than Intellectual Property and Excluded Collateral (in each case as defined in the Loan Agreement), and contains customary covenants and representations, including a financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include but are not limited to, failing to make a payment, breach of covenant, or occurrence of a material adverse change. If an event of default occurs, the Lenders are entitled to accelerate the loan amounts due, or take other enforcement actions. The accelerated payment obligations would include the outstanding principal balance (inclusive of the 3% final payment fee), a prepayment charge on the outstanding principal balance of up to3%, and any accrued and unpaid interest. As of the filing date of this Quarterly Report on Form 10-Q, the Company was not aware of any breach of covenants, occurrence of material adverse change, nor had it received any notice of event of default from the Lenders.

On June 4, 2021, pursuant to the Loan Agreement, the Company issued warrants to the Lenders to purchase403,844 shares of the Company's common stock with an exercise price of $2.60 per share (the "Warrants"). The Warrants are exercisable for ten years from the date of issuance. The Lenders may exercise the Warrants either by (a) cash or check or (b) through a net issuance conversion. The 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 valued the Warrants at issuance, which resulted in a discount on the debt, and allocated the proceeds from the loan proportionately to the Notes and to the Warrants, of which $0.9 million was allocated to the Warrants.

In the second quarter of 2021, the Company incurred $2.1 million in debt issuance costs, including legal fees in connection with the Loan Agreement, fees paid directly to the lender, and other direct costs. All fees, warrants, and costs paid to the Lenders and all direct costs incurred by the Company are recognized as a debt discount and are amortized to interest expense using the effective interest method over the term of the loan. The $1.1 million final payment fee is included in the contractual cash flows and is accreted to interest expense using the effective interest method over the term of the loan.

The effective interest rate of the Notes, including the accretion of the final payment, was13.7% as of March 31, 2022.

Balance sheet information related to the note payable for the Notes is as follows (in thousands):

	As of		
	March 31, 2022	December 31, 2021	Maturity
Initial Note	20,600	20,600	January 2025
Second Note	10,300	10,300	February 2025
Third Note	5,150	5,150	April 2025
Notes payable, gross[1]	36,050	36,050	
Less: Unamortized debt discount and issuance costs	2,867	3,217	
Carrying value of notes payable, non-current	$ 33,183	$ 32,833	

[1] *Balance includes $1.1 million final payment fee for the Notes, which represents 3% of the principal loan amount.*

As of March 31, 2022, the estimated future principal payments due on the Notes were as follows (in thousands):

	As of March 31, 2022
2022	$ —
2023	10,278
2024	23,333
2025	2,439
Total principal payments[1]	$ 36,050

[1] *Balance includes $1.1 million final payment fee, which represents 3% of the principal loan amount.*

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 March 31, 2022, 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.

Common Stock

2021 Financings

Q3 2021 Equity Financing

On September 17, 2021, the Company closed an underwritten public offering of 14,308,878 shares of its common stock for net proceeds of $29.0 million. Armistice participated in the offering by purchasing 5,454,545 shares of common stock, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC (collectively, "Nantahala"), which beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering, participated in the offering on the same terms as all other investors.

At-the-Market Offering Program

In July 2021, the Company entered into an "at-the-market" sales agreement with Cantor Fitzgerald & Co. and RBC Capital Markets, LLC (together, the "Agents"), pursuant to which the Company may sell from time to time, shares of its common stock having an aggregate offering price of up to $50.0 million through the Agents. In August 2021, the Company sold 2.0 million shares of common stock under the ATM Program for net proceeds of approximately $5.2 million.

Q2 2021 Debt Financing Agreement

As part of the Loan Agreement entered into in the second quarter of 2021, on June 4, 2021, the Company issued Warrants to Horizon and Powerscourt to purchase 403,844 shares of the Company's common stock with an exercise price of $2.60 per share. The Warrants are exercisable for ten years from the date of issuance. Refer to Note 9 for additional information.

Q1 2021 Financing

In January 2021, the Company closed an underwritten public offering of 13,971,889 shares of its common stock and 1,676,923 pre-funded warrants for net proceeds of $37.7 million. Armistice participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors. Nantahala participated in the offering by purchasing 1,400,000 shares of common stock, on the same terms as all other investors.

