# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# **FORM 10-Q**

 UARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the quarterly period ended September 30, 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 (State of incorporation) 540 Gaither Road, Suite 400 Rockville, Maryland 20850 (Address of principal executive offices) 45-0705648 (I.R.S. Employer Identification No.) (410) 522-8707 (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 1 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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □ Non-accelerated filer ☑ Emerging growth company □ Accelerated filer □ Smaller reporting 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.  $\Box$ 

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

As of November 3, 2022, the registrant had 9,414,104 shares of common stock outstanding.

# AVALO THERAPEUTICS, INC.

# FORM 10-Q

# For the Quarter Ended September 30, 2022

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# Item 1. Financial Statements.

# PART I - FINANCIAL INFORMATION

# AVALO THERAPEUTICS, INC. and SUBSIDIARIES

# Condensed Consolidated Balance Sheets (Unaudited) (In thousands, except share and per share data)

	Septe	mber 30, 2022	Dece	mber 31, 2021
Assets	_			
Current assets:				
Cash and cash equivalents	\$	16,943	\$	54,585
Accounts receivable, net		—		1,060
Other receivables		1,314		3,739
Inventory, net		22		38
Prepaid expenses and other current assets		1,118		2,372
Restricted cash, current portion		53		51
Total current assets		19,450		61,845
Property and equipment, net		2,507		2,695
Other long-term asset		_		1,000
Intangible assets, net		_		38
Goodwill		14,409		14,409
Restricted cash, net of current portion		181		227
Total assets	\$	36,547	\$	80,214
Liabilities and stockholders' (deficit) equity			-	
Current liabilities:				
Accounts payable	\$	1,447	\$	3,369
Deferred revenue		442		_
Accrued expenses and other current liabilities		13,696		16,519
Notes payable, current		2,564		_
Total current liabilities		18,149		19,888
Notes payable, non-current		16,502		32,833
Royalty obligation		2,000		2,000
Deferred tax liability, net		133		113
Other long-term liabilities		1,791		2,298
Total liabilities		38,575		57,132
Stockholders' (deficit) equity:		, í		,
Common stock—\$0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021;9,414,104 and 9,399,517 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively		9		9
Additional paid-in capital <sup>1</sup>		291,975		285,239
Accumulated deficit		(294,012)		(262,166)
Total stockholders' (deficit) equity		(2,028)		23,082
Total liabilities and stockholders' (deficit) equity	\$	36,547	\$	80,214

<sup>1</sup> Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022 See Note 1 for details.

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)

		т	hree Months Ended September 30,			N	ine Months Ended September 30,	
		2022	September 50,	2021		2022	September 20,	2021
Revenues: Produc	t \$	432	\$	1,350	\$	2,638	\$	4,554
revenue, net License			Ş	1,550	Ф		¢	625
revenue Tota revenues, net	1	<u> </u>		1,350		14,517		5,179
Operating expenses:								
Cost of product sales		528		908		2,814		1,067
Research and development		7,042		10,551		25,136		48,325
Selling,		3,284		5,926		17,752		18,677
general and administrativ Amortiza		5,284						
expense Tota	.1	10.954		428		38		1,281
operating expenses		10,854 4,095		17,813 (16,463)		<u>45,740</u> (28,585)		69,350 (64,171)
Other exper Interest	ise:							
expense, net Other		(898)		(985)		(3,221)		(1,207)
expense, net Total other				(15)		(20)		(20)
expense, net from continuin operations	g	(898)		(1,000)		(3,241)		(1,227)
Income (los from continuing operations before taxes		3,197		(17,463)		(31,826)		(65,398)
Income tax expense (benefit)		5		8		20		(180)
Income (los from continuing operations	\$	3,192	\$	(17,471)	\$	(31,846)	\$	(65,218)
Income from discontinued operations				76				38
(loss) Net income	\$	3,192	\$	(17,395)	\$	(31,846)	\$	(65,180)
Net income (loss) per share of common stock, basic and diluted <sup>1</sup> :								
Continui operations	ng \$	0.34	\$	(2.09)	\$	(3.39)	\$	(8.02)
Discontino	nued	0.00		0.01		0.00		0.00
Net income (loss) per share of common stock, basic and diluted	\$	0.34	\$	(2.08)	\$	(3.39)	\$	(8.02)
Net loss per share of preferred stock, bas and diluted <sup>1</sup> :	sic							
Continui operations	ng						\$	(3.34)
Discontino	nued							0.00
Net loss per share of preferred stock, bas and diluted	sic						\$	(3.34)

<sup>1</sup> Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022. See Note 1 for details.

See accompanying notes to the unaudited condensed consolidated financial statements.

# AVALO THERAPEUTICS, INC. and SUBSIDIARIES

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

	Commo	on ste	ock	A	dditional paid in	Accumulated	Tot	al stockholders'
	Shares1		Amount <sup>1</sup>		capital <sup>1</sup>	deficit		deficit
Three Months Ended September 30, 2022								
Balance, June 30, 2022	9,405,724	\$	9	\$	291,244	\$ (297,204)	\$	(5,951)
Impact of reverse stock split fractional share round-up	8,380				—	—		
Stock-based compensation	_		_		731	_		731
Net income	—				—	3,192		3,192
Balance, September 30, 2022	9,414,104	\$	9	\$	291,975	\$ (294,012)	\$	(2,028)

	Commo	on sto	ock	A	dditional paid- in	Accumulated	Tot	al stockholders'
	Shares1		Amount <sup>1</sup>		capital <sup>1</sup>	deficit		deficit
Nine Months Ended September 30, 2022								
Balance, December 31, 2021	9,399,517	\$	9	\$	285,239	\$ (262,166)	\$	23,082
Restricted stock units vested during period	938				—	—		—
Shares purchased through employee stock purchase plan	5,269		_		25	_		25
Impact of reverse stock split fractional share round-up	8,380				—	—		—
Stock-based compensation	_		_		6,711	_		6,711
Net loss	—				—	(31,846)		(31,846)
Balance, September 30, 2022	9,414,104	\$	9	\$	291,975	\$ (294,012)	\$	(2,028)

	Comme	on ste	ock	A	dditional paid- in	Accumulated	Tof	al stockholders'
	Shares <sup>1</sup>		Amount <sup>1</sup>		capital <sup>1</sup>	deficit		equity
Three Months Ended September 30, 2021								
Balance, June 30, 2021	8,000,746	\$	8	\$	247,155	\$ (225,575)	\$	21,588
Issuance of common stock in underwritten public offering, net	1,192,407		1		29,045	—		29,046
Issuance of common stock pursuant to ATM Program, net	166,667		_		5,312	_		5,312
Stock-based compensation	—				1,758	—		1,758
Net loss	—		_			(17,395)		(17,395)
Balance, September 30, 2021	9,359,820	\$	9	\$	283,270	\$ (242,970)	\$	40,309

	Commo	n stock	Preferre	d Stock	A	dditional paid- in	Accumulated	Total stockholders'
	Shares <sup>1</sup>	Amount <sup>1</sup>	Shares	Amount	capital <sup>1</sup>		deficit	equity
Nine Months Ended September 30, 2021								
Balance, December 31, 2020	6,250,344	\$ 6	1,257,143	\$ 1	\$	202,345	\$ (177,790)	\$ 24,562
Issuance of shares of common stock and pre-funded warrants in underwritten public offering, net	1,164,323	1	_	_		37,652	_	37,653
Issuance of common stock in underwritten public offering, net	1,192,407	1	_	_		29,045	_	29,046
Issuance of common stock pursuant to ATM Program, net	166,667	—	—	—		5,312	—	5,312
Issuance of equity classified warrants related to venture loan and security agreement	_	_	_	_		861	_	861
Exercise of stock options	48,385	—	—	_		1,568	—	1,568
Conversion of preferred stock to common stock	523,810	1	(1,257,143)	(1)	)	_	_	_
Shares purchased through employee stock purchase plan	7,391	—	—	—		207	—	207
Restricted stock units vested during period	6,493		—	_		_	_	_
Stock-based compensation	—	—	—	—		6,280	—	6,280
Net loss	_			_		_	(65,180)	(65,180)
Balance, September 30, 2021	9,359,820	\$ 9		<u>\$                                    </u>	\$	283,270	\$ (242,970)	\$ 40,309

<sup>1</sup> Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022See Note 1 for details.

See accompanying notes to the unaudited condensed consolidated financial statements.

# AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows (Unaudited) (Amounts in thousands)

(Amounts in thousands)	N' M	Nine Months Ended September 30,				
	2022	ths Ended Se	2021			
Operating activities						
Net loss	\$ (3	1,846) \$	(65,180)			
Adjustments to reconcile net loss used in operating activities:						
Depreciation and amortization		131	1,362			
Stock-based compensation		6,711	6,280			
Accretion of debt discount		1,040	445			
Allowance for other long-term asset		1,000	_			
Deferred taxes		20	40			
Changes in assets and liabilities:						
Accounts receivable, net		1,060	742			
Other receivables		2,425	(269)			
Other long-term asset		_	(2,000)			
Inventory, net		16	(13)			
Prepaid expenses and other assets		1,254	1,252			
Accounts payable	(	1,922)	994			
Deferred revenue		442				
Accrued expenses and other liabilities	(1	3,144)	2,604			
Lease liability, net		2	(50)			
Net cash used in operating activities	(2)	2,811)	(53,793)			
Investing activities						
Purchase of property and equipment		(95)	(102)			
Net cash used in investing activities		(95)	(102)			
Financing activities						
Proceeds from issuance of common stock and pre-funded warrants in underwritten public offering, net		_	37,653			
Proceeds from Notes and warrants, net of debt issuance costs paid		—	32,900			
Prepayment on Notes	(1-	4,806)	_			
Proceeds from issuance of common stock in underwritten public offering, net		—	29,046			
Proceeds from common stock pursuant to ATM Program, net		—	5,312			
Proceeds from exercise of stock options		—	1,568			
Proceeds from issuance of common stock under employee stock purchase plan		25	207			
Net cash (used in) provided by financing activities	× .	4,781)	106,686			
(Decrease) increase in cash, cash equivalents and restricted cash		7,687)	52,791			
Cash, cash equivalents, and restricted cash at beginning of period		4,864	19,106			
Cash, cash equivalents, and restricted cash at end of period	\$ 1	7,177 \$	71,897			
Supplemental disclosures of cash flow information						
Cash paid for interest	\$	2,256 \$	796			
•		=				

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

		September 30,			
	2022			2021	
Cash and cash equivalents	\$	16,943	\$	71,506	
Restricted cash, current		53		164	
Restricted cash, non-current		181		227	
Total cash, cash equivalents and restricted cash	\$	17,177		71,897	

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" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for Herpesvirus Entry Mediator ("HVEM"), a receptor expressed by T lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin  $\beta$  receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator ("BTLA"), and CD160 (collectively, the "LIGHT-signaling network" or the "LIGHT network"). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

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

On July 7, 2022, Avalo effected a 1-for-12 reverse stock split. The Company retroactively applied the reverse stock split to share and per share amounts for periods prior to July 7, 2022, including the unaudited condensed consolidated financial statements for the nine months ended September 30, 2022, three and nine months ended September 30, 2021, and the year ended December 31, 2021. Additionally, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company's outstanding options and warrants, and the number of shares authorized for issuance pursuant to the Company's equity incentive plans have been reduced proportionately. Avalo retroactively applied such adjustments in the notes to the unaudited condensed consolidated financial statements for periods prior to July 7, 2022, including the nine months ended September 30, 2021, and the year ended September 30, 2021, and the year ended December 31, 2021. The reverse stock split did not reduce the number of authorized shares of common and preferred stock and did not alter the par value.

#### 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 September 30, 2022, Avalo had \$ 16.9 million in cash and cash equivalents. For the nine months ended September 30, 2022, Avalo generated a net loss of \$31.8 million and negative cash flows from operations of \$22.8 million. As of September 30, 2022, Avalo had an accumulated deficit of \$294.0 million.

In the second quarter of 2022, as collectively agreed upon with the Lenders (as defined below), the Company made a partial prepayment of \$5.0 million (\$14.8 million of which was applied to principal) on the notes (the "Notes) issued under its venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments XXV, LP ("Powerscourt", and together with Horizon, the "Lenders"). Avalo intends to consider additional prepayments prior to principal loan amounts coming due, if collectively agreed upon with the Lenders. As of September 30, 2022, the carrying value of the Notes (as defined in Note 9) was \$19.1 million.

The accompanying unaudited 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 within one year after the date the unaudited condensed consolidated financial statements included herein were issued. We anticipate that the cash and cash equivalents as of September 30, 2022 will not be sufficient for us to fund our product candidates through their next anticipated milestones, which include topline data from the AVTX-002 Phase 2 PEAK trial and pivotal data from the AVTX-803 LADDER trial, both expected in the first half of 2023. We will need to raise additional capital to reach these milestones. 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 nondilutive financings, (ii) out-licensing or strategic alliances/collaborations of its current pipeline assets, (iii) out-licensing or sale of its non-core assets, and (iv) federal and/or private grants. 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, the Loan Agreement prohibits the Company from incurring certain additional indebtedness, making certain asset dispositions, and entering into certain mergers, acquisitions or other business combination transactions without the prior consent of the

Lenders. Additionally, the Loan 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 outstanding 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 of the condensed unaudited 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.

#### 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.

In the second quarter of 2022, the Company concluded that it would include sales and marketing expenses within the selling, general and administrative line in the Company's condensed consolidated statement of operations. The Company reclassified \$0.7 million and \$2.0 million from sales and marketing expense to selling, general and administrative expense for the three and nine months ended September 30, 2021, respectively, to conform with the current period presentation.

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

#### Significant Accounting Policies

During the nine months ended September 30, 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

In July 2022, Avalo entered into a license agreement with Apollo AP43 Limited, a wholly owned subsidiary of Apollo Therapeutics Group Limited (collectively, "Apollo") pursuant to which the Company granted Apollo a worldwide, exclusive license to research, develop, manufacture and commercialize AVTX-007, an anti-IL-18 monoclonal antibody (the "Apollo License Agreement"). Pursuant to the Apollo License Agreement, the Company received an upfront payment of \$14.5 million, which was recognized as license revenue for the three and nine months endedSeptember 30, 2022.



The Company generates substantially all of its product revenue from sales of Millipred<sup>®</sup>, 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 September 30, 2022, the Company's two largest customers accounted for approximately 65% and 35%, respectively, of the Company's total net product revenues. For the nine months ended September 30, 2022, the Company's two largest customers accounted for approximately 72% and 28%, respectively, of the Company's total net product revenues. Net revenue from sales of prescription drugs was \$0.4 million and \$1.4 million for the three months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, deferred revenue was \$0.4 million due to the receipt of payment from wholesale distributors related to product that had not yet been sold to the customer.

The Company has a license and supply agreement for the Millipred<sup>®</sup> product with a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which expires on September 30, 2023. Beginning July 1, 2021, Avalo was required to pay Teva fifty percent of the net profit of the Millipred<sup>®</sup> product following each calendar quarter, subject to a \$0.5 million quarterly minimum payment unless total net profit is below a specified threshold. For the three and nine months ended September 30, 2022, the Company recognized \$0.4 million and \$1.4 million, respectively, 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<sup>®</sup> 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<sup>®</sup> from the second quarter of 2020 through the third-party logistics provider and providing accounting reporting services. Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred<sup>®</sup> from the second quarter of 2020 through the third-party distribution and began managing Millipred<sup>®</sup> 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 first quarter of 2022. As of September 30, 2022, the total receivable balance was approximately \$1.8 million. As disclosed in its Annual Report on Form 10-K for the year ended June 30, 2022 (filed September 27, 2022), Aytu concluded that substantial doubt exists with respect to their ability to continue as a going concern within one year after the date that the financial statements were issued, or until September 30, 2022. The remaining \$0.8 million is included within other receivables and is contractually owed in the fourth quarter of 2022.

## 4. Net (Loss) Income 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 and nine months ended September 30, 2022 and three months ended September 30, 2021. The Company hadwo classes of stock outstanding during the nine months ended September 30, 2021; common stock and preferred stock. The preferred stock outstanding during the prior period converted to shares of common stock on an approximately 1-for-0.42 ratio (ratio adjusted for the reverse stock split) 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, served on Avalo's Board until August 8, 2022, converted the then outstanding 1,257,143 shares of convertible preferred stock into 523,810 shares of Avalo's common stock. 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 and nine months ended September 30, 2022 and three months ended September 30, 2021, and both common stock and preferred stock for the nine months ended September 30, 2022 and three months ended September 30, 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 September 30, 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) income 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) income per share of common stock for the three and nine months ended September 30, 2021 and three months ended September 30, 2021, and common stock and preferred stock for the nine months ended September 30, 2021 (in thousands, except share and per share amounts):

	Three Months Ended September 30, 2022	
	Common stock	
Basic income per share:		
Net income	\$ 3	,192
Weighted average shares	9,413	,466
Basic net income per share	\$	0.34
Diluted income per share:		
Net income	\$ 3.	,192
Weighted average shares - basic	9,413	,466
Effect of dilutive securities:		
Potentially dilutive shares		166
Weighted average shares - diluted	9,413	,632
Diluted net income per share	\$	0.34

	Ni	ne Months Ended
	Se	ptember 30, 2022
		Common stock
Net loss	\$	(31,846)
Weighted average shares		9,404,679
Basic and diluted net loss per share	\$	(3.39)

		onths Ended per 30, 2021
	Com	non stock
	Continuing Operations	<b>Discontinued Operations</b>
Allocation of undistributed net (loss) income	\$ (17,471)	\$ 76
Weighted average shares	8,374,200	8,374,200
Basic and diluted net (loss) income per share	\$ (2.09)	\$ 0.01

	Nine Months Ended								
	September 30, 2021								
		Common stock				Preferred stock			
	Contin	uing Operations	Disco	ntinued Operations	Co	ntinuing Operations	Disc	ontinued Operations	
Allocation of undistributed net (loss) income	\$	(63,602)	\$	37	\$	(1,616)	\$	1	
Weighted average shares		7,927,152		7,927,152		483,517		483,517	
Basic and diluted net (loss) income per share	\$	(8.02)	\$	0.00	\$	(3.34)	\$	0.00	

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three and nine months ended September 30, 2022 and 2021, as they could have been anti-dilutive:

Three and Nine Mo	nths Ended			
September	September 30,			
2022	2021			
1,260,906	1,122,785			
366,990	367,186			
—	6,493			
	2022			

<sup>1</sup> The weighted average number of common shares outstanding as of September 30, 2021 included the weighted average effect of the139,747 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 (\$0.012 per share exercise price for each pre-funded warrant). During 2021, the holder exercised 25,740 of the pre-funded warrants. As of September 30, 2022, the weighted average number of common shares outstanding included the weighted average effect of the remaining 114,007 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):

		September	r 30, 2022				
	Fair Value Measurements Using						
Qu	oted prices in	Significant other		her Signific			
acti	ve markets for	observ	able	unobserv	able		
id	entical assets	inputs		inputs			
(Level 1)		(Leve	el 2)	(Level	3)		
-							
\$	16,079	\$	_	\$			

			Decen	ıber 31, 2021			
			Fair Value N	leasurements Usin	g		
	Q	uoted prices in	Signi	icant other		Significant	
	ac	tive markets for	ob	servable		unobservable	
	i	dentical assets		inputs		inputs	
		(Level 1)	(1	Level 2)		(Level 3)	
ents 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 September 30, 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 September 30, 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 nine months ended September 30, 2022 and 2021. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 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 offhree 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 September 30, 2022 was5.8 years.