Nantahala also purchased the pre-funded warrants to purchase up to an aggregate of 1,676,923 shares of common stock at a purchase price of $2.599, which represents the per share public offering price for the common stock less the $0.001 per share exercise price for each pre-funded warrant.

The pre-funded warrants are exercisable at any time after their original issuance at the option of each holder, in such holder's discretion, by (i) payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise or (ii) a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant. A holder will not be entitled to exercise any portion of any pre-funded warrant if the holder's ownership of the Company's common stock would exceed 9.99% following such exercise.

In the event of certain fundamental transactions, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind of amounts of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the pre-funded warrants.

The pre-funded warrants were classified 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 pre-funded warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants, of which $4.4 million was allocated to the pre-funded warrants and recorded as a component of additional paid-in capital.

During 2021, the holder exercised 308,880 of the pre-funded warrants. As of March 31, 2022, 1,368,043 pre-funded warrants were outstanding.

Common Stock Warrants

At March 31, 2022, the following common stock warrants were outstanding:

Number of common shares underlying warrants		Exercise price per share	Expiration date
2,380	$	8.68	May 2022
4,000,000	$	12.50	June 2024
1,368,043	$	0.001	—
403,844	$	2.60	June 2031
5,774,267			

11. Stock-Based Compensation

2016 Equity Incentive Plan

On April 5, 2016, the Company's board of directors adopted the 2016 Equity Incentive Plan (the "2016 Plan") as the successor to the 2015 Omnibus Plan (the "2015 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on May 18, 2016 (the "2016 Plan Effective Date"). Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as 464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. An Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan") was approved by the Company's stockholders in May 2018, which increased the share reserve by an additional 1.4 million shares. A Second Amended and

Restated 2016 Equity Incentive Plan (the "2016 Second Amended Plan") was approved by the Company's stockholders in August 2019, which increased the share reserve by an additional 850,000 shares. A Third Amended and Restated Equity Incentive Plan (the "2016 Third Amended Plan") was approved by the Company's stockholders in June 2020 which increased the share reserve by an additional 2,014,400 shares. During the term of the 2016 Third 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, 2026, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. On January 1, 2022, pursuant to the terms of the 2016 Third Amended Plan an additional 4,511,768 shares were made available for issuance. As of March 31, 2022, there were 2,501,823 shares available for future issuance under the 2016 Third 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. In addition, in the first quarter of 2022 employees were also granted options that vest on the first anniversary of the grant date. 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 months ended March 31, 2022 and 2021 was as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 287	$ 298
General and administrative	4,184	1,045
Sales and marketing	841	105
Total stock-based compensation	$ 5,312	$ 1,448

As a result of separation agreements that the Company entered into in the first quarter of 2022 and in accordance with the terms of the pre-existing employment agreements, the Company accelerated the vesting of certain separated employees' stock options and modified certain awards to extend the exercisability periods. The Company recognized $4.3 million of compensation cost for the three months ended March 31, 2022, of which, $3.5 million of expense was recognized in general and administrative expense and $0.8 million of expense was recognized and sales and marketing expense.

Stock options with service-based vesting conditions

The Company has granted awards that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periods. A summary of option activity for the three months ended March 31, 2022 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, 2021	12,650,978	$ 3.69	$ 2.29	8.1
Granted	4,898,451	$ 0.79	$ 0.57	
Forfeited	(1,445,139)	$ 2.68	$ 1.83	
Expired	(16,250)	$ 2.40	$ 1.63	
Balance at March 31, 2022	16,088,040	$ 2.90	$ 1.80	7.0
Exercisable at March 31, 2022	8,333,750	$ 3.86	$ 2.32	4.8

In March 2022, the Company granted 3.3 million options with service-based vesting conditions to its employees as part of its annual stock option award that vest over four years. Additionally in March 2022, the Company granted 1.0 million options to its employees that vest on the first anniversary of the grant date. As a result of the reduction of workforce plan, 1.0 million options were forfeited during the period, and 0.4 million options were forfeited as a result of other terminations during the period.

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 March 31, 2022, the aggregate intrinsic value of options outstanding was $0.1 million. There were 3,243,910 options that vested during the three months ended March 31, 2022 with a weighted average exercise price of $3.45 per share, which included the acceleration of vesting of certain options in accordance with the separation agreements entered in in the first quarter of 2022. The total grant date fair value of shares which vested during the three months ended March 31, 2022 was $7.2 million.

The Company recognized stock-based compensation expense of $5.3 million related to stock options with service-based vesting conditions for the three months ended March 31, 2022. At March 31, 2022, there was $10.9 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 2.2 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options with service-based vesting conditions granted under the Black-Scholes valuation model for the three months ended March 31, 2022:

Service-based options	
Expected term of option (in years)	5 - 6.25
Expected stock price volatility	84.0% - 85.6%
Risk-free interest rate	1.50% - 2.42%
Expected annual dividend yield	—%

Stock options with market-based vesting conditions

As of March 31, 2022 there were 1.0 million exercisable stock options that contained market-based vesting conditions (that had been previously satisfied). The options have a weighted average share price per share of $3.29 and a weighted average remaining contractual term of 2.2 years. There were no stock options with market-based vesting conditions granted, exercised, or forfeited for the three months ended March 31, 2022.

Restricted Stock Units

The Company measures the fair value of the restricted stock units using the stock price on the date of the grant. The restricted shares typically vest annually over a four-year period beginning on the first anniversary of the award. As of March 31, 2022, there were 11,250 unvested restricted stock units outstanding. The unvested restricted stock units have a weighted average grant date fair value of $4.50. There were no restricted stock units granted, vested, or forfeited for the three months ended March 31, 2022.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by the Company's stockholders and became effective on May 18, 2016 (the "ESPP Effective Date").

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 or 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.

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increases by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of

the Company's common stock as determined by the Company's board of directors or compensation committee. The number of shares were increased by500,000 on January 1, 2022. As of March 31, 2022, 2,235,611 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 stock-based compensation expense of $43.2 thousand for the three months ended March 31, 2022.

12. Income Taxes

The Company recognized minimal income tax expense for the three months ended March 31, 2022 and 2021 due to the significant valuation allowance against the Company's deferred tax assets and the current year losses.

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. 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.

Deerfield Guarantee

As consideration of the sale of the rights to the Company's rights, title and interest in assets relating to certain commercialized products to Aytu in 2019, Aytu assumed our financial obligations to Deerfield CSF, LLC ("Deerfield"), which currently includes the remaining contingent consideration related to future royalties on the divested products. In conjunction with the closing of the transaction in 2019, the Company entered into a guarantee in favor of Deerfield, which guarantees the payment of the assumed liabilities to Deerfield (the "Guarantee"). Aytu publicly reported that it had entered into a Waiver, Release and Consent in June 2021, pursuant to which it paid a portion of the contingent consideration early and agreed to pay the remaining fixed obligations of $3.0 million in six equal quarterly payments of $0.5 million commencing September 30, 2021.

Avalo is required to make a payment under the Guarantee upon demand by Deerfield if all or any part of the fixed payments are not paid by Aytu when due or upon breach of a covenant. The remaining minimum commitments payable (as most recently publicly reported by Aytu) was $3.0 million as of September 30, 2021, which represents Avalo's estimated maximum potential future payments under the Guarantee. The Company concluded that the expected credit loss of the Guarantee was de minimis as of March 31, 2022 based on considerations of Aytu's ability to meet its financial commitments including recent financings, cash position, operating cash flows and trends.

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, which closed in 2019, the Company assigned all 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.

Possible Future Milestone Payments for In-Licensed Compounds

General

The Company is a party to license and development agreements with various third parties, which contain future payment obligations such as royalties and milestone payments (discussed further below). 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 its own 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-002 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 AVTX-002, 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.

Under the KKC License Agreement, the Company paid KKC an upfront license fee equal to $10.0 million. The Company is also required to pay KKC up to $112.5 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay KKC sales-based milestones aggregating up to $75.0 million tied to the achievement of annual net sales targets.