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

	As of			
	September 30, 2022			December 31, 2021
Property and equipment, net	\$	1,813	\$	2,001
Accrued expenses and other current liabilities	\$	526	\$	485
Other long-term liabilities		1,791		2,018
Total operating lease liabilities	\$	2,317	\$	2,503

The operating lease right-of-use (ROU) assets are included in property and equipment, net and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our 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 and nine months ended September 30, 2022 and 2021 were as follows (in thousands):

	Three Months Ended September 30,			Nine Months End	led Sept	ember 30,	
	2022		202	21	2022		2021
Operating lease cost*	\$	134	\$	97	\$ 373	\$	287

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

The following table shows a maturity analysis of the operating lease liabilities as of September 30, 2022 (in thousands):

	Undiscounted Cash Flows
October 1, 2022 through December 31, 2022	\$ 130
2023	528
2024	537
2025	547
2026	557
2027	258
Thereafter	426
Total lease payments	\$ 2,983
Less implied interest	(666)
Total	\$ 2,317

#### 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2022 and December 31, 2021 consisted of the following (in thousands):

	1	As of
	September 30, 2022	December 31, 2021
h and development	\$ 7,094	\$ 8,221
pensation and benefits	2,972	4,310
ng, general and administrative	903	1,386
mercial operations	1,798	1,733
ty payment	399	375
se liability, current	526	485
	4	9
rued expenses and other current liabilities	\$ 13,696	\$ 16,519

## 8. Cost Reduction Plan

In the first quarter of 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 announced plans to wind down internal development efforts of AVTX-006 and pause development efforts of AVTX-802. Accordingly, a reduction in workforce plan was approved to reduce headcount and related expenses. The reduction in workforce plan, which was considered a one-time termination benefit, was completed in the second quarter of 2022.

The one-time termination benefits mainly relate to severance payments to separated employees. As a result, the Company recognized \$1.5 million of expense during the first quarter of 2022, of which \$0.7 million was recognized in research and development expense, and \$0.8 million was recognized in selling, general and administrative expense.

Of the \$1.5 million initial liability recognized in the first quarter of 2022, \$1.2 million was paid in the nine months ended September 30, 2022. The remaining severance liability will be paid over the next two to six 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 first quarter of 2022, the Company separated 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 \$1.7 million expense for the nine months ended September 30, 2022 within selling, general and administrative expenses. Additionally, the Company accelerated the vesting of certain outstanding stock options and extended the exercisability periods, which resulted in \$3.9 million of compensation cost recognized in first quarter of 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 the \$35.0 million Loan Agreement with 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").

In June 2022, the Company, as collectively agreed upon with the Lenders, prepaid \$15.0 million to the Lenders, of which \$14.8 million was applied to principal and the remainder applied to accrued interest. As of September 30, 2022, the outstanding notes payable balance was \$21.2 million, inclusive of the final payment fee. Avalo intends to consider additional prepayments prior to principal loan amounts coming due, if collectively agreed upon with the Lenders.

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 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 to 3%, and any accrued and unpaid interst. 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 a 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 purchase 33,656 shares of the Company's common stock with an exercise price of \$31.20 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 Lenders, 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, was18.7% as of September 30, 2022.



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

and the pulse of the note pulse for the note is as follows (in thousands).			
	As o	f	
	September 30, 2022	December 31, 2021	Maturity
Initial Note	12,139	20,600	January 2025
Second Note	6,070	10,300	February 2025
Third Note	3,035	5,150	April 2025
Notes payable, gross <sup>1</sup>	21,244	36,050	
Less: Unamortized debt discount and issuance costs	2,178	3,217	
Carrying value of notes payable	19,066	32,833	
Less: Current portion	2,564		
Carrying value of notes payable, non-current	16,502	32,833	

<sup>1</sup> Balance includes \$1.1 million final payment fee for the Notes, which represents 3% of the original principal loan amount.

As of September 30, 2022, the estimated future principal payments due on the Notes were as follows (in thousands):

	As o	f September 30, 2022
2022	\$	—
2023		5,930
2024		13,463
2025		1,851
Total principal payments <sup>1</sup>	\$	21,244

<sup>1</sup> Balance includes \$1.1 million final payment fee, which represents 3% of the original principal loan amount.

#### 10. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issuetwo classes of stock, common stock and preferred stock. At September 30, 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 approximately 1.2 million shares of its common stock for net proceeds of \$20.0 million. Armistice participated in the offering by purchasing approximately 0.5 million 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 approximately 0.2 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 purchase33,656 shares of the Company's common stock with an exercise price of \$31.20 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 approximately1.2 million shares of its common stock and 139,747 pre-funded warrants for net proceeds of \$37.7 million. Armistice participated in the offering by purchasing approximately 0.2 million shares of common stock, on the same terms as all other investors. Nantahala participated in the offering by purchasing approximately 0.1 million 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 139,747 shares of common stock at a purchase price of \$1.188, which represents the per share public offering price for the common stock less the \$0.012 per share exercise price for each pre-funded warrant. During 2021, the holder exercised25,740 of the pre-funded warrants. As of September 30, 2022, 114,007 pre-funded warrants were outstanding.

#### **Common Stock Warrants**

At September 30, 2022, the following common stock warrants were outstanding:

Number of common shares	Number of common shares Exercise price		Expiration
underlying warrants	1	date	
333,334	\$	150.00	June 2024
114,007	\$	0.012	_
33,656	\$	31.20	June 2031
480,997			

#### 11. Stock-Based Compensation

#### 2016 Equity Incentive Plan

In April 2016, our board of directors adopted the 2016 Equity Incentive Plan, which was approved by our stockholders in May 2016 and which was subsequently amended and restated in May 2018 and August 2019 with the approval of our board of directors and our stockholders (the "2016 Third Amended Plan"). 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 and Restated Plan, an additional 375,981 shares were made available for issuance. As of September 30, 2022, there were361,892 shares available for future issuance under the 2016 Third Amended Plan. In October 2022, the Company granted 225,000 options to its employees that vest on the first anniversary of the grant date.

Option grants expire after ten years. Employee options typically vest overfour 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 and nine months ended September 30, 2022 and 2021 was as follows (in thousands):

	Three Months	nded September 30,	Nine Months Ended September 30,			
	2022	2021	2022	2021		
Research and development	\$ 27	\$ 480	\$ 931	\$ 1,244		
Selling, general and administrative	452	1,278	5,780	5,036		
Total stock-based compensation	\$ 73	\$ 1,758	\$ 6,711	\$ 6,280		



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. As a result, the Company recognized \$4.3 million of compensation cost in the first quarter of 2022, all of which was recognized in selling, general and administrative expense. There was no additional expense related to the modifications in the three months ended September 30, 2022.

#### Stock options with service-based vesting conditions

The Company has granted options that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periodsA summary of option activity for the nine months ended September 30, 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	1,054,277	\$	44.26	\$	27.45	8.1		
Granted	447,022	\$	9.19	\$	6.59			
Forfeited	(262,852)	\$	30.14	\$	20.14			
Expired	(60,876)	\$	53.48	\$	35.76			
Balance at September 30, 2022	1,177,571	\$	33.62	\$	20.72	6.4		
Exercisable at September 30, 2022	713,994	\$	44.28	\$	26.55	4.7		

In March 2022, the Company granted 0.3 million options with service-based vesting conditions to its employees as part of its annual stock option award that vest overfour years. In March 2022, the Company granted 0.1 million options to its employees that vest on the first anniversary of the grant date. As a result of the reduction of workforce plan,0.1 million options were forfeited as a result of other terminations during the nine months ended September 30, 2022. In October 2022, the Company granted 0.2 million options to its employees that vest on the first anniversary of the grant date.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2022, the aggregate intrinsic value of options outstanding was zero. There were 349,405 options that vested during the nine months ended September 30, 2022 with a weighted average exercise price of \$9.76 per share, which included the acceleration of vesting of certain options in accordance with the separation agreements entered into in the first quarter of 2022. The total grant date fair value of shares which vested during the nine months ended September 30, 2022 was \$9.0 million.

The Company recognized stock-based compensation expense of \$0.7 million and \$6.6 million related to stock options with service-based vesting conditions for the three and nine months ended September 30, 2022, respectively. At September 30, 2022, there was \$4.8 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 nine months ended September 30, 2022:

Service-based options	
Expected term of option (in years)	5 - 6.25
Expected stock price volatility	84.0% - 93.5%
Risk-free interest rate	1.50% - 4.06%
Expected annual dividend yield	0%

Stock options with market-based vesting conditions

As of September 30, 2022, there were 0.1 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 \$39.53 and a weighted average remaining contractual term of 1.7 years. There were no stock options with market-based vesting conditions granted, exercised, or forfeited for the nine months ended September 30, 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 September 30, 2022, there were no unvested restricted stock units outstanding. During the nine months ended September 30, 2022,937 restricted stock units vested and had a weighted average grant date fair value of \$54.00 per unit.

#### **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.

The Company initially reserved and authorized up to 41,667 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 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) 41,667 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 by 41,667 on January 1, 2022. As of September 30, 2022,181,028 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 \$33,000 and \$117,000 for the three and nine months ended September 30, 2022, respectively.

#### 12. Income Taxes

The Company recognized minimal income tax expense for the three and nine months ended September 30, 2021 and the three months ended September 30, 2021 due to the significant valuation allowance against the Company's deferred tax assets and the current and prior period losses. The Company recognized an income tax benefit of \$0.2 million for the nine months ended September 30, 2021 due to the receipt of its refund claim related to the tax year 2017. The tax benefit recognized for the nine months ended September 30, 2020 was a result of a tax law change signed into law as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which allowed the Company to carry back certain losses for taxes paid in fiscal year 2017 and thus resulted in a refund claim. The 2021 income tax benefit was a result of the updated estimate of interest receivable and abatement of penalties on the refund claim, as the final refund payment was received from the Internal Revenue Service in the second quarter of 2021.

#### 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 ertain commercialized products to Aytu in 2019, Aytu assumed our financial obligations to Deerfield CSF, LLC ("Deerfield"), which currently includes the remaining contingent consideration of future royalties on the divested products. In conjunction with the closing of the transaction in 2019, the Company entered into an agreement, 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. As reported in Aytu's Annual Report on Form 10-K for the year ended June 30, 2022, the fixed payment arrangement was 60 million.

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. In accordance with the Waiver, Release and Consent, as of September 30, 2022, the Company estimates Aytu has one quarterly payment of \$0.5 million remaining, 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 September 30, 2022, based on considerations of Aytu's ability to meet its current 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, 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 \$0.0 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 the KKC License Agreement was recognized in the nine months ended September 30, 2022. The Company recognized the upfront license fee of \$0.0 million within research and development expenses in the nine months ended September 30, 2021. There has been no cumulative expense recognized as of September 30, 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 (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 nine months ended September 30, 2022. There has been \$0.5 million of cumulative expense recognized as of September 30, 2022 related to the milestones under this license agreement, which was recognized in the nine months ended September 30, 2021. 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 (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 the Sanford Burnham Prebys License Agreement was recognized in the nine months ended September 30, 2022. The Company recognized the upfront license fee of **6**.4 million within research and development expenses and the upfront patent expense of \$0.5 million within selling, general and administrative expenses in the nine months ended September 30, 2021. There has been no cumulative expense recognized as of September 30, 2022 related to the milestones under the Sanford Burnham Prebys 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 \$8.6 million based on the achievement of specified development, regulatory and commercial sale milestones (net of the payments due to Merck pursuant to the original license agreement, which Alto is responsible for). 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 nine months ended September 30, 2021. The Company hasnot recognized any milestones as of September 30, 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"), an affiliate of Armistice. The transaction with ES was approved in accordance with Avalo's related party transaction policy. The Company initially in-licensed the compound from Merck in 2013.

Under the assignment agreement, the Company received a low-six digit upfront payment from ES. The Company is also eligible to receive up to \$.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 is no longer responsible for future milestones or royalties under the original license with Merck.

Avalo recognized the upfront fee as license revenue in the nine months ended September 30, 2021. The Company hasnot recognized any milestones as of September 30, 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, payable in either shares of Avalo's common stock or cash, at the election of Avalo.

The first milestone was the enrollment of a patient in a Phase 2 study related to 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 September 30, 2022 andno future contingent consideration will be recognized.

The second milestone is the receipt of 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 September 30, 2022. The Company will continue to monitor the second development milestone 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 the Company's 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 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 condensed consolidated balance sheet as of September 30, 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, payable in either shares of Avalo's common stock or cash, at the election of Avalo.

The first and second milestones were marketing approval of the first and second product, respectively, by the FDA on or prior to December 31, 2021, which would have resulted in milestone payments of \$6.0 million and \$5.0 million, respectively. The Company did not meet the first or second milestone as of December 31, 2021. As a result, no contingent consideration related to these milestones was recognized as of September 30, 2022 and no future contingent consideration will be recognized.

The third milestone is the marketing approval of a protide molecule 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 estimatedNo contingent consideration related to the third development milestone has been recognized as of September 30, 2022. The Company will continue to monitor the third development milestone at each reporting period.

#### 14. Subsequent Events

On November 4, 2022, Avalo entered into an agreement to sell its economic rights to future payments for previously out-licensed assets including AVTX-007, AVTX-501, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice, in exchange for \$5.0 million, payable upon closing (the "ES Transaction"). The ES Transaction is expected to close in November 2022. The ES Transaction was approved in accordance with Avalo's related party transaction policy. The Company will evaluate the accounting impact of the transaction in the fourth quarter of 2022.

Upon closing of the ES Transaction, the Company will no longer be entitled to receive the possible future milestones and royalties related to AVTX-007, AVTX-501 and AVTX-611, as discussed further below:

#### AVTX-007

On July 29, 2022, Avalo entered into a license agreement with Apollo pursuant to which the Company granted Apollo a worldwide, exclusive license to research, develop, manufacture and commercialize AVTX-007. Upon closing of the ES Transaction, the future economic rights to milestones and royalties for AVTX-007 under the Apollo License Agreement will be transferred to ES.

The program was originally licensed to Avalo from MedImmune Limited, a subsidiary of AstraZeneca plc ("MedImmune"), and such license was transferred to Apollo. Avalo is not responsible for future milestone or royalties under the original license with MedImmune.

#### AVTX-501

In 2017, Avalo sold its worldwide rights to AVTX-501 to Janssen Pharmaceuticals, Inc. Upon closing of the ES Transaction, the future economic rights to milestones for AVTX-501 will be transferred to ES.

The Company had initially in-licensed the compound from Eli Lilly Company ("Lilly"). Avalo is not responsible for future milestones or royalties under the original license with Lilly.

AVTX-611



In 2019, Avalo assigned its rights, title, interest and obligations under an in-license covering its non-core asset, AVTX-611, to ES. Upon closing of the ES Transaction, Avalo will waive all rights, including payments due to the Company from ES, under the original license agreement.

Avalo initially in-licensed the compound from Lilly. Avalo is not responsible for future milestones or royalties under the original license with Lilly.

#### 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 sinilar 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 equivalent of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item IA, "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 erelied upon as of any subsequent date. Unless otherwise required by anylicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking 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.

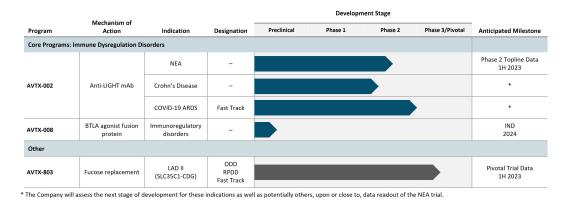
## Overview

Avalo Therapeutics, Inc. (the "Company" or "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for Herpesvirus Entry Mediator ("HVEM"), a receptor expressed by T lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin  $\beta$  receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator ("BTLA"), and CD160 (collectively, the "LIGHT-signaling network" or the "LIGHT network"). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

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:





ARDS, acute respiratory distress syndrome; BTLA, B and T lymphocyte attenuator, Ig superfamily checkpoint; CDG, congenital disorder of glycosylation; LAD, leukocyte adhesion deficiency; LIGHT, Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes; mAb, monoclonal antibody; NEA, non-eosinophilic asthma; ODD, orphan drug designation; REDQ, rare pediatric disease designation

#### **Recent Developments**

In the third quarter of 2022, we were focused on progressing our pipeline programs forward to meaningful data readouts, notably AVTX-002 for the treatment of non-eosinophilic asthma ("NEA"). We remain on track to deliver topline data in the first half of 2023 from our Phase 2 PEAK (A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX-002 for the treatment of Poorly Controlled Non-Eosinophilic Asthma K) trial.