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 double-digit percentage (less than 30%) of the payments that the Company receives from sublicensing of its rights under the KKC License Agreement, subject to certain exclusions. Avalo is responsible for the development and commercialization of AVTX-002 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 AVTX-002 in Japan).

No expense related to this license agreement was recognized in the three months ended March 31, 2022. The Company recognized the upfront license fee of $10.0 million within research and development expenses in the first quarter of 2021. There has been no cumulative expense recognized as of March 31, 2022 related to the milestones under this license agreement. The Company will continue to monitor the milestones at each reporting period.

AVTX-006 Astellas License Agreement

The Company has 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 (which we refer to as AVTX-006). 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 $5.5 million based on the achievement of specified development and regulatory milestones. The Company is also required to pay Astellas a tiered mid-to-high single digit percentage of the payments that Avalo receives from 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. Avalo is fully responsible for the development and commercialization of the program.

No expense related to this license agreement was recognized in the three months ended March 31, 2022.There has been $0.5 million of cumulative expense recognized as of March 31, 2022 related to the milestones under this license agreement, which was recognized in the first quarter of 2021. The Company will continue to monitor the remaining milestones at each reporting period.

AVTX-007 AstraZeneca License Agreement

The Company has an exclusive global license with Medimmune Limited, a subsidiary of AstraZeneca plc ("AstraZeneca"), to develop and commercialize a fully human, anti-IL-18 monoclonal antibody (which we refer to as AVTX-007). Under the terms of the license agreement, there was an upfront license fee of $6.0 million in cash and equity. The Company is required to pay AstraZeneca up to $71.5 million based on the achievement of certain development and regulatory milestones. Upon commercialization, the Company is required to pay AstraZeneca sales-based milestone payments aggregating up to $90.0 million tied to the achievement of annual net sales targets. Additionally, the Company is also required to pay AstraZeneca royalties during a country-by-country royalty term equal to a tiered low double digit percentage of annual net sales. Avalo is fully responsible for the development and commercialization of the program.

No expense related to this license agreement was recognized in the three months ended March 31, 2022. There has been $1.5 million of cumulative expense recognized as of March 31, 2022 related to the milestones under this license agreement. The Company will continue to monitor the remaining milestones at each reporting period.

AVTX-008 Sanford Burnham Prebys License Agreement

On June 22, 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 (which we refer to as AVTX-008).

Under the terms of the agreement, the Company incurred an upfront license fee of $0.4 million, as well as patent costs of $0.5 million. The Company is required to pay Sanford Burnham Prebys up to $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 low-to-mid single digit percentage of annual net sales. The Company is also required to pay Sanford Burnham Prebys a tiered low-double digit percentage of the payments that Avalo receives from sublicensing of its rights under the Sanford Burnham Prebys license agreement, subject to certain exclusions. Avalo is fully responsible for the development and commercialization of the program.

No expense related to this license agreement was recognized in the three months ended March 31, 2022. The Company recognized the upfront license fee of $0.4 million within research and development expenses and the upfront patent expense of $0.5 million within general and administrative expenses in second quarter of 2021. There has beenno cumulative expense recognized as of March 31, 2022 related to the milestones under this license agreement. The Company will continue to monitor the milestones 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. ("Merck") in 2013.

Under the out-license agreement, the Company received a mid-six digit upfront payment from Alto. The Company is also eligible to receive up to $18.6 million based on the achievement of specified development, regulatory and commercial sale milestones. Additionally, the Company is entitled to a less than single digit percentage royalty based on annual net sales. Alto is fully responsible for the development and commercialization of the program.

Avalo recognized the upfront fee as license revenue in the second quarter of 2021. The Company hasnot recognized any milestones as of March 31, 2022.

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 Therapeutics, LLC ("ES"), a wholly-owned subsidiary of Armistice. The transaction with ES was approved in accordance with Avalo's related party transaction policy.

Under the assignment agreement, the Company received a low-six digit upfront payment from ES. The Company is also eligible to receive up to $5.0 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. ES is fully responsible for the development and commercialization of the program.

Avalo recognized the upfront fee as license revenue in the second quarter of 2021. The Company hasnot recognized any milestones as of March 31, 2022.

AVTX-501 Sale to Janssen

In August 2017, the Company sold its worldwide rights to AVTX-501 to Janssen Pharmaceuticals, Inc. ("Janssen") in exchange for initial gross proceeds of $25.0 million. The Company is also eligible to receive up to $20.0 million based on the achievement of

specified development and regulatory milestones. Janssen is fully responsible for the development and commercialization of the program.

The Company has not recognized any milestones as of March 31, 2022.

AVTX-611 License Assignment

In August 2019, the Company assigned its rights, title, interest, and obligations under an in-license covering its non-core asset, AVTX-611, to ES, a wholly-owned subsidiary of Armistice.

Upon commercialization, the Company is eligible to receive sales-based milestone payments aggregating up to $20.0 million tied to annual net sales targets. ES is fully responsible for the development and commercialization of the program.

The Company has not recognized any milestones as of March 31, 2022.

Acquisition Related and Related Party Contingent Liabilities

Aevi Merger Possible Future Milestone Payments

In the first quarter of 2020, the Company consummated its merger with Aevi Genomic Medicine Inc. (“Aevi”), in which Avalo acquired the rights to AVTX-002, 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.

The first milestone was the enrollment of a patient in a Phase 2 study related to AVTX-002 (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 March 31, 2022 andno future contingent consideration will be recognized.

The second milestone is the receipt of a 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 development milestone has been recognized as of March 31, 2022. The Company will continue to monitor the second development milestones at 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 the Company upon closing the Aevi Merger in February 2020. The royalty agreement provided certain Aevi investors, including LeoGroup Private Investment Access, LLC on behalf of Garry Neil, the Company’s Chief Executive Officer, 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 our second generation mTORC1/2 inhibitor, AVTX-006. 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 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 consolidated balance sheet as of March 31, 2022. 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.

Ichorion Asset Acquisition Possible Future Milestone Payments

In September 2018, the Company acquired Ichorion Therapeutics, Inc. including acquiring three compounds for inherited metabolic disorders known as CDGs (AVTX-801, AVTX-802 and AVTX-803) and one other preclinical compound. Consideration for the transaction included shares of Avalo common stock and three future contingent development milestones for the acquired compounds worth up to an additional $15.0 million.

The first and second milestone were marketing approval of the first and second product, respectively, by the FDA on or prior to December 31, 2021. The Company did not meet the first or second milestone as of December 31, 2021. The Company would have been required to make a $6.0 million and $5.0 million milestone payment, respectively, if the first and second milestone were met. As a result, no contingent consideration related to these milestones were recognized as of March 31, 2022 and no future contingent consideration will be recognized.

The third milestone is a protide molecule being approved by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of $4.0 million. The contingent consideration related to the third development milestone will be recognized if and when such milestone is probable and can be reasonably estimated. No contingent consideration related to the third development milestone has been recognized as of March 31, 2022. The Company will continue to monitor the third development milestones at each reporting period.

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 below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," as well as in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 2, 2022, 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, 2021 appearing in our Annual Report on Form 10-K filed with the SEC on March 2, 2022.

Overview

Avalo Therapeutics, Inc. (the "Company" or "Avalo" or "we") is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases. We have built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. Our clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

Management's primary evaluation of the success of the Company is the ability to progress its pipeline assets forward towards commercialization or opportunistically out-licensing rights to indications or geographies. This success depends not only on the operational execution of the programs, but also the ability to secure sufficient funding to support the programs. We believe the ability to achieve the anticipated milestones represents our most immediate evaluation points. The following chart summarizes key information about our clinical-stage pipeline and anticipated research & development milestones:

Program	Mechanism of Action	Lead Indication	Designation	Clinical Development Stage			Anticipated Milestone
				Phase 1	Phase 2	Phase 3/Pivotal	
Immunology							
AVTX-002	Anti-LIGHT mAb	NEA	–				Phase 2 Top-line Data 4Q 2022
		Inflammatory bowel disease	–				*
		COVID-19 ARDS	Fast Track				**
AVTX-007	Anti-IL-18 mAb	Still's disease	–				Top-line Data 2023‡
Rare Genetic Diseases							
AVTX-801	D-Galactose replacement	PGM1-CDG	ODD RPDD Fast Track				Pivotal Trial Data 2023‡‡
AVTX-803	L-Fucose replacement	LAD II (SLC35C1-CDG)					Pivotal Trial Data 4Q 2022