In August 2022, we narrowed our focus to dysregulated inflammation specifically as it relates to the LIGHT-signaling network. LIGHT (TNFSF14) has emerged as an important modulator of critical innate and adaptive immune responses. LIGHT and its signaling receptors, herpesvirus entry mediator (TNFRSF14), and lymphotoxin  $\beta$  receptor, form an immune regulatory network with two correceptors of herpesvirus entry mediator, checkpoint inhibitor BTLA, and CD160. There is increasing evidence that the dysregulation of the LIGHT-signaling network is a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs, including COVID-19 acute respiratory distress syndrome and inflammatory bowel diseases. We have two drug candidates that modulate the LIGHT-signaling network, AVTX-002, an anti-LIGHT monoclonal antibody ("mAb") in Phase 2, and AVTX-008, a BTLA agonist fusion protein in lead optimization.

In August 2022, we announced that AVTX-008, which we in-licensed in 2021 from Sanford Burnham Prebys Medical Discovery Institute as a portfolio of patents covering an immune checkpoint program, is a BTLA agonist fusion protein. We also announced that AVTX-008 has now entered IND-enabling studies. We added AVTX-008 to our product development pipeline milestone chart as a result of reaching the IND-enabling phase and our recent change in focus to the LIGHT-signaling network. We are targeting IND submission in 2024.

We are proceeding with the AVTX-803 LADDER (A Phase 3, Randomized, Double-Blind, Two-Period, Crossover, Withdrawal Study to Assess the Efficacy and Safety of AVTX-803 in Subjects with Leukocyte Adhesion Deficiency Type II (LADD) (ER)) trial and remain on track to deliver pivotal data in the first half of 2023. We will continue to consider strategic alternatives for AVTX-803, as well as AVTX-801 and AVTX-802.

On November 4, 2022, Avalo entered into an agreement to sell its economic rights to future payments for previously out-licensed assets including AVTX-007, AVTX-501, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice, in exchange for \$5.0 million payable upon closing (the "ES Transaction"). The ES Transaction is expected to close in November 2022. The ES Transaction was approved in accordance with Avalo's related party transaction policy. Refer to Note 14 of the condensed consolidated financial statements for additional information.

#### **Our Strategy**

Our strategy for increasing stockholder value includes:

· Advancing our pipeline of compounds through development and to regulatory approval;

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

## **Results of Operations**

#### Comparison of the Three Months Ended September 30, 2022 and 2021

#### Product Revenue, Net

Net product revenue was \$0.4 million for the three months ended September 30, 2022, compared to \$1.4 million for the three months ended September 30, 2021. The decrease was mainly attributable to a decrease in units sold, which may have been caused by disruptions to the sales channel as a result of the transition of commercial operations from Aytu BioScience, Inc. ("Aytu") to Avalo in the second half of 2021. The Company is uncertain whether these potential disruptions will be temporary or have a permanent impact on future sales.

#### License Revenue

In the third quarter of 2022, Avalo granted a worldwide, exclusive license to Apollo Therapeutics Group Limited ("Apollo") to research, develop, manufacture and commercialize AVTX-007, Avalo's anti-IL-18 mAb. The Company recognized \$14.5 million of license revenue for the three months ended September 30, 2022 related to the receipt of upfront fees pursuant to the license.

#### Cost of Product Sales

Cost of product sales were \$0.5 million for the three months ended September 30, 2022, compared to \$0.9 million for the same period in 2021. The decrease was mainly attributable to a decrease in units sold, as discussed above.

# Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021 (in thousands):

	T	Three Months Ended September 30,			
		2022	1	2021	
Preclinical expenses	\$	479	\$	1,485	
Clinical expenses		3,003		2,658	
CMC expenses		1,687		3,366	
Internal expenses:					
Salaries, benefits and related costs		1,533		2,499	
Stock-based compensation expense		279		480	
Other		61		63	
	\$	7,042	\$	10,551	

Research and development expenses decreased \$3.5 million for the three months ended September 30, 2022, compared to the same period in 2021.

Notably, chemistry, manufacturing, and controls ("CMC") and preclinical expenses decreased \$1.7 million and \$1.0 million, respectively. CMC expenses decreased largely due to the increased manufacturing activities to support clinical development in the third quarter of 2021 that did not repeat in the third quarter of 2022. Preclinical expenses decreased due to non-clinical activities and biomarker studies in the third quarter of 2021 that did not repeat in the third quarter of 2022. Clinical expenses increased \$0.3 million, which was driven by increased clinical trial activities for the AVTX-002 PEAK study partially offset by fewer clinical trials overall in the current period as a result of the out-license of AVTX-007 and de-prioritization of certain programs in 2022.

Additionally, salaries, benefits and related costs decreased \$1.0 million due to the reduction in headcount implemented in the first quarter of 2022 and cost savings initiatives.

# Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Mon	Three Months Ended September 30,			
	2022		2021		
Salaries, benefits and related costs	\$	839 \$	1,434		
Legal, consulting and other professional expenses	1.	687	2,425		
Stock-based compensation expense		452	1,279		
Advertising and marketing expense		6	482		
Other		300	306		
	\$ 3	284 \$	5,926		

Selling, general and administrative expenses decreased \$2.6 million for the three months ended September 30, 2022 compared to the same period in 2021 due to decreased headcount and cost savings initiatives. Notably, non-cash stock-based compensation expense and salaries, benefits, and related costs decreased \$0.8 million and \$0.6 million, respectively, as a result of decreased headcount. Legal, consulting and other professional expenses decreased \$0.7 million due to reduced recruiting, information technology services and legal expenses as a result of cost savings initiatives.

We expect selling, general and administrative expenses to continue to decrease as compared to historical periods prior to the reduction in headcount and other cost savings initiatives implemented in the first quarter of 2022.

#### Amortization Expense

The following table summarizes our amortization expense for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Month	30,	
	2022	202	1
Amortization of intangible assets		— \$	428

Avalo's acquired assembled workforce and acquired product marketing rights were fully amortized in the first quarter of 2022 and fourth quarter of 2021, respectively, thus driving the \$0.4 million decrease as compared to the prior period. We expect amortization expense to decrease as compared to historical prior periods given the intangible assets are fully amortized.

## Other Expense, Net

The following table summarizes our other expense, net for the three months ended September 30, 2022 and 2021 (in thousands):

	Т	Three Months Ended September 30,		
		2022	202	1
Other expense, net		—		(15)
Interest expense, net		(898)		(985)
	\$	(898)	\$	(1,000)

Other expense, net was mainly comprised of interest expense related to the venture loan and security agreement for the three months ended September 30, 2022. In June 2022, the Company made a partial prepayment of \$15.0 million under the venture loan and security agreement, of which \$14.8 million was applied to principal, which drove the \$0.1 million decrease in interest expense compared to the prior period.

We expect interest expense to decrease as compared to prior periods as a result of the lower outstanding principal balance.

#### Income Tax Expense

The following table summarizes our income tax expense for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,			
	2022	2021		
Income tax expense	\$5	\$	8	

The Company recognized minimal income tax expense for both the three months ended September 30, 2022 and 2021.

#### Comparison of the Nine Months Ended September 30, 2022 and 2021

#### Product Revenue, Net

Net product revenue was \$2.6 million for the nine months ended September 30, 2022, compared to \$4.6 million for the nine months ended September 30, 2021. The decrease was mainly attributable to a decrease in units sold, which may have been caused by disruptions to the sales channel as a result of the transition of commercial operations from Aytu to Avalo in the second half of 2021. The Company is uncertain whether these potential disruptions will be temporary or have a permanent impact on future sales.

#### License Revenue

Avalo recognized \$14.5 million of license revenue for the nine months ended September 30, 2022 compared to \$0.6 million of license revenue for the prior period. The license revenue recognized in the current period related to receipt of upfront fees pursuant to the out-license of AVTX-007 to Apollo. The license revenue in the prior period related to upfront fees received pursuant to the out-license and assignment of the rights to its non-core neurology pipeline assets, AVTX-301 and AVTX-406, respectively.

#### Cost of Product Sales

Cost of product sales were \$2.8 million for the nine months ended September 30, 2022, compared to \$1.1 million for the same period in 2021. In the second quarter of 2022, we fully reserved the \$1.0 million receivable due from Aytu in December 2024 pursuant to the transition service agreement, given Aytu disclosed in their Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 that substantial doubt existed with respect to their ability to continue as a going concern within one year after the date the financial statements were issued, or May 2023. We recognized the expense in the cost of product sales for the nine months ended September 30, 2022. Aytu most recently disclosed in their Annual Report on Form 10-K for the year ended June 30, 2022, that it does not have sufficient cash to cover its cash needs for the following twelve months following the filing of its Annual Report on Form 10-K, or until September 20.3.

The remainder of the increase from the prior period was mainly driven by the fifty percent net profit share with the supplier, which began on July 1, 2021.

#### Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Mon	Nine Months Ended September 30,		
	2022		2021	
expenses	\$ 2	,047 \$	5,829	
	9	,037	10,558	
	(	,800	13,005	
e expenses			10,900	
efits and related costs	(	,093	6,595	
pensation expense		931	1,244	
		228	194	
	\$ 2:	,136 \$	48,325	

Research and development expenses decreased \$23.2 million for the nine months ended September 30, 2022 compared to the same period in 2021. In the first quarter of 2021, the Company recognized a \$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 \$13.2 million decrease was primarily driven by a decrease in CMC, preclinical and clinical expenses. CMC expenses decreased \$6.2 million due to the timing of raw material purchases and increased manufacturing activities in the prior period that did not repeat in the nine months ended September 30, 2022. Preclinical expenses decreased \$3.8 million primarily due to non-clinical activities and biomarker studies in the in the prior period that did not repeat in the nine months ended September 30, 2022. Clinical expenses decreased \$1.5 million due to fewer clinical trials ongoing in the current period as a result of certain programs being paused or wound down in 2022 and the out-license of AVTX-007. However, these decreases were partially offset by increased clinical activities related to the AVTX-002 PEAK study.

Salaries, benefits and related costs decreased \$0.5 million compared to the same period in 2021. The decrease was primarily driven by decreased headcount and cost savings initiatives implemented in 2022.

#### Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine	Nine Months Ended September 30,			
	202	2	2021		
Salaries, benefits and related costs	\$	5,435 \$	3,842		
Legal, consulting and other professional expenses		5,484	7,703		
Stock-based compensation expense		5,780	5,036		
Advertising and marketing expense		64	1,044		
Other		989	1,052		
	\$	17,752 \$	18,677		

Selling, general and administrative expenses decreased \$0.9 million for the nine months ended September 30, 2022 compared to the same period in 2021. The decrease was primarily driven by a \$2.2 million decrease in legal, consulting and other professional expenses and a \$1.0 million decrease in advertising and marketing expenses. These decreases were driven by reduced recruiting, information technology services, legal and consulting expenses as a result of cost savings initiatives.

Salaries, benefits and related costs and stock-based compensation expense increased \$1.6 million and \$0.7 million, respectively, as a result of severance expense and modifications of separated employee's stock options recognized in the nine months ended September 30, 2022. Such increases were partially offset by overall decreased headcount in the current period.

We expect selling, general and administrative expenses to continue to decrease as compared to historical periods prior to the reduction in headcount and other cost savings initiatives implemented in the first quarter of 2022.

#### Amortization Expense

The following table summarizes our amortization expense for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months End	ded September 30,	
	2022	2021	
Amortization of intangible assets	\$ 38	\$	1,281

Avalo's acquired assembled workforce and acquired product marketing rights were fully amortized in the first quarter of 2022 and fourth quarter of 2021, respectively, thus driving the \$1.2 million decrease as compared to the prior period. We expect amortization expense to decrease as compared to historical periods given the intangible assets are fully amortized.

#### Other Expense, Net

The following table summarizes our other expense, net for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Er	ided September 30,
	2022	2021
Other expense, net	(20)	(20)
Interest expense, net	(3,221)	(1,207)
	\$ (3,241)	\$ (1,227)

Other expense, net was comprised of interest expense related to the venture loan and security agreement for the nine months ended September 30, 2022 and 2021. Avalo entered into the loan agreement in June 2021 and therefore only recognized a partial period of interest expense in the prior period, which drove the increase for the nine months ended September 30, 2022.

In June 2022, the Company made a partial prepayment of \$15.0 million under the venture loan and security agreement, of which \$14.8 million was applied to principal. Therefore, we expect interest expense to decrease as compared to prior periods.

Income Tax Expense (Benefit)

The following table summarizes our income tax expense for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,			
		2022		2021
Income tax expense (benefit)	\$	20	\$	(180)

The Company recognized minimal income tax expense for the nine months ended September 30, 2022 compared to an income tax benefit of \$0.2 million for the nine months ended September 30, 2021. The income tax benefit in the prior period was a result of the updated estimate of interest receivable and abatement of penalties on the refund claim, as the final refund payment was received from the Internal Revenue Service in the second quarter of 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 September 30, 2022, Avalo had \$16.9 million in cash and cash equivalents. For the nine months ended September 30, 2022, Avalo generated a net loss of \$31.8 million and negative cash flows from operations of \$22.8 million. As of September 30, 2022, Avalo had an accumulated deficit of \$294.0 million.

In the second quarter of 2022, as collectively agreed upon with the Lenders (as defined below), the Company made a partial prepayment of \$15.0 million (\$14.8 million of which was applied to principal) on notes (the "Notes") issued under its venture loan and security agreement (the "Lenders") with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments XXV, LP ("Powerscourt", and together with Horizon, the "Lenders"). Avalo intends to consider additional prepayments prior to principal loan amounts coming due, if collectively agreed upon with the Lenders. As of September 30, 2022, the carrying value of the Notes (as defined in Note 9) was \$19.1 million.

The accompanying unaudited 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 within one year after the date the unaudited condensed consolidated financial statements included herein were issued. We anticipate that the cash and cash equivalents as of September 30, 2022 will not be sufficient for us to fund our product candidates through their next anticipated milestones, which include topline data from the AVTX-002 Phase 2 PEAK trial and pivotal data from the AVTX-803 LADDER trial, both expected in the first half of 2023. We will need to raise additional capital to reach these milestones. 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 nondilutive financings, (ii) out-licensing or strategic alliances/collaborations of its current pipeline assets, (iii) out-licensing or sale of its non-core assets, and (iv) federal and/or private grants. 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, the Loan Agreement prohibits the Company from incurring certain additional indebtedness, making certain asset dispositions, and entering into certain mergers, acquisitions or other business combination transactions without the prior consent of the Lenders. Additionally, the Loan 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 outstanding 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 of the condensed unaudited 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 nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,		
	 2022		2021
Net cash (used in) provided by:			
Operating activities	\$ (22,811)	\$	(53,793)
Investing activities	(95)		(102)
Financing activities	(14,781)		106,686
Net (decrease) increase in cash and cash equivalents	\$ (37,687)	\$	52,791

#### Net cash used in operating activities

Net cash used in operating activities was \$22.8 million for the nine months ended September 30, 2022, and consisted primarily of a net loss of \$31.8 million and non-cash adjustments to reconcile net loss to net cash used in operating activities including stock-based compensation of \$6.7 million and the full \$1.0 million reserve on the Aytu receivable due December 2024. Additionally, changes in net assets increased by \$0.1 million.

Net cash used in operating activities was \$53.8 million for the nine months ended September 30, 2021, consisting of a net loss of \$65.2 million. The decrease was partially offset by non-cash stockbased compensation of \$6.3 million. Additionally, changes in net liabilities increased \$3.5 million, mainly driven by a \$2.6 million increase in accrued expenses. In April 2021, the Company paid the \$10.0 million upfront license fee related to the expanded indication license agreement for AVTX-002 with KKC.

#### Net cash used in investing activities

Net cash used in investing activities, which primarily consisted of purchases of property and equipment, was minimal for the nine months ended September 30, 2022 and September 30, 2021.

## Net cash used in financing activities

Net cash used in financing activities for the nine months ended September 30, 2022 consisted of the principal portion of the \$15.0 million partial prepayment the Company made in the second quarter of 2022 under its the Loan Agreement.

Net cash provided by financing activities was \$106.7 million for the nine months ended September 30, 2021 and consisted primarily of net proceeds of \$104.9 million from equity and debt financings. Specifically, the Company received net proceeds of

\$37.7 million from an underwritten public offering closed in January 2021, net proceeds of \$32.9 million as part of the Loan Agreement entered into in the second quarter of 2021, and net proceeds of \$29.0 million from an underwritten public offering that closed in September 2021.

## **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 nine months ended September 30, 2022.

#### **Off-Balance Sheet Arrangements**

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

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# 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 affect our business, financial condition, or future results of operations and the trading price of our common stock.

## Item 5. Other Information.

On November 4, 2022, the Company entered into a Purchase Agreement (the "Purchase Agreement") with ES Therapeutics, LLC ("ES"), pursuant to which the Company will (i) sell to ES all of the Company's (a) rights to any milestone payments, under the Asset Purchase Agreement, dated August 14, 2017, by and between the Company and Janssen Pharmaceuticals, Inc. (relating to AVTX-501), and (b) any future milestone and royalty payments under the License Agreement, dated July 29, 2022, by and between Apollo AP43 Limited and the Company (relating to AVTX-007), and (ii) waive all rights, including all payments due to the Company from ES, under the Assignment of License Agreement, dated August 8, 2019 (relating to AVTX-611), by and among the Company, ES and Armistice Capital Master Fund Ltd ("Armistice"). ES is required to pay the Company \$5.0 million for all such rights and the waiver upon closing of the transaction. The sale is expected to close in November 2022.

The Purchase Agreement contains customary representations and warranties and covenants of the Company and ES, including indemnification of ES by the Company up to the amount of the purchase price.

ES is an affiliate of Armistice. Armistice is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on the Company's board of directors until August 8, 2022. The Company's board of directors approved the transaction in accordance with its related party transaction policy.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, a copy of which is filed as Exhibit 10.3 to this Quarterly Report.



# Item 6. Exhibits. Exhibit **Description of Exhibit** Number 10.1\*+License Agreement, dated July 29, 2022, by and between Apollo AP43 Limited and Avalo Therapeutics, Inc. 10.2 Waiver, dated August 11, 2022 (incorporated by reference to Exhibit 10.1to the Form 8-K filed on August 11, 2022). 10.3\*+Purchase Agreement, dated November 4, 2022, by and between ES Therapeutics, LLC and Avalo Therapeutics, Inc. 31.1+ Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 31.2 +32.1+† Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets (Unaudited) as of September 30, 2022 and December 31, 2021; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2022 and 2021; (iv) Condensed Consolidated Statements of Changes in Stockholders' (Deficit) Equity (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021; and (v) Notes to Unavdited Financial Changes in Stockholders' (Deficit) Equity (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021; and (v) Notes to 101 Unaudited Financial Statements. 104 Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

\* Certain confidential portions and/or the schedules and attachments to this exhibit have been omitted from this filing pursuant to Item 601(a)(5) or 601(b)(10), as applicable, of Regulation S-K. The Company will furnish copies of the unredacted exhibit to the SEC upon request.

#### + Filed herewith.

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

## SIGNATURES

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

# Avalo Therapeutics, Inc.

/s/ Christopher Sullivan
Christopher Sullivan

Chief Financial Officer

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

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Date: November 7, 2022

### CERTAIN INFORMATION IDENTIFIED WITH THE MARK "(\*\*\*)" HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE SUCH INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

## LICENSE AGREEMENT

This License Agreement (this "*Agreement*"), dated the 29th day of July, 2022 (the "*Effective Date*"), is by and between Apollo AP43 Limited, a company incorporated under the laws of England and Wales ("*Licensee*"), and Avalo Therapeutics, Inc., a Delaware corporation ("*Avalo*"). Avalo and Licensee may each be referred to herein individually as a "*Party*" and collectively as the "*Parties*."

### **INTRODUCTION**

WHEREAS, Avalo owns or otherwise controls certain intellectual property relating to AVTX-007, a fully human anti-IL-18 monoclonal

antibody;

WHEREAS, Licensee is a pharmaceutical company with a focus on developing and commercializing products for the treatment of various diseases; and

WHEREAS, Licensee is interested in developing and commercializing products that contain AVTX-007 on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

## **ARTICLE 1**

## **DEFINITIONS**

1.1. <u>Definitions</u>. When used in this Agreement, each of the following terms shall have the following meanings:

1.1.1. "Accounting Standards" means with respect to a Party, as applicable, (a) United States generally accepted accounting principles ("GAAP") or (b) International Financial Reporting Standards, in each case consistently applied.

1.1.2. "*Affiliate*" means, with respect to any Person, any other Person which controls, is controlled by, or is under common control with such Person as of or after the Effective Date. A Person shall be regarded as in control of another entity if it owns or controls fifty percent (50%) or more of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority) or has the power to control the management and policies of the subject entity, whether through ownership, contract or otherwise.

1.1.3. "Annual Net Sales" means the combined Net Sales for all Products in the Territory within a Contract Year.

1.1.4. *"Applicable Law"* means, with respect to a country in the Territory, its laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, Manufacturing or Commercialization of Products, that may be in effect from time to time in such country.

1.1.5. "Assigned Product Agreements" means those agreements between Avalo or an Affiliate thereof and certain Third Parties set forth on <u>Schedule 1.1.5</u> attached hereto.

1.1.6. "Bankruptcy Code" means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.1.7. "*Biosimilar*" means, with respect to a reference brand biologic product and a particular jurisdiction, a biologic product: (a) that is highly similar to such reference brand biologic product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences from such reference brand biologic product in terms of safety, purity and potency; and (c) for which a Biosimilar Application is approved by the relevant Regulatory Authority of such jurisdiction.

1.1.8. *"Biosimilar Application"* means a Regulatory Approval Application for a product claimed to be biosimilar or interchangeable to any Product, or otherwise relying on the approval of such Product, in each case in accordance with Applicable Law in the jurisdiction in which the product is sought to be marketed and sold.

1.1.9. "**BLA**" means a Biologics License Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.

1.1.10. "Blocking Patent" means any Patent Rights owned or controlled by a Third Party (other than Licensed Patent Rights or MedImmune Patent Rights (as defined in the MedImmune License as of the Effective Date)) that are infringed or are reasonably likely to be infringed by the manufacture, use, offer for sale, sale or import of a Molecule that is a part of a Product in the Field in the Territory.

1.1.11. "Business Day" means a day on which banking institutions in New York, New York are open for business.

1.1.12. "Change of Control" means, with respect to a Party, (a) a merger, reorganization or consolidation of such Party with a Third Party which results in the stockholders or equity holders of such Party not owning at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation or (b) except in the case of a bona fide equity or debt financing, whether private or public, in which a Party issues (i) new shares of its capital stock, (ii) securities convertible into shares of capital stock of such Party or (iii) debt securities, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all, or substantially all, of such Party's assets or business (or that portion thereof to which the subject matter of this Agreement relates).

1.1.13. "CMC" means chemistry, manufacturing and controls.

1.1.14. "Combination Product" means a Product that is comprised of or contains a Molecule as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units.

1.1.15. "Commercialization" means any and all activities constituting using, marketing, promoting, distributing, offering for sale, selling and importing a Product in the Field in the Territory and shall include, but not be limited to, promotion, as well as activities required to fulfill ongoing post-approval regulatory obligations, including adverse event reporting and sales force training. When used as a verb, "Commercialize" means to engage in Commercialization.



1.1.16. "Commercially Reasonable Efforts" means a measure of effort consistent with Applicable Law and industry standards and practices followed by pharmaceutical companies in the United States of similar size and resources as Licensee and its Affiliates in total with respect to their pharmaceutical products of a similar value, stage, development, life cycle, and commercial potential, taking into consideration safety and efficacy, development costs, the anticipated prescription label and all other relevant factors, including, without limitation, the nature of the Product and the clinical setting in which it is expected to be used.

1.1.17. "Confidential Information" means, with respect to each Party, proprietary data or information that belongs in whole or in part to such Party, its Affiliates or (sub)licensees, including, without limitation, (a) all information designated as Confidential Information of such Party hereunder, in all cases that, if disclosed in writing, is marked with the words "Confidential," "Proprietary" or words of similar import, and if disclosed orally or visually, is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral or visual disclosure requesting that such information be treated as Confidential Information hereunder, (b) all information that a reasonable person would reasonably understand to be confidential or proprietary in nature, whether or not marked as such, and (c) all "Confidential Information" (as defined in the Confidentiality Agreement) of such Party. Notwithstanding the foregoing or any provision to the contrary in this Agreement, (i) the existence and terms of this Agreement shall be deemed to be the Confidential Information of both Parties, with each Party being deemed a Receiving Party with respect thereto; (ii) the Licensed Intellectual Property shall be deemed to be the Confidential Information disclosed to Avalo or its Related Parties pursuant to the MedImmune License or the Novated MedImmune License shall be deemed to be the Confidential Information disclosed to Avalo or its Related Parties with each Party being deemed a Receiving Party with respect thereto.

1.1.18. "Confidentiality Agreement" means that certain Mutual Non-Disclosure Agreement, dated June 9, 2022, between Avalo and Apollo Therapeutics Group Limited.

1.1.19. "Contract Quarters" means the successive three (3) month periods in each Contract Year ending on March 31, June 30, September 30 or December 31.

1.1.20. "Contract Year" means the twelve (12) month period beginning on January 1 and ending on December 31 of each calendar year, provided, however, that the first Contract Year shall be the period of time beginning on the Effective Date and ending on December 31 of that year. Each Contract Year, except the first Contract Year, shall be divided into four (4) Contract Quarters.

1.1.21. "Control" or "Controlled" means with respect to any (a) material, item of information, method, data or other Know-How or (b) intellectual property right (including any Patent Right), the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party and, to the extent contemplated by this Agreement, its Affiliates, access or a license as provided herein under such item or right without violating any Third Party's contractual rights thereto or the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.

1.1.22. "Cover" (in all its verb and adjectival forms, such as "Covered," "Covering" and "Covers") means that the use, offer for sale, sale, importation or manufacture of the subject matter in question by an unlicensed entity would infringe a Valid Claim.

1.1.23. "Data Room" means that certain virtual data room provided via the Firmex Corp platform to which Licensee was initially granted access on June 9, 2022, as such data room may have been updated prior to the Effective Date.

1.1.24. "Development" means all pre-clinical, clinical, CMC and regulatory activities with respect to a Product in the Field in a given country in the Territory from the Effective Date until Regulatory Approval of such Product in such country is obtained for the indication under study. When used as a verb, "Develop" means to engage in Development.

1.1.25. "*Executive Officers*" means the Chief Executive Officer or President of Licensee (or an executive officer of Licensee designated by such person(s)) and the Chief Executive Officer or President of Avalo (or an executive officer of Avalo designated by such officer).

1.1.26. "*Existing Regulatory Documentation*" means the Regulatory Documentation Controlled by Avalo or any of its Affiliates as of the Effective Date.

1.1.27. "FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time (21 U.S.C. Section 301 et seq.), together with any rules and regulations promulgated thereunder.

1.1.28. "*FDA*" means the United States Food and Drug Administration, or a successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration.

1.1.29. "Field" means all indications and uses.

1.1.30. "First Commercial Sale" means, with respect to a given Product in a country in the Territory, the first commercial sale in an arms-length transaction of such Product to a Third Party by or on behalf of Licensee, its Affiliate or a Sublicensee in such country following receipt of the applicable Regulatory Approval of such Product to Commercialize such Product in such country.

1.1.31. "Hatch-Waxman Act" means the U.S. Drug Price Competition and Patent Term Restoration Act, as amended from time to time.

1.1.32. "*IND*" means an Investigational New Drug Application, as defined in the FD&C Act, or similar application or submission inside or outside the United States that is required to be filed with any Regulatory Authority before beginning clinical testing of a Molecule or a Product in human subjects.

1.1.33. "*Indirect Taxes*" means value added, sales, consumption, goods and services taxes or other similar taxes required by Applicable Law to be disclosed as a separate item on the relevant invoice.

1.1.34. "*Initiation*" means the administration of the first dose of a Product to a human being in a human clinical trial for which Licensee or one of its Related Parties is the sponsor or which is otherwise conducted by or on behalf of Licensee or one of its Related Parties.

1.1.35. "*Know-How*" means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, trade secret, material, drawings, illustrations or other artwork, technology or other know-how, whether or not patentable or copyrightable.

## 1.1.36. "Licensed Intellectual Property" means Licensed Know-How and Licensed Patent Rights.

1.1.37. "Licensed Know-How" means all Know-How that (a) is Controlled by Avalo or any of its Affiliates as of the Effective Date (other than MedImmune Know-How), or comes under the Control of Avalo or any Affiliate thereof following the Effective Date as a result of Avalo's development, manufacture, or commercialization of a Molecule or any Product at any time during the Term, (b) is not generally known, and (c) is necessary or reasonably useful to Develop, Manufacture, Commercialize or otherwise exploit any Molecule or any Product in the Field, including Avalo's interest in the Joint Know-How; provided that Licensed Know-How shall not include any Know-How to the extent relating to any active pharmaceutical ingredient other than any Molecule (or the use or manufacture of any such active pharmaceutical ingredient) and not relating to a Molecule (or its use or manufacture). Licensed Know-How includes all Know-How (other than MedImmune Know-How) included under the portions of the Data Room identified in <u>Schedule 1.1.37</u>.

1.1.38. "Licensed Patent Rights" means all Patent Rights that (a) are Controlled by Avalo or any of its Affiliates as of the Effective Date (other than the MedImmune Patent Rights), or come under the Control of Avalo or any Affiliate thereof following the Effective Date as a result of Avalo's development, manufacture, or commercialization of a Molecule or any Product, and (b) Cover or are necessary for (or, with respect to patent applications, would, if such patent applications were to issue as patents, Cover or be necessary for) the Development, Manufacture, Commercialization or other exploitation of any Molecule or any Product in the Field, including Avalo's interest in the Joint Patent Rights; provided that Licensed Patent Rights shall not include any Patent Rights to the extent Covering any active pharmaceutical ingredient other than any Molecule (or containing any pending claims in any patent application that cover or claim any such active pharmaceutical ingredient or its use or manufacture). Licensed Patent Rights include, as of the Effective Date, all Patent Rights set forth on <u>Schedule 1.1.38</u>.

1.1.39. "*Manufacturing*" means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of a Molecule or Products, including process and formulation development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, "*Manufacture*" means to engage in Manufacturing.

1.1.40. "MedImmune Know-How" means the Know-How Controlled by Avalo pursuant to the MedImmune License immediately prior to the novation thereof contemplated by Section 2.3.

1.1.41. *"MedImmune License*" means that certain License Agreement, dated August 6, 2019, between Avalo and MedImmune Limited (*"MedImmune"*), as amended, as it exists immediately prior to the novation thereof contemplated by Section 2.3.

1.1.42. "*MedImmune Patent Rights*" means the Patent Rights Controlled by Avalo pursuant to the MedImmune License immediately prior to the novation thereof contemplated by Section 2.3 (which shall include the "MedImmune Patent Rights" as defined in the MedImmune License).

1.1.43. "*MedImmune Valid Claim*" means any claim in an issued and unexpired patent within the MedImmune Patent Rights which has not been disclaimed, abandoned, revoked, or held unenforceable, unpatentable or invalid by a governmental agency or competent court.

1.1.44. "*Molecule*" means (a) the fully human anti-IL-18 monoclonal antibody known at Avalo as AVTX-007 (as further described on Exhibit A attached hereto) (the "*Original Molecule*") or (b) any derivative thereof that is Covered by a Valid Claim of any of the Licensed Patent Rights or a MedImmune Valid Claim.

1.1.45. "NDA" means a New Drug Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.

1.1.46. "*Net Sales*" means, with respect to a Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates, or Sublicensees (including distributors of authorized generic versions of the Product(s)) to Third Parties for the sale of such Product (the "*Invoiced Sales*"), less deductions for:

(a) normal and customary trade, quantity and prompt settlement discounts (including chargebacks and allowances) actually allowed;

(b) amounts repaid or credited by reason of rejection, return or recall of goods, rebates or bona fide price reductions;

(c) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced;

(d) customs and excise duties and other taxes or duties related to the sales to the extent that such items are included in the gross amount invoiced;

(e) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Product;

(g) any actual bad debt expense recorded in accordance with the Accounting Standards from customers related to sales of a Product, such bad debt not to exceed four percent (4%) of the total Invoiced Sales less the deductions set forth above in clauses (a) to (f) above. If any bad debt is subsequently recovered, it shall be included as Net Sales.

Any of the deductions listed above that involves a payment by Licensee, its Affiliates or Sublicensees shall be taken as a deduction in the Contract Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions of such Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee's, its Affiliates', or Sublicensees' transfer of any Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Product is consumed or administered by such Affiliate or Sublicensees in the course of its commercial activities. With respect to any Product that is consumed or administered by Licensee, its Affiliates, or Sublicensees, Net Sales shall include any amount billed or invoiced with respect to such consumption or administration, including any services provided in connection therewith.

In the event that a Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Product that contains the same Molecule as such Combination Product as its sole active ingredient(s), if sold separately in such country and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Molecule(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country; provided that the invoice price in a country for each Product that contains only such Molecule(s) and each product that contains solely active ingredient(s) other than the Molecule(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency. If either such Product that contains such Molecule(s) as its sole active ingredient(s) or a product that contains an active ingredient (other than a Molecule) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors reasonably relevant to the relative value of, the Molecule(s), on the one hand and all of the other active ingredient(s), collectively, on the other hand. In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Licensee's, its Affiliates', or Sublicensees' existing allocation method; <u>provided</u> that any such allocation to a Product shall be (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no greater than a pro rata allocation, such that the portion of each of foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from Invoiced Sales hereunder in any amount greater than the proportion of the number of units of such Product sold by Licensee, its Affiliates, or Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by Licensee, such Affiliates and such Sublicensees to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted. Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates, or Sublicensees, which must be in accordance with the Accounting Standards.

1.1.47. "Novated MedImmune License" means the MedImmune License, as novated to Licensee as contemplated by Section 2.3, as such agreement may be amended from time to time in accordance with the terms thereof and this Agreement following such novation to Licensee.

1.1.48. "*Patent Rights*" means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, revivals or revalidations, supplementary protection certificates and patents of addition) and patent applications (including all provisional applications, continuations-in-part and divisions).

1.1.49. "*Person*" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.1.50. "Phase 2/3 Clinical Trial" means a human clinical trial of a Product that is designed to evaluate both dosing requirements and the effectiveness of the Product for a particular indication in patients with the disease or condition under study and is consistent with

the requirements of 21 C.F.R. §312.21(b) (as hereafter modified or amended) and 21 C.F.R. §312.21(c) (as hereafter modified or amended).

1.1.51. "*Phase 3 Clinical Trial*" means (a) a controlled study in humans of the efficacy and safety of a Product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file for Regulatory Approval for human therapeutic, ameliorative, or prophylactic use, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(c), as amended from time to time, or (b) any analogous clinical trial described or defined in Applicable Laws and guidelines for a clinical trial conducted in another country in the Territory.

1.1.52. "PHS Act" means the Public Health Services Act (Title 42, U.S.C., Chapter 6A). As used herein the PHS Act will refer, more specifically, to 42 USC § 262, which governs the regulation of biological products.

1.1.53. "*Product*" means a product containing a Molecule, alone or in combination with one or more other active pharmaceutical ingredients.

1.1.54. "*Product Trademarks*" means the Trademarks or indicia of origin used in connection with the distribution, marketing, promotion or Commercialization of any Product in a country in the Territory. For purposes of clarity, the term Product Trademark(s) shall not include the corporate names and logos of either Party, their Affiliates, or Sublicensee(s).

1.1.55. "*Registrational Study*" means (a) a Phase 3 Clinical Trial or (b) any other human clinical trial of a Product that is intended to support the submission of an NDA or BLA (or any corresponding foreign application in the Territory to seek Regulatory Approval of a Product in any country or multinational jurisdiction) without conduct of any subsequent human clinical trial.

1.1.56. "*Regulatory Approval*" means the approval of the applicable Regulatory Authority necessary for the testing, commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Product in a country in the Territory, including, where required, separate pricing or reimbursement approvals.

1.1.57. "*Regulatory Approval Application*" means an application submitted to the appropriate Regulatory Authority seeking Regulatory Approval of a Product in a country in the Territory, including, without limitation, NDAs and BLAs.