* The Company is considering a possible randomized, double-blind, placebo-controlled clinical trial in moderate to severe refractory patients with IBD

** Further development of AVTX-002 for treatment of COVID-19 ARDS is currently dependent on third party funding

‡ Management is currently reviewing preliminary data and path forward related to this indication; updates will be forthcoming upon finalization of the review

‡‡ This study is sponsored by a third party; currently working with study sponsor to refine milestone timing

ARDS, acute respiratory distress syndrome; CDG, congenital disorder of glycosylation; IL, interleukin; LAD, leukocyte adhesion deficiency; mAb, monoclonal antibody; NEA, non-eosinophilic asthma; ODD, orphan drug designation; PGM1, phosphoglucomutase 1; RPDD, rare pediatric disease designation

Recent Developments

Our focus during the first quarter of 2022 was progressing our pipeline programs forward to meaningful data readouts, notably AVTX-002 for the treatment of non-eosinophilic asthma ("NEA") and AVTX-803 for the treatment of leukocyte adhesion deficiency type II ("LAD-II"). We initiated a Phase 2 randomized, double-blind, placebo-controlled clinical trial evaluating AVTX-002 in 80 patients with poorly controlled NEA. We expect top-line data in the fourth quarter of 2022. Further, we initiated a single-center, double-blind pivotal study of AVTX-803 in patients with LAD-II, to be followed by an open-label extension. We expect pivotal data from this trial in the fourth quarter of 2022.

In early 2022, Dr. Garry Neil and Chris Sullivan were promoted to Chief Executive Officer and Chief Financial Officer, respectively. Our Board approved a cost reduction plan in the first quarter of 2022 to enable the Company to execute its strategy of prioritizing the development of our most promising programs (the "Plan"). As part of the Plan, the Company is winding down internal development efforts of AVTX-006 and is pausing current development efforts of AVTX-802. Additionally, the Company previously announced that it is winding down internal development efforts of AVTX-007 in multiple myeloma. The Plan includes a reduction in workforce to reduce headcount and related expense.

As an immediate result of the Plan and the prior separations of certain executive officers in the first quarter of 2022, operating expenses increased as the Company recognized $3.1 million of severance expense and $4.3 million of non-cash stock-based compensation expense during the period. We expect decreases to salary and stock-based compensation related expenses beginning in the second quarter of 2022.

Our Strategy
Our strategy for increasing stockholder value includes:

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

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

Product Revenue, net

Net product revenue was $1.2 million for the three months ended March 31, 2022, compared to $0.5 million for the three months ended March 31, 2021. The increase was mainly attributable to a full return allowance on sales of short-dated inventory sold in the first quarter of 2021 that did not repeat in the first quarter of 2022.

Cost of Product Sales

Cost of product sales were $0.7 million for the three months ended March 31, 2022, compared to $0.1 million for the same period in 2021. The increase was primarily driven by the Company's requirement to pay its supplier fifty percent of the net profit of the Millipred® product following each calendar quarter beginning July 1, 2021, subject to a $0.5 million quarterly minimum payment. We expect cost of product sales to increase as compared to historic periods prior to the net profit share beginning.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Preclinical expenses	$ 999	$ 2,234
Clinical expenses	2,785	5,440
CMC expenses	2,147	4,734
License and milestone expenses	—	10,500
Internal expenses:		
Salaries, benefits and related costs	3,270	1,937
Stock-based compensation expense	287	298
Other	96	63
	$ 9,584	$ 25,206

Research and development expenses decreased $15.6 million for the three months ended March 31, 2022 compared to the same period in 2021. In the first quarter of 2021, the Company recognized $10.0 million upfront license fee related to the expanded indication license agreement for AVTX-002 with Kyowa Kirin Co., Ltd. ("KKC"), which did not repeat in the current period.