1.1.58. "*Regulatory Authority*" means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity involved in granting of Regulatory Approval for a Product in a jurisdiction within the Territory, including, without limitation, the FDA.

1.1.59. "*Regulatory Documentation*" means all (a) applications (including Regulatory Approval Applications) and any amendments, updates and supplements with respect thereto, registrations, licenses, authorizations and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), in each case (a) and (b) directly relating to a Molecule or a Product.

1.1.60. "*Regulatory Exclusivity*" means, with respect to a Product, that Third Parties are prevented from legally developing, manufacturing or commercializing a product that could compete with such Product in a country, either through data exclusivity rights, orphan drug

designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights.

1.1.61. "*Related Party*" means Licensee's Affiliates and any Sublicensees under this Agreement. For clarity, Avalo shall not be deemed to be a Related Party.

1.1.62. "*Royalty Term*" means, on a country-by-country and Product-by-Product basis, the period of time commencing on the date of the First Commercial Sale of a particular Product in a particular country and extending until the later of (X) the latest of (a) the date (\*\*\*) years from the date of the First Commercial Sale of the first Product in such country, (b) the first date on which there are no Valid Claims included in the Licensed Patent Rights that Cover such Product in such country, or (c) expiration of Regulatory Exclusivity with respect to such Product in such country or (Y) the expiration of the "Royalty Term" as defined in the MedImmune License (without taking into account any amendments to or termination of the Novated MedImmune License occurring following the Effective Date) for such country and Product.

- 1.1.63. "Territory" means worldwide.
- 1.1.64. "Third Party" means any Person other than a Party or any of its Affiliates.

1.1.65. "*Trademark*" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.1.66. "Valid Claim" means any claim in an issued and unexpired patent within the Licensed Patent Rights which has not been disclaimed, abandoned, revoked, or held unenforceable, unpatentable or invalid by a governmental agency or competent court.

1.2. Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Defined Term	Section Reference
"Action"	11.2.1
"Agreement"	Preamble
"Anti-Bribery Laws"	10.1.5
"Applicable Patheon Activities"	3.4.3
"Applicable Patheon Proposals"	3.4.3
"Assigned Patheon Agreement"	3.4.3
"Audited Party"	6.7.2
"Avalo"	Preamble
"Avalo Indemnitees"	10.5.1
"Avalo Material"	3.3
"Blocking Patent Claim"	7.5.3(a)
"BPCIA"	7.4.2
"Competing Product"	2.6.1

"Competitive Activities"	2.6.2
"Consulting Activities"	3.2
"Continued Existing Clinical Studies"	4.1.2
"Disclosing Party"	8.1
"Effective Date"	Preamble
"embodiments of intellectual property"	9.5
"Existing Clinical Studies"	4.1.2(b)
"Force Majeure"	11.6
"GAAP"	1.1.1
"Indemnitee"	10.5.3
"Infringement Claim"	7.5.1
"Infringement Defense Costs"	7.5.3(d)
"Invoiced Patheon Amount"	3.4.3
" <i>IP</i> "	9.5
"Joint Intellectual Property"	2.4
"Joint Know-How"	2.4
"Joint Patent Rights"	2.4
"Licensee"	Preamble
"Licensee Patheon Amount"	3.4.3
"Licensee Indemnitees"	10.5.2
"Losses"	10.5.1
"MedImmune"	1.1.41
"Milestone Event"	6.3
"Milestone Payment"	6.3
"Newly Generated Regulatory Documentation"	4.2.3
"Novation Agreement"	2.3
"Original Molecule"	1.1.44
"Parties"	Preamble
"Party"	Preamble
"Patent Challenge"	7.2.2
"Patheon"	3.4.3
"Receiving Party"	8.1
"Section 351(k) Applicant"	7.4.1
"Study Transfer Plan"	4.1.2(b)
"Sublicense"	2.2.1
"Sublicensee"	2.2.1
"Term"	9.1
"Third Party Claim"	10.5.1
"Total Patheon Amount"	3.4.3

"Transition Plan"	3.1.1
"Wind-Down Existing Clinical Studies"	4.1.2(a)

## **ARTICLE 2**

### LICENSES AND INTELLECTUAL PROPERTY OWNERSHIP

2.1. <u>License Grant</u>. Subject to the terms and conditions of this Agreement, Avalo hereby grants to Licensee:

2.1.1. an exclusive (even as to Avalo) worldwide license, with the right to sublicense as provided in Section 2.2, under the Licensed Intellectual Property to Develop, have Developed, Manufacture, have Manufactured, make, have made, use, sell, offer for sale, import, Commercialize and have Commercialized Molecules and Products in the Field in the Territory; and

2.1.2. an exclusive worldwide license and right of reference, with the right to sublicense and grant further rights of reference as provided in Section 2.2, under the Newly Generated Regulatory Documentation, to Develop, have Developed, Manufacture, have Manufactured, Commercialize and have Commercialized Molecules and Products in the Field in the Territory until such time as the respective Newly Generated Regulatory Documentation is actually assigned and delivered to Licensee or its Related Party in accordance with the terms of this Agreement.

### 2.2. Sublicenses.

2.2.1. **Right to Sublicense**. Licensee may sublicense the rights granted to it under Section 2.1 through multiple tiers to one or more of its Affiliates or Third Parties at any time (each such Affiliate or Third Party, or any subsequent grantee of such a sublicense from a Sublicensee, a "*Sublicensee*" and each such sublicense, a "*Sublicensee*"). Licensee shall remain responsible for the performance of its Sublicensees under this Agreement, including for all payments due hereunder, whether or not such payments are made by Licensee, its Affiliates or Sublicensees. Licensee shall notify Avalo of any sublicense within five (5) Business Days of the grant of the sublicense.

2.2.2. **Terms**. Each sublicense granted under this Agreement shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement including, in the case of agreements with any Third Party commercializing Sublicensee, the following provisions: (a) a requirement that such Sublicensee submit applicable sales or other reports consistent with those required hereunder; (b) an audit requirement similar to the requirement set forth in Section 6.7; and (c) a requirement that such Sublicensee comply with confidentiality and non-use provisions at least as stringent as those confidentiality and non-use obligations set forth in ARTICLE 8 with respect to both Parties' Confidential Information. Notwithstanding any sublicense, Licensee shall remain at all times fully liable for its obligations under this Agreement.

2.2.3. Effect of Termination on Sublicenses. If this Agreement terminates for any reason, then, on a Sublicensee-by-Sublicensee basis, if (a) a Sublicensee is not, at the time of such termination, in material breach of any of its obligations under the applicable Sublicense and (b) the acts or omissions of such Sublicensee did not cause or result in the termination of this Agreement, then, upon such Sublicensee's written election delivered to Avalo within fifteen (15)

Business Days after the effective date of such termination, Avalo and such Sublicensee shall promptly enter into a direct license with each other, effective as of the effective date of termination of this Agreement, on substantially the same terms as the applicable Sublicense to the extent such terms (i) relate to the intellectual property rights granted hereunder that are subject to such sublicense and (ii) do not impose obligations on Avalo in excess of those imposed on Avalo under this Agreement, provided that the financial terms of such direct license will be substantially the same terms as set forth in Sections 6.3, 6.4, 6.5, 6.6, 6.7, 7.3.3(b) and 7.5.3(d) of this Agreement.

2.3. <u>MedImmune License</u>. Prior to or simultaneously with the execution of this Agreement, the Parties and MedImmune Limited shall enter into that certain novation agreement in substantially the form attached hereto as <u>Schedule 2.3</u> (the "*Novation Agreement*") pursuant to which the MedImmune License will be replaced by the Novated MedImmune License. During the Term, Licensee shall comply with and maintain in full force and effect the Novated MedImmune License for the term thereof, and shall not amend or modify the Novated MedImmune License in any manner that does or would reasonably be anticipated to (a) reduce the duration or amount of any payments to Avalo hereunder or (b) otherwise adversely affect (as determined with respect to Avalo) Avalo's rights to any payments, or Licensee's payment obligations to Avalo, under this Agreement, in each case ((a) and (b)) without the prior written consent of Avalo. In any event, the Parties agree that Licensee's payment obligations to Avalo under this Agreement shall not be affected by any amendment or modification to the Novated MedImmune License and shall be deemed to remain effective in such manner as if such amendment or modification had not occurred. Licensee shall promptly provide Avalo copies of any correspondence to or from MedImmune, an Affiliate thereof, or any successor in interest thereto with respect to any actual or alleged breach of the Novated MedImmune License or termination thereof. Licensee shall not terminate this Agreement prior to any termination of the Novated MedImmune License nor terminate the Novated MedImmune License prior to any termination of this Agreement.

2.4. <u>Ownership of and Rights to Intellectual Property</u>. Subject to the license grants and other rights herein, as between the Parties, each Party shall solely own all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made solely by or on behalf of such Party (or its Affiliates) in the course of activities conducted pursuant to this Agreement, and any and all Patent Rights and other intellectual property rights with respect thereto. Subject to the license grants and other rights herein, as between the Parties, the Parties shall jointly own all right, title and interest in and to all Know-How conceived, discovered, developed or otherwise made jointly by or on behalf of Licensee (or its Affiliates) on the one hand, and by or on behalf of Avalo (or its Affiliates) on the other hand, in the course of activities conducted pursuant to this Agreement (the "Joint Know-How") and any and all Patent Rights with respect thereto (the "Joint Patent Rights") and other intellectual property rights with respect to (including claiming) the Joint Know-How (together with Joint Know-How and Joint Patent Rights, the "Joint Intellectual Property"). The determination of whether Know-How is conceived, discovered, developed or otherwise made by or on behalf of a Party or its Affiliates for the purpose of allocating proprietary rights (including patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with United States patent law, without regard to conflict of law, irrespective of where or when such conception, discovery, development or making occurs. Avalo shall promptly disclose to Licensee in writing, and shall cause its Affiliates to so disclose, all Know-How and Patent Rights conceived, discovered, developed or otherwise made solely by or on behalf of Avalo (or its Affiliates) in the course of activities conducted pursuant to this Agreement that relate to a Molecule or Product. Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their licensees and sublicensees to so disclose, all Joint Know-How and Joint Patent Rights. Subject to the licenses granted under Section 2.1 and, in the case of Avalo, Section 2.6, each Party shall have



the right to independently exploit the Joint Intellectual Property and the right to grant sublicensable, transferable licenses under Joint Intellectual Property to any Person, without a duty of seeking consent of or accounting to the other Party, and to the extent any such consent or accounting is required by any jurisdiction, such consent is hereby granted and the requirement of such accounting is hereby waived.

2.5. <u>No Other Rights</u>. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest or other right in any, Know-How or Patent Rights of the other Party, including items Controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.

## 2.6. <u>Exclusivity</u>.

2.6.1. During the Term, except for activities conducted pursuant to this Agreement in accordance with the terms hereof, neither Avalo nor its Affiliates shall (a) directly or indirectly develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the Territory or (b) license, authorize, appoint, or otherwise knowingly enable any Third Party to develop, manufacture, commercialize or otherwise exploit any Competing Product anywhere in the Territory; <u>provided</u> that this Section 2.6.1 will not prohibit Avalo or its Affiliates from developing, manufacturing, commercializing or otherwise exploiting any Competing Product after the (\*\*\*) anniversary of the first Regulatory Approval of a Product in the Territory <u>unless</u> Licensee (i) determines in writing prior to such (\*\*\*) anniversary and annually thereafter that the restriction set forth in this Section 2.6.1 remains permissible under Applicable Law and (ii) provides notice of such determination to Avalo at least thirty (30) days prior to each such anniversary. A "*Competing Product*" is any molecule, compound, product, or other therapeutic agent that is known to preferentially or selectively bind to, inhibit, activate, or modulate the activity or expression of IL-18.

2.6.2. Notwithstanding Section 2.6.1, neither Avalo nor any Affiliate thereof will be in breach of the restrictions set forth in Section 2.6.1 if Avalo is subject to a Change of Control and the Third Party that is party to such Change of Control (or any Affiliate thereof other than (i) Avalo or (ii) an Affiliate of Avalo existing prior to such Change of Control) (a) is performing at, or has performed within the twelve (12) months prior to, the closing of the Change of Control transaction, any activity that would be in breach of Section 2.6.1 if performed by or on behalf of Avalo or an Affiliate thereof (such prohibited activities, "*Competitive Activities*") or (b) commences any Competitive Activities after the closing of the Change of Control transaction; and such Third Party and its Affiliates may perform such Competitive Activities as long as (i) no Licensed Intellectual Property is used in connection with the performance of any Competitive Activities and (ii) Avalo (or the applicable Third Party, as applicable) institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating reasonably appropriate firewalls.

2.7. <u>License Grant to Avalo</u>. Licensee hereby grants Avalo a non-exclusive license under the Licensed Intellectual Property for the sole purpose of conducting any Development or other activities that are allocated to Avalo under this Agreement in accordance with the terms thereof. This Section 2.7 will terminate automatically upon the earlier of (a) Licensee's written notice to Avalo thereof or (b) Avalo ceasing to conduct any such activities.



## **ARTICLE 3**

#### **TECHNOLOGY TRANSFER**

### 3.1. Transition Activities.

3.1.1. **Transition Plan**. The Parties will complete, within thirty (30) days following the Effective Date (or such other time frame set forth in the Transition Plan), the activities set forth in the transition plan attached as <u>Schedule 3.1.1</u> ("*Transition Plan*") in accordance with the terms of the Transition Plan and this Agreement, to transfer to Licensee or its designee all Development and Manufacturing activities relating to the Molecules and Products then being undertaken by or on behalf of Avalo or its Affiliates

3.1.2. **Transition Activities**. Upon Licensee's request, without limiting Section 3.1.1, without additional consideration to Avalo (except as set forth in Section 3.2), and consistent with the Transition Plan:

(a) Within thirty (30) days after the Effective Date, Avalo shall transfer to Licensee (i) copies of all then-existing material data, reports, records, written materials, and other information within the Licensed Know-How and MedImmune Know-How, including all such Know-How constituting adverse event or other safety data resulting from any of Avalo's or its Affiliates' activities in connection with any Molecule or Product, that is known to or in the possession of Avalo or any Affiliate thereof and (ii) to the extent in the possession of Avalo or any Affiliate thereof or their respective patent counsel and not constituting freedom-to-operate or infringement analyses or related communications, the file wrappers and other documents and written materials relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and any Patent Rights that Avalo was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof to Licensee. Thereafter during the Term, from time to time, Avalo shall transfer to Licensee copies of (A) any additional materials relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and any patent rights that Avalo was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof to Licensee, in each case ((A) and (B)), of which Avalo becomes aware, that has not been previously transferred to Licensee, that does not constitute freedom-to-operate or infringement analyses or related communications, and is necessary or reasonably useful for Licensee to perform its obligations or exercise its rights under this Agreement;

(b) Avalo shall reasonably assist and cooperate with Licensee, as Licensee may reasonably request, in the transition to Licensee of the prosecution, maintenance, enforcement and defense of the Licensed Patent Rights and any patent rights that Licensee was responsible for prosecuting pursuant to the MedImmune License prior to the novation thereof as contemplated by Section 2.3; and

(c) Avalo shall duly execute and deliver or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary under or as Licensee may reasonably request in connection with or to carry out more effectively the purpose of, or to better assure and confirm unto Licensee its rights to exploit the Molecules and Products in accordance with, this Agreement.

3.2. <u>Post-Transition Consulting Activities</u>. Without limiting the foregoing Section 3.1.1 and Section 3.1.2, during the period beginning on the Effective Date and ending on the (\*\*\*) anniversary of the completion of activities under the Transition Plan, Avalo will, to the extent

such personnel are employed or engaged by Avalo or any Affiliate at the time of any applicable inquiry by Licensee, make its employees and consultants previously and materially involved in the Development or Manufacture of a Molecule or a Product reasonably available to respond to Licensee's reasonable inquiries regarding any Licensed Know-How or activities transferred under the Transition Plan or regarding any Avalo Materials ("*Consulting Activities*"). In the event that Avalo ceases to engage any such personnel during such period, Avalo will, upon Licensee's written request, use Commercially Reasonable Efforts, subject to any limitations imposed by any subsequent employment or engagement thereof by any Third Party, to facilitate Licensee's negotiation of a consulting arrangement between such individual and Licensee in order to facilitate such individual's continued provision of Consulting Activities, provided that Avalo shall not have any obligation to incur any material additional costs or expenses with respect to such obligation. Avalo will conduct the first (\*\*\*) person hours of Consulting Activities at its own expense, and Licensee will reimburse Avalo for all Consulting Activities conducted by Avalo's or its Affiliates' employees or consultants beyond the first (1<sup>st</sup>) (\*\*\*) person hours thereof at the applicable rate(s) set forth on <u>Schedule 3.2</u> based on the type of employee or consultant performing such activities. Licensee shall pay Avalo for any such Consulting Activities within thirty (30) days of receipt of an invoice therefor from Avalo.

3.3. <u>Transfer of Avalo Material</u>. Promptly upon Licensee's request given at any time within ninety (90) days of the Effective Date or at such time as otherwise set forth in the Transition Plan or Study Transfer Plan, Avalo or its designee shall deliver to Licensee or its designee quantities of the Molecule(s), Product(s), and other biological and chemical materials related thereto in each case Controlled by Avalo or any of its Affiliates, each in the forms and amounts described on <u>Schedule 3.3</u> (collectively, the "*Avalo Material*") at no charge to Licensee, provided that Avalo shall not have such obligation to the extent Licensee can cause delivery thereof to Licensee or its designee pursuant to the terms of an Assigned Product Agreement (or novated form thereof) to which Apollo or an Affiliate thereof is a party. Any such delivery by Avalo (or to be caused by Avalo) shall be EXW (Incoterms 2020) the location(s) indicated for the various Avalo Materials on <u>Schedule 3.3</u>, unless otherwise agreed to in writing by the Parties. Avalo shall maintain, shall ensure that its Affiliates maintain, and that its subcontractors maintain in accordance with the applicable subcontracts, the quality of all Avalo Materials until the earliest of (i) such time as responsibility for the shipment of such materials transfers to Licensee pursuant to the terms of this Section 3.3, (ii) the assignment or novation of any Assigned Product Agreement governing such Avalo Material to Licensee or an Affiliate thereof as contemplated by this Agreement, or (iii) the ninetieth (90<sup>th</sup>) day following the Effective Date.

### 3.4. Assignment of Product Agreements.

3.4.1. <u>General</u>. Avalo shall assign to Licensee, and Licensee shall and hereby does assume, the Assigned Product Agreements and all rights, obligations, and liabilities thereunder, pursuant to the terms set forth on <u>Schedule 3.4.1</u>, provided that, notwithstanding anything to the contrary, (i) the timing of such assignment and assumption of each Assigned Product Agreement shall, subject to clause (ii) below, be as specified on <u>Schedule 3.4.1</u> (and the Parties shall, in connection with each assignment, execute a reasonable and mutually acceptable confirmatory document establishing the date of such assignment for each Assigned Product Agreement), (ii) if an Assigned Product Agreement pertains to any product other than a Molecule or Product, such Assigned Product Agreement shall only be assigned and assumed hereunder with respect to Molecules and Products, as applicable, (iii) if the terms of an Assigned Product Agreement do not permit assignment thereof to Licensee (either in its entirety, if solely pertaining to Molecules and Products, or in part, if pertaining to any product other than a Molecule or Product), the Parties shall seek to obtain such permission in a manner consistent with the desired timing for such assignment and assumption set forth in <u>Schedule 3.4.1</u> and (x) if such permission is obtained, such assignment and assumption shall be effected in a manner consistent with this

Section 3.4 and such permission and (y) if such permission is not obtained and the following is elected by Licensee by written notice to Avalo, the Parties shall negotiate in good faith and enter into a written arrangement pursuant to which Avalo shall otherwise transfer to Licensee, to the extent permitted by such agreement, or otherwise enable Licensee to obtain the benefit of such agreement for the purpose of Developing or Manufacturing Molecules and Products and Licensee shall assume (or perform on Avalo's behalf and indemnify Avalo with respect to) all future obligations, payments, and liabilities thereunder (which shall in any event include all payment obligations thereunder incurred after July 31, 2022).

3.4.2. Previously Undisclosed Agreements. In addition, if Avalo becomes aware of any agreement between Avalo (or an Affiliate thereof) and a Third Party that (i) was executed prior to the Effective Date, (ii) directly relates to the Development or Manufacture of a Molecule or Product, and (iii) was not included in the Data Room prior to the Effective Date, Avalo shall promptly provide written notice thereof (and a copy thereof) to Licensee and, if elected by Licensee by notice to Avalo within thirty (30) days of such notice from Avalo, promptly assign to Licensee such agreement, provided that, (i) if any such agreement pertains to any product other than a Molecule or Product and assignment in part thereof is permitted by its terms, then Avalo shall assign such agreement to Licensee solely to the extent it pertains to a Molecule or Product and (ii) if any such agreement does not permit assignment to Licensee as contemplated hereby, (1) Avalo shall promptly seek to obtain permission to assign such agreement as contemplated hereby from such Third Party (and, upon obtaining such permission, so assign such agreement to Licensee) and (2) in the event such permission is not obtained and the following is elected by Licensee by written notice to Avalo, the Parties shall negotiate in good faith and enter into a written arrangement pursuant to which Avalo shall otherwise transfer to Licensee, to the extent permitted by such agreement, or otherwise enable Licensee to obtain the benefit of such agreement for the purpose of Developing or Manufacturing Molecules and Products and Licensee shall assume (or perform on Avalo's behalf and indemnify Avalo with respect to) all future obligations, payments, and liabilities thereunder.

3.4.3. <u>Patheon Agreement</u>. Avalo hereby represents and warrants to Licensee that, as of the Effective Date and with respect to that certain Master Umbrella Development Services Agreement, between Patheon-Biologics LLC ("Patheon") and Avalo, effective November 12, 2020, as amended and those certain Project Proposals executed thereunder included in the Assigned Product Agreements (the "Assigned Patheon Agreement") and all activities through Drug Substance (as referred to in the Applicable Patheon Proposals (as defined below)) manufacturing under the Applicable Patheon Proposals, excluding Drug Product (as referred to in the Applicable Patheon Proposals) manufacturing (the "Applicable Patheon Activities"), (i) Avalo has received invoices from Patheon totaling \$(\*\*\*) through the latest accounts payable update that occurred on approximately July 20, 2022 (such amount the "Invoiced Patheon Amount") and (ii) the total amount known to Avalo that was, is, or will become due with respect to Applicable Patheon Activities (including corresponding change orders with respect thereto) under the Assigned Patheon Agreement, including the above-referenced \$(\*\*\*), is, as of such update, reasonably estimated by Avalo to be \$(\*\*\*) (the "**Total Patheon Amount**"). To the extent Avalo has not paid any portion of the Invoiced Patheon Amount as of the Effective Date, Avalo shall, notwithstanding anything to the contrary in this Agreement, remain and be responsible for paying Patheon that amount, and Licensee shall be responsible for paying (and shall, upon assignment of the Assigned Patheon Agreement to Licensee and, consistent with and without limitation of the terms of <u>Schedule 3.4.1</u>, assume the obligation to pay) any portion of the Total Patheon Amount in excess of the Invoiced Patheon Amount (such excess, the "Licensee Patheon Amount"), provided that if invoices for any portion of the Licensee Patheon Amount are received and paid by Avalo prior to the assignment of the Assigned Patheon Agreement to Licensee, then Licensee shall reimburse Avalo in the amount of any such payment within thirty (30) days of receipt of an invoice therefor from Avalo. For the sake of clarity, the

Assigned Patheon Agreement also contains additional potential services for which Licensee will be responsible upon assignment to Licensee of the Assigned Patheon Agreement, pursuant to <u>Schedule 3.4.1</u>. For purposes of this Section 3.4.3, "**Applicable Patheon Proposals**" means the following included in the Assigned Patheon Agreement: Project Proposal Number OS-02176-R3 (dated March 11, 2021 and also known as Project Proposal OS-01276-P-FEP-260191-R1), Change of Scope COS-08-02 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated July 16, 2021), Change of Scope COS-02-01 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated July 27, 2021), Change of Scope COS-03-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated Juny 27, 2021), Change of Scope COS-04-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated January 11, 2022), Change of Scope COS-05-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated Juny 11, 2022), Change of Scope COS-05-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated Juny 11, 2022), Change of Scope COS-05-R1 to Project Proposal No. OS-01276-B-GROBL-122395-R5-WS2 (dated June 6, 2022), Change of Scope COS-06-R1 to Proposal No. OS-02176-GROBL-122395-R5-WS2 (June 28, 2022), and Change of Scope COS-08-R1 to Proposal No. OS01276-B-GROBL-122395-R5-WS2 (dated Juny 8, 2022).

3.5. <u>Assignment of Regulatory Documentation</u>. Within five (5) Business Days of the Effective Date or such later date as may be (i) consistent with the Transition Plan, Study Transfer Plan, or <u>Schedule 3.4.1</u> or (ii) otherwise necessary to enable Avalo and its Affiliates to perform their obligations with respect to the Existing Clinical Studies without violating Applicable Law or the terms of any applicable agreement with any Third Party, Avalo shall and hereby does assign to Licensee all of its right, title and interest in and to all Regulatory Documentation (including all INDs) owned by Avalo and its Affiliates relating to each Molecule or Product, and Avalo shall deliver such Regulatory Documentation to Licensee in the format reasonably requested by Licensee within thirty (30) days after Licensee's request therefor. The Parties shall execute and file such documentation (including transfer letters) with the applicable Regulatory Authorities as shall be required to effect such transfer and coordinate such execution and filing as appropriate.

3.6. <u>Disclaimers</u>. EXCEPT FOR THE IMPLIED WARRANTY OF TITLE OR AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, AVALO PROVIDES THE AVALO MATERIAL "AS-IS", AND AVALO DISCLAIMS ANY AND ALL IMPLIED WARRANTIES (OTHER THAN THE IMPLIED WARRANTY OF TITLE) CONCERNING THE AVALO MATERIAL, INCLUDING WARRANTIES CONCERNING THE QUALITY, CONDITION, EFFICACY, SAFETY OR UTILITY OF THE AVALO MATERIAL, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. FOR THE AVOIDANCE OF DOUBT, EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, AVALO HAS NO LIABILITY FOR ANY CLAIMS, LOSSES OR CASUALTY ARISING FROM LICENSEE'S USE OF ANY AVALO MATERIAL.

## **ARTICLE 4**

#### DEVELOPMENT, MANUFACTURE AND RELATED DILIGENCE

### 4.1. Development.

4.1.1. **Responsibility; General Obligation**. Except as set forth in Section 4.1.2, Licensee is solely responsible for all Development and regulatory activities, and the expenses related thereto, with respect to the Development of the Molecule(s) and the Product(s) in the Field in the Territory.

## 4.1.2. Existing Clinical Studies.

(a) Avalo shall, as soon as reasonably practicable following the Effective Date, (i) wind-down all remaining activities with respect to those certain clinical studies set forth on <u>Schedule 4.1.2(a)</u> (the "**Wind-Down Existing Clinical Studies**") and (ii) conduct any post-completion obligations with respect thereto as required by Applicable Law, in accordance with the timelines set forth on such schedule.

(b) Avalo shall conduct those certain clinical studies set forth on <u>Schedule 4.1.2(b)</u> (the "**Continued Existing Clinical Studies**"; collectively, with the Wind-Down Existing Clinical Studies, the "**Existing Clinical Studies**") in accordance with the protocols therefor and Applicable Law, at Licensee's expense, until such time as responsibility for performing such studies, has been transferred to Licensee pursuant to the plan therefor set forth on <u>Schedule 4.1.2(b)</u> (the "**Study Transfer Plan**"), <u>provided</u> that, notwithstanding anything to the contrary, (i) Avalo shall not amend, modify or deviate from any existing protocol with respect to the Continued Existing Clinical Studies, as such protocol exists as of the Effective Date, or suspend or terminate the Continued Existing Clinical Studies, in each case without Licensee's prior written consent (not to be unreasonably withheld or delayed) except solely to the extent required by any Regulatory Authority, Applicable Law, or investigational review board or similar body and (ii) Avalo shall not be obligated under this Agreement to enroll any additional patients or subjects in the Continued Existing Clinical Studies. The Parties shall perform and complete the Study Transfer Plan (including but not limited to assignment to Licensee of any applicable Regulatory Documentation owned or controlled by Avalo or any Affiliate thereof or, to the extent permitted by the terms thereof or consent to assignment is obtained, agreements between Avalo and any Third Parties solely relating to the Continued Existing Clinical Studies, each as set forth in the Study Transfer Plan) in accordance with the timelines set forth threein. Licensee shall reimburse Avalo for all internal and external costs incurred by Avalo or any Affiliate thereof following the Effective Date with respect to the performance of its obligations under this Section 4.1.2(b) within thirty (30) days of the receipt of any invoice with respect thereto. For clarity, neither Licensee nor its Affiliates will be res

(c) At any time during which Avalo or its Affiliate or a subcontractor of either of the foregoing is conducting the Continued Existing Clinical Studies, (i) Avalo shall promptly provide Licensee with all information relating to the Continued Existing Clinical Studies coming under the Control of Avalo or an Affiliate thereof that is reasonably requested by Licensee and (ii) Avalo shall promptly (and in any event, within two (2) days) notify Licensee of any adverse safety event or other material issue relating to the Continued Existing Clinical Studies of which Avalo becomes aware.

(d) Upon reasonable notification by Licensee and at Licensee's cost and expense, Licensee may conduct an audit of Avalo and its Affiliates and, to the extent permitted by the applicable subcontracts or clinical site agreements, subcontractors and all clinical trial sites engaged by Avalo or its Affiliates or subcontractors, in each case, to determine whether the Existing Clinical Studies were or are, during any period following the Effective Date during which Avalo is responsible for performing such studies, being conducted in compliance with the terms of this Agreement and Applicable Law. Such audit will be conducted no more than once per each six (6)-month period, except with respect to any "for cause" audit, which may be conducted any number of times, provided that, with respect to any such audit of any subcontractor or clinical site, the frequency thereof hereunder shall not exceed such frequency permitted by the applicable subcontracts or clinical site agreements. After preparing or receiving an audit report, Licensee will provide Avalo with a written summary of its findings of any



material deficiencies or other areas of remediation that Licensee identifies during any such audit. Avalo will use best efforts remediate any undisputed deficiencies no later than thirty (30) days after receipt of such report, at Apollo's cost and expense.

(e) With respect to any inspection of Avalo or its Affiliates or subcontractors by a governmental authority relating to the Existing Clinical Studies, Avalo will notify Licensee of such inspection (i) no later than two (2) days after Avalo receives notice of such inspection (or in any event with as much advance notice as is possible prior to such inspection if Avalo receives notice thereof less than two (2) days in advance of the applicable inspection) or (ii) within two (2) days after the completion of any inspection of which Avalo did not receive prior notice. Avalo will promptly provide Licensee with all available information known to Avalo related to any such inspection. Avalo will, will ensure that its Affiliates, and will ensure that its subcontractors will (in accordance with the terms of the applicable subcontract), permit and cooperate with all governmental authority inspections and inquiries relating to the Existing Clinical Studies. Licensee or its designee will, subject to the applicable terms of any subcontract or site agreement, have the right, but not the obligation, to be present at and participate in any such inspection. Following any such inspection, Avalo will provide Licensee with an unredacted copy of any findings, notice, or report provided by any governmental authority related to such inspection (to the extent relating to the Existing Clinical Studies) within two (2) days of receiving the same.

## 4.2. Specific Development Responsibilities.

4.2.1. **Manufacturing**. Except to the extent any applicable Molecule or Product is provided under Section 3.3, and subject to the completion of the applicable transition activities set forth in this Agreement, Licensee is solely responsible for the Manufacture of a Molecule and each Product in the Field in the Territory for clinical Development purposes. To the extent not included in the Licensed Know-How or MedImmune Know-How, Licensee is solely responsible for generating necessary CMC data on a Molecule and each Product for regulatory filings, including any Regulatory Approval Application.

4.2.2. **Regulatory Strategy**. With respect to each Product, except for any interaction or communication with a Regulatory Authority that Avalo is required to conduct under Applicable Law in connection with Avalo's conduct of the Existing Clinical Studies in accordance with the terms of this Agreement, Licensee and its Related Parties are solely responsible for all interactions and communications with Regulatory Authorities including, without limitation, in relation to INDs, BLAs, label development, advisory committee meetings or their equivalent (if applicable) and negotiation with Regulatory Authorities regarding post-approval requirements/commitments.

4.2.3. **Regulatory Documentation**. All Regulatory Documentation (including all Regulatory Approval Applications and Regulatory Approvals) shall, except (a) with respect to such Regulatory Documentation useful or necessary to enable Avalo and its Affiliates to perform their obligations and exercise their rights with respect to the Existing Clinical Studies or as otherwise set forth in the Study Transfer Plan and (b) as provided in this Section 4.2.3, be owned by and held in the name of, Licensee or its Related Party. Without limiting Avalo's obligations under Section 3.5, at Licensee's election, to the extent not already assigned and delivered to Licensee, Avalo shall, to the extent permitted under Applicable Law, assign and deliver promptly (in no event later than ten (10) days following receipt of Licensee's notice electing for such assignment and delivery) to Licensee all or a portion of the Existing Regulatory Documentation and any newly-created Regulatory Documentation arising from any Existing Clinical Studies (*"Newly Generated Regulatory Documentation"*); provided that (i) with respect to the safety data contained in the Newly Generated Regulatory Documentation with respect to each Existing

Clinical Study, during the pendency of such Existing Clinical Study, Avalo shall promptly transfer such safety data to Licensee as it becomes available to Avalo or its Affiliates on an ongoing basis and in any event no later than ten (10) days after the completion of the applicable Existing Clinical Study and (ii) Avalo shall be entitled to delay the transfer of Existing Regulatory Documentation or Newly Generated Regulatory Documentation solely as necessary to permit Avalo and its Affiliates to perform their obligations with respect to the Existing Clinical Studies or as otherwise set forth in the Study Transfer Plan. Avalo shall duly execute and deliver or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary under or as Licensee may reasonably request in connection with or to carry out more effectively the purpose of, or to better assure and confer unto Licensee its rights under, this Section 4.2.3.

4.2.4. **Records**. Each Party shall maintain written scientific records of Development activities conducted pursuant to this Agreement in reasonable detail consistent with such Party's record keeping for its other products, which practices shall at least be commercially reasonable and consistent with reasonable, customary scientific and pharmaceutical industry standards.

4.3. <u>Third Parties</u>. Licensee and its Related Parties shall be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development activities; <u>provided</u>, <u>however</u>, that Licensee shall remain at all times fully liable for its responsibilities under this Agreement. Any agreement with a Third Party to perform Licensee's Development obligations under this Agreement shall be consistent with Licensee's obligations under this Agreement including confidentiality and non-use provisions which are no less stringent than those set forth in ARTICLE 8 (<u>provided</u> that the term of such confidentiality and non-use provisions may be shorter than those set forth in ARTICLE 8 to the extent consistent with applicable industry practice).

## ARTICLE 5

### COMMERCIALIZATION AND RELATED DILIGENCE

5.1. <u>Commercialization</u>. Licensee is solely responsible for all, and, as between Avalo and Licensee, shall record all top line revenues in connection with, Commercialization activities relating to Products in the Field in the Territory.

5.2. <u>Commercial Manufacturing and Supply</u>. Licensee is solely responsible for the Manufacture of a Molecule and each Product for commercial purposes in the Field in the Territory.

5.3. <u>Medical and Scientific Affairs</u>. Licensee is solely responsible for medical and scientific affairs and programs, including professional symposia and other educational activities with respect to each Product in the Field in the Territory. Licensee shall have the exclusive right to respond to all questions or requests for information about the Products made by any medical professionals or any other Person in the Field in the Territory.

### **ARTICLE 6**

# FINANCIAL PROVISIONS

6.1. <u>Upfront Payment</u>. Within five (5) Business Days following the Effective Date, Licensee shall pay Avalo a nonrefundable, noncreditable amount equal to Five Million Dollars



(\$5,000,000) by wire transfer of immediately available and cleared funds pursuant to wire transfer instructions provided by Avalo to Licensee in writing prior to the Effective Date.