The remaining $5.6 million decrease was primarily driven by a decrease in clinical and chemistry, manufacturing, and controls ("CMC"). Notably, clinical expenses for the AVTX-800 programs decreased due to the fact that during the first quarter of 2021, phase 1 trials for multiple AVTX-800 programs were ongoing, while in the current quarter costs were primarily limited to minor initiation costs for the AVTX-803 pivotal trial. Additionally, CMC decreased $2.6 million largely due to the timing of raw material purchases in the first quarter of 2021 that did not repeat in the first quarter of 2022.

The decreases noted above were partially offset by a $1.3 million increase to salaries, benefits and related costs largely driven by severance expense incurred as a result of the headcount reduction implemented in the first quarter of 2022 coupled with headcount increases in the second half of 2021 to support the maturing pipeline, which were not impacted by the headcount reduction. We expect decreases to salary related costs beginning in the second quarter of 2022.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Salaries, benefits and related costs	$ 3,072	$ 920
Legal, consulting and other professional expenses	2,243	2,592
Stock-based compensation expense	4,184	1,045
Other	257	354
	$ 9,756	$ 4,911

General and administrative expenses increased $4.8 million for the three months ended March 31, 2022 compared to the same period in 2021. The increases were mainly comprised of severance expense and non-cash stock-based compensation expense as a result of the headcount reduction from the Plan and the separation of certain executives during the first quarter of 2022. Specifically, the Company recognized $3.5 million of stock-based compensation expense driven by the accelerated vesting and modification of certain separated employees' stock options and $1.6 million in severance expense for the three months ended March 31, 2022.

We expect decreases to general and administrative expenses as a result of the reduction in headcount and other cost savings initiatives beginning in the second quarter of 2022.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Salaries, benefits and related costs	$ 1,027	$ 189
Stock-based compensation expense	841	105
Advertising and marketing expense	43	129
Other	17	12
	$ 1,928	$ 435

Sales and marketing expenses primarily consist of expenses related to initiatives to support the go-to-market strategy of our pipeline assets. Sales and marketing expenses increased $1.5 million for the three months ended March 31, 2022 compared to the same period in 2021 which was the immediate impact of the headcount reduction from the Plan and the separation of certain executives during the first quarter of 2022. The increase was mainly comprised of severance expense of $0.8 million and non-cash stock-based compensation expense of $0.8 million driven by the accelerated vesting and modification of separated employees' stock options.

Amortization Expense

The following table summarizes our amortization expense for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Amortization of intangible assets	$ 38	$ 424

The Company's acquired product marketing rights was fully amortized in the fourth quarter of 2021 resulting in the $0.4 million decrease as compared to the prior period. For the three months ended March 31, 2022, there was minimal amortization expense related to an assembled workforce acquired as part of a previous merger. The assembled workforce was fully amortized in the first quarter of 2022 and therefore, we will not incur amortization expense from historical transactions in future periods.

Other (Expense) Income, Net

The following table summarizes our other (expense) income, net for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Other expense, net	(20)	—
Interest (expense) income, net	(1,169)	17
	$ (1,189)	$ 17

Other expense, net was comprised of interest expense of $1.2 million for the three months ended March 31, 2022. The interest expense recognized was related to the venture debt financing agreement entered into in June 2021. We expect interest expense to increase as compared to historical periods as a result of recognizing a full period of interest.

Income Tax Expense

The following table summarizes our income tax expense for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Income tax expense	$ 9	$ 11

The Company recognized minimal income tax expense for both the three months ended March 31, 2022 and 2021.

Liquidity and Capital Resources

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. As of March 31, 2022, Avalo had $38.5 million in cash and cash equivalents. For the three months ended March 31, 2022, Avalo generated a net loss of $22.1 million and negative cash flows from operations of $16.1 million. As of March 31, 2022, Avalo had an accumulated deficit of $284.2 million.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, losses are expected to continue as the Company continues to invest in its research and development pipeline assets. The Company will require additional financing to fund its operations and to continue to execute its business strategy at least one year after the date the condensed consolidated financial statements included herein were issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) dilutive and/or non-dilutive financings, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. 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. Subject to limited exceptions, our venture debt financing agreement prohibits us from incurring certain additional indebtedness, making certain asset dispositions, and entering into certain mergers, acquisitions or other business combination transactions without prior consent of the Lenders. Additionally, our venture debt financing agreement contains certain covenants and certain other specified events that could result in an event of default, which if not cured or waived, could result in the immediate acceleration of all or a substantial portion of the Notes. As of the filing date of this Quarterly Report on Form 10-Q, the Company was not aware of any breach of covenants or occurrence of material adverse change, nor had it received any notice of event of default from the Lenders (refer to Note 9 to our unaudited condensed consolidated financial statements for more information).