6.2. <u>Payment for Transition Activities</u>. Within five (5) Business Days following the Effective Date, Licensee shall pay Avalo a nonrefundable, noncreditable amount equal to Nine Million Five Hundred Sixteen Thousand Five Hundred Forty-Nine Dollars (\$9,516,549) as partial consideration for Avalo's transition activities and Consulting Activities and for the transfer of Avalo Materials and Assigned Product Agreements, by wire transfer of immediately available and cleared funds pursuant to wire transfer instructions provided by Avalo in writing.

6.3. <u>Milestones</u>. Licensee shall make the following one-time, nonrefundable, and noncreditable milestone payments to Avalo (each, a "*Milestone Payment*") following the first achievement by Licensee or any of its Related Parties of the milestone event corresponding to such Milestone Payment (each, a "*Milestone Event*"). Licensee shall notify Avalo of the achievement of each Milestone Event as follows: (a) within ten (10) Business Days following the achievement of any Milestone Event labeled a "Development Milestone" below and (b) within thirty (30) days following the end of the Contract Quarter during which the achievement of any Milestone Event labeled a "Sales Related Milestone" below occurs. Avalo will invoice Licensee for each Milestone Payment no earlier than the earlier of (i) receipt of such a notice from Licensee with respect to the corresponding Milestone Event or (ii) the date Licensee is required to provide such a notice for the corresponding Milestone Event, and Licensee shall pay such Milestone Payment no later than forty five (45) days following its receipt of the applicable invoice from Avalo. For clarity, each Milestone Payment will be payable no more than one (1) time, upon the first achievement of the corresponding Milestone Event by Licensee or any of its Related Parties, regardless of whether the relevant Milestone Event is achieved in respect of more than one (1) Product.

Development Milestones	Payment
1. (***)	\$(***)
2. (***)	\$(***)
3. (***)	\$(***)
Total Development Milestones	\$6,250,000

Sales Related Milestones	Payment
Annual Net Sales first exceed \$(***)	\$(***)
Annual Net Sales first exceed \$(***)	\$(***)
Annual Net Sales first exceed \$(***)	\$(***)
Annual Net Sales first exceed \$(***)	\$(***)
Total Sales Related Milestones	\$67,500,000

Notwithstanding anything to the contrary in this Agreement,

(i) if Milestone Event 2 or 3 or the First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 1, then Milestone Event 1 shall be deemed to have occurred and the applicable Milestone Payment therefor shall be due (in addition to any Milestone Payment due for Milestone Event 2 or 3); and

(ii) if Milestone Event 3 or First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 2, then Milestone Event 2 shall be deemed to

have occurred and the applicable Milestone Payment therefor shall be due (in addition to any Milestone Payment due for Milestone Event 3); and

(iii) if First Commercial Sale of a Product in the United States occurs prior to the achievement of Milestone Event 3, then Milestone Event 3 shall be deemed to have occurred and the applicable Milestone Payment therefor shall be due.

## 6.4. Royalties.

6.4.1. **Full Royalty Rate**. Licensee shall, subject to any applicable adjustments set forth in Section 6.4.2 below, pay Avalo an amount equal to the applicable percentage of Annual Net Sales set forth below:

Annual Net Sales	Royalty Rate
That portion of Annual Net Sales in a given Contract Year that is less than \$(***)	(***)%
That portion of Annual Net Sales in a given Contract Year that is equal to or greater than \$(***)	(***)%

6.4.2. **Reduced Royalty Rate**. On a Product-by-Product and country-by-country basis, Licensee shall pay Avalo royalties on Net Sales of a Product in a country at (\*\*\*) % of the rates set forth in the table in Section 6.4.1 during the period in which (a) no Valid Claim of the Licensed Patent Rights and no MedImmune Valid Claim Covers such Product in such country and no Regulatory Exclusivity exists for such Product in such country or (b) a Biosimilar with respect to such Product is commercialized in such country.

6.4.3. **Expiration of Royalty**. Net Sales for purposes of calculating the royalties due under this Section 6.4 shall only include Net Sales of a Product in a country occurring during the applicable Royalty Term for such Product in such country.

6.5. <u>Reports and Royalty Payments</u>. Within sixty (60) days after the end of each Contract Quarter commencing in the Contract Quarter immediately following the Contract Quarter in which there was the First Commercial Sale of any Product, Licensee shall deliver to Avalo a report setting forth for the previous Contract Quarter the following information on a Product-by-Product basis: (a) the gross sales and Net Sales of each Product, (b) the number of units sold by Licensee and its Related Parties, (c) the royalty due hereunder, (d) the applicable exchange rate as determined pursuant to Section 6.6.5; and (e) the calculation of any true-up required with respect Net Sales reported and payments made in connection with prior Contract Quarter(s). The total royalty due to Avalo for the sale of Products during such Contract Quarter shall be remitted at the time such report is made, but in any event no later than the sixtieth (60<sup>th</sup>) day after the end of each Contract Quarter.

## 6.6. Payment Provisions Generally.

6.6.1. **Taxes and Withholding**. All amounts payable under this Agreement shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 6.6, each Party shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from payments and remitted by the other Party) levied on account of, or measured in whole or in part by reference to, any payments it receives. Each Party shall deduct or withhold from the payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if a Party is entitled under any applicable tax treaty to a reduction



of rate of, or the elimination of, applicable withholding tax, it may deliver to the other Party or the appropriate governmental authority (with the assistance of the other Party to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve such Party of its obligation to withhold such tax and that Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; <u>provided</u> that a Party has received evidence of the other Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time the payments are due. If, in accordance with the foregoing, a Party withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount and send to the other Party proof of such payment within ten (10) days following such payment.

6.6.2. **Gross Up**. If the paying Party transfers (whether by way of legal or equitable assignment, declaration of trust, novation or otherwise) the benefit in whole or in part of this Agreement or, after the Effective Date, changes its tax residence or the permanent establishment to which the rights under the Agreement are allocated and a payment under this Agreement is subject to withholding tax where the payment would not have been subject to withholding tax or would have been subject to a lower rate of withholding tax in the absence of such transfer, change in tax residence or permanent establishment, then the paying Party or its assignee (as the case may be) shall be obliged to pay to the recipient such sum as will after such deduction or withholding has been made leave the recipient with the same amount as it would have been entitled to receive had no transfer, change in tax residence or permanent establishment taken place.

6.6.3. **Anti-Tax Evasion**. (a) Each of Licensee and Avalo represents, warrants and undertakes that it nor its Affiliates shall commit a UK tax evasion facilitation offence under section 45(5) of the UK Criminal Finances Act 2017 in connection with or attributable to this Agreement or the transactions contemplated hereby, (b) each Party shall promptly report to the other Party any apparent breach of Section 6.6.3 clause (a) and shall (i) answer, in reasonable detail, any written or oral inquiry from the other Party related to its and its Affiliates compliance with Section 6.6.3 clause (a), (ii) facilitate the interview of employees of such Party by the other Party (or any agent of such Party) at any reasonable time specified by the inquiring Party related to such Party's compliance with Section 6.6.3 clause (a) and (iii) co-operate with the inquiring Party or any governmental authority in relation to any investigation relating to the matters referred to in Section 6.6.3 clause (a), in all cases, as reasonably required to enable that other Party to comply with its undertaking in Section 6.6.3 clause (a).

6.6.4. **Indirect Taxes**. Notwithstanding anything to the contrary contained in this Section 6.6.4 or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. All payments are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the payer shall pay such Indirect Taxes as the applicable rate in respect of any such payments, following the receipt, where applicable, of an Indirect Taxes invoice issued in the appropriate form by the payee in respect of those payments to which such Indirect Taxes relate. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, the parties shall cooperate to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements. Avalo acknowledges that based on current Applicable Law, Avalo does not intend to invoice Licensee for value added taxes in respect of the transactions effected by this Agreement.

6.6.5. **Payment and Currency Exchange**. All amounts payable and calculations hereunder shall be in United States dollars and shall be paid by bank wire transfer in immediately

available and cleared funds to such bank account as may be designated in writing by Avalo from time to time. Whenever for the purposes of calculating royalties payable under this Agreement, conversion from any foreign currency will be required, all amounts will first be calculated in the currency in which the activity was paid or sale was recorded and then converted into United States dollars equivalent using its, its Affiliates, or Sublicensee's, as applicable, standard conversion methodology consistent with the relevant applicable Accounting Standards. All payments will be non-refundable and not creditable once received by Avalo except for any applicable accounting true-ups.

6.6.6. **Overdue Payments**. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest compounding on a daily basis) of (\*\*\*) basis points above the U.S. effective federal funds rate, as adjusted each Business Day and published by the Federal Reserve Bank of New York through its website (<u>https://apps.newyorkfed.org/markets/autorates/fed%20funds</u>), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

### 6.7. Maintenance of Records; Audits.

6.7.1. **Record-Keeping**. Licensee shall keep, and shall cause its Related Parties to keep, books and accounts of record in connection with the sale of Products and in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder. Avalo shall keep, and shall cause its Affiliates to keep, books and accounts of record in connection with all amounts to be paid to Avalo under this Agreement for the conduct of Consulting Activities and Continued Existing Clinical Studies, in order to enable Licensee to verify all amounts to be reimbursed under this Agreement in connection with such activities. Each Party shall maintain, and shall cause its Related Parties to maintain, such records for a period of at least three (3) years after the end of the Contract Year in which they were generated.

6.7.2. Audits. Upon thirty (30) days' prior written notice from the other Party, Licensee or Avalo, as applicable, (the "Audited Party") shall permit an independent certified public accounting firm of nationally recognized standing selected by the other Party and reasonably acceptable to the Audited Party, to examine, at the other Party's sole expense, the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the amounts reported in accordance with Section 6.5 and the payment of royalties hereunder or the amounts invoiced or paid under Section 3.2. An examination by the other Party under this Section 6.7.2 shall occur not more than once in any Contract Year and shall be limited to the pertinent books and records for any Contract Year ended not more than two (2) years before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept, and such examination shall be conducted during the Audited Party's normal business hours. The Audited Party is accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide the other Party and the Audited Party a written report disclosing any discrepancies. No other information pertaining to the Audited Party's books and records shall be provided to the other Party.

## 6.7.3. Underpayments/Overpayments.

(a) If such accounting firm correctly concludes (such conclusion subject to the dispute resolution procedures set forth in Section 11.17) that additional royalties were due to

Avalo, Licensee shall, if applicable, pay to Avalo the additional royalties within sixty (60) days after the date Licensee receives such accountant's written report so correctly concluding (unless disputed in good faith hereunder). If such underpayment exceeds five percent (5%) of the royalties that were to be paid for all audited periods, Licensee also shall reimburse Avalo for all out-of-pocket expenses incurred in conducting the audit. If such accounting firm correctly concludes that Licensee overpaid royalties to Avalo, then Avalo shall refund such overpayments to Licensee within sixty (60) days after the date Avalo receives such accountant's report so correctly concluding, or, if mutually agreed by the Parties, during such sixty (60) day period, credit the amount of such overpayments against any existing or future payments due to Avalo hereunder, as mutually agreed by the Parties.

(b) If such accounting firm correctly concludes (such conclusion subject to the dispute resolution procedures set forth in Section 11.17) that Licensee was overcharged for payments relating to the conduct of Consulting Activities and Continued Existing Clinical Studies, then Avalo shall refund such overpayments to Licensee within sixty (60) days after the date Avalo receives such accountant's report so correctly concluding, or, if mutually agreed by the Parties, during such sixty (60) day period, credit the amount of such overpayments against any existing or future payments due to Avalo hereunder, as mutually agreed by the Parties. If such overpayment exceeds five percent (5%) of the proper amount due for all audited activities, Avalo also shall reimburse Licensee for all out-of-pocket expenses incurred in conducting the audit.

6.7.4. **Confidentiality**. All financial information of the Audited Party that is subject to review under this Section 6.7 shall be deemed to be the Confidential Information of the Audited Party subject to the provisions of ARTICLE 8, and Avalo shall not disclose such Confidential Information to any Third Party and shall not use such Confidential Information for any purpose other than verifying payments to be made by Licensee to Avalo hereunder.

6.7.5. Audit of Third Party Sublicensees. Within thirty (30) days following Licensee's receipt of a written notice from Avalo with respect thereto, Licensee will initiate an audit of a Third Party Sublicensee that is the subject of Avalo's written notice in accordance with the terms of the applicable Sublicense agreement.

### **ARTICLE 7**

# INTELLECTUAL PROPERTY PROTECTION AND RELATED MATTERS

### 7.1. Filing, Prosecution and Maintenance of Licensed Patent Rights.

7.1.1. **Responsibility**. Subject to Section 7.1.4, Licensee shall have, subject to the remainder of Section 7.1, sole responsibility for and control over the prosecution and maintenance of the Licensed Patent Rights throughout the Territory in Avalo's or its applicable Affiliate's name, all at Licensee's sole cost and expense.

7.1.2. **Information Sharing; Comment**. Licensee shall keep Avalo reasonably informed of patent prosecution activities concerning the Licensed Patent Rights in the Territory and provide Avalo with copies of material correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution of the Licensed Patent Rights. Licensee shall provide Avalo a reasonable opportunity to provide comments and suggestions with respect to any material actions to be taken by Licensee under this Section 7.1, and Licensee shall reasonably consider all comments, suggestions and prosecution actions recommended by Avalo.

7.1.3. **Common Interest**. All information provided by or on behalf of Avalo to Licensee or its Affiliate or counsel regarding preparation, filing, prosecution or maintenance of the Licensed Patent Rights shall be deemed both Parties' Confidential Information, with each Party being deemed a Receiving Party with respect thereto. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution and maintenance of the Licensed Patent Rights, the interests of the Parties are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patent Rights, including, without limitation, privilege under the common interest doctrine and similar or related doctrines. To be clear, all information exchanged between counsel to each of the Parties regarding the preparation, filing, prosecution or maintenance of any Licensed Patent Rights shall be subject to the common interest doctrine.

7.1.4. **Election Not to Continue Prosecution; Abandonment.** If Licensee elects not to continue the prosecution or maintenance of a Licensed Patent Right in the Territory, then (a) Licensee shall so notify Avalo promptly in writing of its intention reasonably (and at least seventy-five (75) days) in advance of any deadlines by which an action must be taken to establish or preserve any such rights in such Patent Rights in the Territory and (b) Avalo shall have the right, but not the obligation, upon written notice to Licensee, to file for, or continue to prosecute, maintain or enforce, or otherwise pursue such Licensed Patent Rights in the Territory and, in the event of such notice, Licensee shall cooperate with Avalo in regards thereto.

7.1.5. **Cooperation**. The Parties shall reasonably cooperate with each other, as reasonably requested by either Party, (a) if necessary and appropriate in gaining patent term extensions and the like wherever applicable to Licensed Patent Rights; and (b) the prosecution and maintenance of the Licensed Patent Rights; both (a) and (b) at Licensee's sole cost and expense. Further, at Licensee's sole cost and expense, Avalo shall reasonably cooperate with Licensee upon Licensee's request to execute any such documents and take any such actions to record this Agreement as required under Applicable Law as a prerequisite for the enforceability of this Agreement by Licensee.

## 7.2. Invalidity or Unenforceability Defenses or Actions.

7.2.1. **Notices**. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patent Rights by a Third Party of which such Party becomes aware.

7.2.2. **Response**. In the event that a Third Party challenges any of the Licensed Patent Rights, regardless of the name or procedure including, without limitation, opposition, validity challenge, interference, re-examination, reissue, derivation, supplemental examination, post-grant review, inter-parties review, negotiation, claim, declaratory judgment action or counterclaim or affirmative defense in an infringement suit brought under Section 7.3 (each, a "*Patent Challenge*"), Licensee shall have the first right, but not the obligation, to: (a) defend and prosecute the Patent Challenge in its own name, at its own expense (provided that such expenses shall be treated as Infringement Defense Costs), and on its own behalf; (b) to the extent applicable to the Patent Challenge, ultimately enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle the Patent Challenge; provided, however, that Avalo shall have the second right, but not the obligation, to take such actions at its own expense and in its own name with respect to a Patent Challenge if Licensee chooses not to defend and prosecute such Patent Challenge. Avalo shall join any such Patent Challenge if necessary, to avoid dismissal of the Patent Challenge. In all cases, the defending Party agrees to keep the other Party reasonably apprised of the status and progress of the Patent Challenge.

## 7.3. Enforcement of Patent Rights.

7.3.1. **Notification**. Each Party shall promptly report in writing to the other Party during the Term any (a) known or suspected infringement of any Licensed Patent Rights or (b) unauthorized use or misappropriation of any Licensed Intellectual Property, in each case ((a) or (b)), by a Third Party of which it becomes aware, and shall provide the other Party with all available evidence supporting such infringement or unauthorized use or misappropriation.

7.3.2. **Rights to Enforce**. Licensee shall have the first right, but not the obligation, to take any reasonable measures it deems appropriate to stop infringement or misappropriation of any Licensed Intellectual Property in the Field in the Territory, including (a) initiating or prosecuting an infringement or other appropriate suit or action against and (b) settling or ceasing any such infringement action or other suit, including, but not limited to, granting adequate rights and licenses necessary for continuing such activities in the Territory to any Third Party who at any time has infringed or misappropriated, or is suspected of infringing or misappropriating, any Licensed Intellectual Property. In the event that Licensee elects not to take action pursuant to this Section 7.3.2, Licensee shall so notify Avalo in writing of its intention within ninety (90) days after Licensee's notice of such infringement or misappropriation activities, or within such shorter time as is necessary to enable Avalo to meet any deadlines by which an action must be taken to establish or preserve any enforcement rights. Thereafter, the Parties shall consult with one another in an effort to determine whether a reasonably prudent licensee would institute litigation to enforce the Licensed Intellectual Property in question in light of all relevant business and economic factors (including, but not limited to, the projected cost of such litigation, the likelihood of success on the merits, the probable amount of any damage award, the prospects for satisfaction of any judgment against the alleged infringer, the possibility of counterclaims against the Parties or likely Patent Challenges, the impact of any possible adverse outcome on the Parties and the effect any publicity might have on the Parties' respective reputations and goodwill). If, after such process, it is unanimously determined that a suit should be filed and Licensee does not file suit or commence settlement negotiations forthwith against the infringer, then Avalo shall have the right, at its own expense, to enforce the Licensed Intellectual Property in guestion on behalf of itself and Licensee and Avalo shall have the right, but not the obligation, to take any such reasonable measures to stop such infringing or misappropriating activities by the applicable Third Party.