If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financing and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report on Form 10-Q were issued.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will depend on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential receipt and sale of any priority review vouchers it receives.

Uses of Liquidity

The Company uses cash to primarily fund the ongoing development of our research and development pipeline assets and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Net cash (used in) provided by:		
Operating activities	$ (16,067)	$ (18,316)
Investing activities	—	(21)
Financing activities	—	37,825
Net (decrease) increase in cash and cash equivalents	$ (16,067)	$ 19,488

Net cash used in operating activities

Net cash used in operating activities was $16.1 million for the three months ended March 31, 2022, and consisted primarily of a net loss of $22.1 million mainly driven by research and development activities as the Company continued to fund its pipeline assets. The decrease was partially offset by non-cash stock-based compensation of $5.3 million.

Net cash used in operating activities was $18.3 million for the three months ended March 31, 2021 and consisted primarily of a net loss of $30.7 million. Changes in net liabilities increased by $10.4 million, mainly driven by a $9.3 million increase in accounts payable and $1.7 million increase in accrued expenses, partially offset by increased accounts receivable of $1.0 million. Accounts payable as of March 31, 2021 included the $10.0 million upfront license fee for the expanded KKC license agreement for AVTX-002.

Net cash used in investing activities

There were no investing activities in the three months ended March 31, 2022. Net cash used in investing activities was minimal for the three months ended March 31, 2021 and consisted primarily of the purchase of property and equipment.

Net cash provided by financing activities

There were no financing activities in the first quarter of 2022.

Net cash provided by financing activities was $37.8 million for the three months ended March 31, 2021 and consisted primarily of net proceeds of $37.7 million from an underwritten public offering. Armistice Capital Master Fund Ltd. (an affiliate of Armistice Capital, LLC and collectively "Armistice"), which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, served on the Board at the time of the transaction and currently serves on the Board, participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors.

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, cash flows used in management's going concern assessment, income taxes, goodwill, and other intangible assets 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, 2021 filed with the SEC on March 2, 2022. There have been no material changes to our critical accounting policies during the three months ended March 31, 2022.

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.

Interest Rate 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.

None.

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, 2021, filed with the SEC on March 2, 2022, 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 Form 10-K referenced above. The risks described in the Form 10-K referenced above 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 also may 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*	Letter Agreement, dated February 18, 2022, by and between Avalo Therapeutics, Inc. and Garry Neil (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 18, 2022).
10.2*	Letter Agreement, dated February 18, 2022, by and between Avalo Therapeutics, Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on February 18, 2022).
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 March 31, 2022 and December 31, 2021; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three Months Ended March 31, 2022 and 2021; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three Months Ended March 31, 2022 and 2021; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the Three Months Ended March 31, 2022 and 2021; and (v) Notes to Unaudited Financial Statements.
104	Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

+ Filed herewith.

* Management contract or compensatory agreement.

† 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 and 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: May 5, 2022

/s/ Christopher Sullivan

Christopher Sullivan

Chief Financial Officer

(on behalf of the registrant and as the registrant's principal financial officer)

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.;

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: May 5, 2022

/s/ Garry Neil, M.D.
Garry Neil, M.D.
Chief Executive Officer
(Registrant's principal executive officer)

Exhibit 31.2

CERTIFICATION OF 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.;
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: May 5, 2022

/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 March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garry Neil, Chief Executive Officer of the Registrant, and I, Christopher Sullivan, Chief 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 and results of operations of the Registrant.

Date: May 5, 2022

/s/ Garry Neil, M.D.
Garry Neil, M.D.
Chief Executive Officer
(Registrant's principal executive officer)

Date: May 5, 2022

/s/ Christopher Sullivan
Christopher Sullivan
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 Cerecor 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.