7.3.3. **Procedures; Expenses and Recoveries**. The Party having the right to initiate any enforcement action under Section 7.3.2 shall have the sole and exclusive right to select counsel for any such suit and shall pay all expenses of the suit, including attorneys' fees and court costs and reimbursement of the other Party's reasonable out-of-pocket expenses in rendering assistance requested by the initiating Party. If required under Applicable Law in order for the initiating Party to initiate or maintain such suit, or if either Party is unable to initiate or prosecute such suit solely in its own name, in each case, the other Party shall join as a party to the suit and shall execute and cause its Affiliates to execute all documents necessary for the initiating Party to initiate litigation to prosecute and maintain such action. In addition, at the initiating Party shall provide reasonable assistance to the initiating Party in connection with an infringement suit at no charge to the initiating Party except for reimbursement by the initiating Party for reasonable out-of-pocket expenses incurred in rendering such assistance. The non-initiating Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation), such amounts shall be allocated as follows:

(a) in all cases, first to reimburse the initiating Party for all expenses of the suit, including attorneys' fees and disbursements, court costs and other litigation expenses, and then to reimburse the other Party for its reasonable attorneys' fees and disbursements, court costs and other litigation expenses;

(b) if Licensee is the initiating Party, any of the remaining amount that relates to a Molecule or Product shall be treated as if it were Net Sales of Licensee, with Avalo receiving a royalty on such remaining amount pursuant to the terms of Section 6.4.1 (without adjustment thereof), and the balance being retained by Licensee; and

(c) if Avalo is the initiating Party, Avalo shall pay Licensee an amount equal to (i) the balance of any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation) following the deductions set forth in Section 7.3.3(a) multiplied by (ii) a fraction, the numerator of which is the reasonable attorneys' fees and disbursements, court costs and other litigation expenses incurred by Licensee in connection with such suit and the denominator of which is the reasonable attorneys' fees and disbursements, court costs and other litigation expenses incurred by Licensee, Avalo, and all Affiliates of the foregoing in connection with such suit.

## 7.4. Biosimilar Arrangements.

7.4.1. Notice of Third Party Applications. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the type described in Section 7.2 or Section 7.3, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) applicable under Section 7.2 or 7.3 will apply. Notwithstanding anything herein to the contrary, within three (3) years after Regulatory Approval is achieved with respect to a Product in the United States (or such shorter time as the Parties agree in the case of a Product in the United States that does not earn reference product exclusivity under the PHS Act), the Parties shall consult as to potential strategies with respect to unexpired Licensed Patent Rights that potentially could be asserted if an unlicensed person engaged in the making, using, offering to sell, selling, or importing into the United States of a product described in a Biosimilar Application filed by a Third Party applicant (a "Section 351(k) Applicant").

7.4.2. **Cooperation and Enforcement**. If Licensee or any Related Party, as the reference product sponsor of the Product within the meaning of section 351(l)(1)(A) of the PHS Act, receives notice of a Biosimilar Application filed by a Section 351(k) Applicant that references such Product and related manufacturing information in accordance with section 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with section 351(l)(8)(A) of the PHS Act, then Licensee shall provide notice thereof to Avalo, and the Parties shall discuss and Avalo shall reasonably cooperate with Licensee in determining Licensee's or its Related Party's course of action with regard to (a) engaging in the information exchange provisions of the Biologics Price Competition and Innovation Act of 2009, Section 351(l) of the Public Health Service Act, as may be amended, supplemented, or replaced (the "*BPCLA*"), including providing a list of patents that relate to the relevant Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under section 351(l)(6) of the PHS Act. In the event that the Parties do not agree with respect to the exercise of any such rights, Licensee shall make the final determination with respect thereto, including without limitation with respect to (a), (b) and (c) above provided, however, that Avalo's obligation shall be to reasonably cooperate with Licensee, and Licensee shall bear all out-of-pocket costs and expenses in connection with the exercise of any such rights or actions. If any patent litigation commences with respect to a



Biosimilar Application filed by a Section 351(k) Applicant that references such Product, then the provisions of Section 7.3 shall thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.

## 7.5. Claimed Infringement of Third Party Rights.

7.5.1. Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of such Party's respective Affiliates or (sub)licensees, claiming infringement of its Patent Rights (including with respect to a Blocking Patent) or unauthorized use or misappropriation of its Know-How, based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory, other than any such claim, action, suit, or proceeding by MedImmune Limited, any Affiliate thereof, or any successor in interest thereto with respect to any MedImmune Patent Rights or MedImmune Know-How ("Infringement Claim"), such Party shall promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served.

7.5.2. **Right to Defend**. As between the Parties, Licensee shall have the right, but not the obligation, to defend all Infringement Claims brought in the Territory against either Party or any of its Affiliates or (sub)licensees arising out of the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory; <u>provided</u> that the foregoing shall not be construed to require Licensee to defend Avalo against a breach of Avalo's representations and warranties set forth herein. For purposes of clarification, but not limitation, to the extent Licensee does not exercise such right with respect to any Infringement Claim against Avalo or any Affiliate thereof, Avalo and its Affiliates shall be entitled to defend themselves against such Infringement Claim, subject to the terms of Section 7.5.3.

### 7.5.3. Procedure.

(a) To the extent that (i) the Infringement Claim, whether in the form of an assertion by a Third Party or a filed litigation (or other formal dispute resolution procedure), directly relates to a Blocking Patent or (ii) a Blocking Patent is otherwise identified by or on behalf of either Party or its Affiliates (a "*Blocking Patent Claim*"), as between the Parties, Licensee shall have the sole and exclusive right to control any negotiations and discussions with the Third Party to resolve the Blocking Patent Claim in the Territory with respect to the Development, Manufacture or Commercialization of a Molecule or a Product in the Territory by acquiring a license to engage in such activities under the Blocking Patent or other Patent Rights or Know-How that are the subject of such Blocking Patent Claim, <u>provided</u> that, notwithstanding the foregoing, if Licensee is unable to resolve the Blocking Patent Claim with respect to any actual or potential Blocking Patent Claims against Avalo or any Affiliate thereof in a manner that is acceptable to Avalo, then Avalo shall be entitled to resolve or defend such Blocking Patent Claims that would reasonably be anticipated to adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensee, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding any provision to the contrary in this Agreement, any expense incurred by Licensee or its Affiliates in other provides or payments payable under this Agreement as Infringement Defense Costs under Section 7.5.3(d).

(b) As between the Parties, Licensee shall have the sole and exclusive right to control any negotiations and discussions with the Third Party to resolve the Infringement Claim in the Territory by acquiring a license under the relevant Patent Rights and Know-How, provided that, notwithstanding the foregoing. if Licensee is unable to resolve an Infringement Claim against Avalo or any Affiliate thereof in a manner that is acceptable to Avalo, then Avalo shall be entitled to settle, resolve or defend such Infringement Claims with respect to Avalo or its Affiliates in any manner in its sole discretion; provided that Avalo shall not settle any Infringement Claims that would reasonably be anticipated to adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensed Patent Rights) or purport to impose any obligations on Licensee or any Affiliate of Licensee without obtaining the prior written consent of Licensee, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding any provision to the contrary in this Agreement, any expense incurred by Licensee in connection with obtaining rights under or to Patent Rights or Know-How to resolve an Infringement Claim shall be offset against any royalties or other payments payable thereunder as Infringement Defense Costs under Section 7.5.3(d).

(c) As between the Parties, Licensee shall have the sole and exclusive right to select counsel to defend any Infringement Claim brought via litigation or other formal dispute resolution procedure, <u>provided</u> that (i) with respect to any Infringement Claim brought against Avalo or its Affiliates, Licensee shall keep Avalo informed, and shall from time to time consult with Avalo regarding the status of any such claims and shall provide Avalo with copies of all material documents filed in, and all material written communications relating to, any suit brought in connection with such claims and (ii) Avalo shall also have the right to participate and be represented in any such claim or related suit against Avalo or any Affiliate thereof, at its own expense. Licensee shall not settle any Infringement Claims that would adversely impact any of the Licensed Patent Rights (such as invalidation of or narrowing the scope of any claim of any of the Licensed Patent Rights) or purport to impose any obligations on Avalo or any Affiliate of Avalo without obtaining the prior written consent of Avalo, which consent shall not be unreasonably withheld, conditioned or delayed.

(d) Except to the extent Avalo owes an indemnification obligation to Licensee under this Agreement, as between the Parties, all litigation costs and expenses incurred by Licensee or its Affiliates in connection with Infringement Claims or Patent Challenges, and all damages and settlement payments, including any ongoing royalties or milestone payments negotiated by Licensee or its Affiliates under Sections 7.2.2, 7.5.3(a) or 7.5.3(b), payable by Licensee or its Affiliate to the Third Party in respect of Infringement Claims or Patent Challenges ("*Infringement Defense Costs*") shall be borne by Licensee; provided that: (i) Licensee may deduct Infringement Defense Costs as incurred against the royalties and Milestone Payments that become payable to Avalo under this Agreement; but (ii) no quarterly payment of royalties or any milestone payment shall be reduced by more than fifty percent (50%) of the amount otherwise payable under Section 6.3 or 6.4, as applicable, solely as a result of this Section 7.5.3(d). For the avoidance of doubt, if Licensee is unable to fully deduct Infringement Defense Costs (as a result of clause (ii) of this Section 7.5.3(d) or otherwise), the un-deducted amount(s) shall carry over to each succeeding accrual of royalties and Milestone Payments until fully deducted.

7.6. <u>Product Trademarks</u>. Licensee or its Related Parties, as applicable, shall select and, subject to Section 9.4, own the Product Trademarks for each Product and shall be solely responsible for filing and maintaining the Product Trademarks in the Territory (including payment of costs associated therewith). Licensee shall assume full responsibility, at its sole cost and expense, for any infringement of a Product Trademark for a Product by a Third Party and

any claims of infringement in the Territory of the rights of a Third Party by the use of a Product Trademark in connection with a Product.

7.7. <u>Patent Term Extensions in the Territory</u>. The Parties shall use reasonable efforts to obtain all available extensions of Licensed Patent Rights (including those available under the Hatch-Waxman Act). Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining such extensions wherever applicable to Licensed Patent Rights. Licensee shall have the sole right to seek extension of any Licensed Patent Right; <u>provided</u> that if Licensee has an option to extend the patent term for only one of several patents, Licensee shall consult with Avalo before making the election. If more than one patent is eligible for extension, the Parties shall select, in good faith, a strategy that shall maximize patent protection and commercial value for each Product.

# **ARTICLE 8**

## CONFIDENTIALITY

8.1. <u>Confidential Information</u>. All Confidential Information disclosed by a Party (together with its Affiliates, the "*Disclosing Party*") to the other Party (together with its Affiliates, the "*Receiving Party*") shall be used by the Receiving Party solely in connection with the activities contemplated by this Agreement (or, in the case of Licensee, as necessary to perform its obligations under the Novated MedImmune License), shall be maintained in confidence by the Receiving Party and shall not otherwise be disclosed by the Receiving Party to any other Person, firm, or agency, governmental or private (other than a Party's Affiliates or, in the case of Licensee, to MedImmune or its Affiliates under the Novated MedImmune License), without the prior written consent of the Disclosing Party, except to the extent that the Disclosing Party's Confidential Information (as determined by competent documentation):

8.1.1. was known or used by the Receiving Party prior to its date of disclosure to the Receiving Party; or

8.1.2. either before or after the date of the disclosure to the Receiving Party, is lawfully disclosed to the Receiving Party or its Affiliates by Third Party sources other than the Disclosing Party or either Party's Related Parties, which Third Party sources are rightfully in possession of the Confidential Information; or

8.1.3. either before or after the date of the disclosure to the Receiving Party, becomes published or generally known to the public (including information known to the public through the sale of products in the ordinary course of business) through no fault or omission on the part of the Receiving Party or its Related Parties; or

8.1.4. is independently developed by or for the Receiving Party without reference to or reliance upon the Disclosing Party's Confidential Information.

8.2. <u>Required Disclosures</u>. Section 8.1 shall not preclude the Receiving Party from disclosing the Disclosing Party's Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, <u>provided</u> that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure. If a public disclosure of Disclosing Party's Confidential Information is required by any Applicable Laws, including, without limitation, in a filing with the United States Securities and Exchange



Commission or submission to an exchange on which any securities of Receiving Party or an Affiliate thereof is listed, the Receiving Party shall provide copies of the disclosure (but shall be permitted to redact or omit portions of any filing, submission or disclosure not relevant to this Agreement) reasonably in advance of such filing or other disclosure, for the Disclosing Party's prior review and comment and to allow the Disclosing Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The Receiving Party shall negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by Receiving Party and for which the obligations of this provision have been satisfied, the Receiving Party need not share such disclosure ahead of it being made.

8.3. <u>Permitted Disclosures</u>. Avalo and Licensee each agree that that they shall provide the other Party's Confidential Information only to their Affiliates and its and their respective directors, officers, employees, consultants, attorneys, vendors, suppliers, (sub)licensees, collaborators and advisors who have a need to know for the Development, Manufacture, and Commercialization of Products in accordance with this Agreement, for prosecution and maintenance of Licensed Patent Rights or to enforce or exercise rights under this Agreement, including in connection with Regulatory Approval Applications and obtaining Regulatory Approvals, or, in the case of Licensee, to MedImmune and its Affiliates as necessary to comply with its obligations under the MedImmune License, <u>provided</u> that such Third Parties are bound by confidentiality obligations at least as strict as this ARTICLE 8 (except that, in the case of agreements with Third Party consultants, attorneys, vendors, advisors and suppliers, the confidentiality term of such obligations may be shorter than that set forth in this Agreement to the extent such shorter confidentiality term sort to their respective accountants, attorneys and other professional advisors; <u>provided</u> that such disclosures shall be subject to continued confidentiality obligations at least as strict as this ARTICLE 8 (except that the confidentiality term of such obligations may be shorter than that set forth in this Agreement (to the extent such terms are confidential) to any Third Party except to actual or prospective lenders, investors, aquirers, licensees/(sub)licensees or strategic partners or to their respective accountants, attorneys and other professional advisors; <u>provided</u> that such disclosures shall be subject to continued confidentiality obligations at least as strict as this ARTICLE 8 (except that the confidentiality term of such obligations may be shorter than that set forth in this Agreement to the extent such shorter confidentiality term of such obligations at least as strict

8.4. <u>Public Announcements and Use of Names</u>. No public disclosure of the existence of, or the terms of, this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party in any publicity, news release or public disclosure relating to this Agreement or its subject matter without the prior express written permission of the other Party, except as may be required by Applicable Law or expressly permitted by the terms hereof. A press release agreed upon by the Parties is attached to <u>Exhibit B</u>. If public disclosure of the terms of this Agreement beyond such press release is required by any Applicable Law or the rules and regulations of any securities exchange on which a Party's securities are traded, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure, but not later than five (5) Business Days prior to the filing, for the non-disclosing Party's prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.

## **ARTICLE 9**

#### **TERM AND TERMINATION**

9.1. <u>Term</u>. This Agreement shall commence on the Effective Date and, subject to any earlier termination of this Agreement in accordance with this ARTICLE 9, remain in effect until expiration of the last-to-expire Royalty Term (the period from the Effective Date until the expiration or, if earlier, termination of this Agreement, the "*Term*"). After expiration of the Royalty Term for a Product in a given country, no further royalties shall be payable in respect of sales of such Product in such country, and the license granted to Licensee under Section 2.1 shall be a fully paid-up, perpetual, irrevocable, royalty-free and sublicensable license with respect to such Product in such country.

### 9.2. Termination by Avalo.

9.2.1. **Breach**. Avalo will have the right to terminate this Agreement in its entirety, subject to Section 9.2.2, upon delivery of written notice to Licensee in the event of any material breach by Licensee of this Agreement, <u>provided</u> that such breach has not been cured within sixty (60) days after written notice of such breach and Avalo's intention to terminate is given by Avalo to Licensee. Subject to Section 9.2.2, any such termination of this Agreement will become effective at the end of such sixty (60) day cure period, unless Licensee has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the sixty (60) day cure period, then, Avalo's right of termination will be suspended only if and for so long as Licensee has provided to Avalo a written plan that is reasonably calculated to effect a cure within six (6) months thereafter and such plan is acceptable to Avalo (such acceptance not to be unreasonably withheld, conditioned, or delayed), and Licensee commits to and carries out such plan as provided to Avalo.

9.2.2. **Dispute**. If Licensee reasonably and in good faith disagrees as to whether Avalo has a basis for terminating this Agreement pursuant to Section 9.2.1, Licensee may contest the allegation in accordance with Sections 11.2 and 11.17. It is understood and acknowledged that, during the pendency of such a dispute, the remaining cure period shall be tolled and all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by Avalo pursuant to Section 9.2.1 will be effective unless and until (a) Avalo's right to terminate this Agreement under Section 9.2.1 has been finally determined by litigation in accordance with Section 11.2 and (b) Licensee fails to cure the breach giving rise to the right to terminate during the cure period that remains following such determination.

9.2.3. **Abandonment**. If Licensee, in its discretion, decides to abandon all of its Development or Commercialization efforts with respect to the Products, Licensee shall promptly notify Avalo in writing of its intent to do so. Avalo will have the right to terminate this Agreement immediately upon receipt of such notice.

9.2.4. **Anti-Shelving**. If the Novated MedImmune License is terminated with respect to one or more Products, one or more countries, or in its entirety, respectively, then (a) Licensee shall promptly provide Avalo written notice thereof and (b) Avalo shall have the right to terminate this Agreement with respect to such Product(s), such country(ies), or in its entirety, respectively, upon written notice to Licensee.

9.3. Termination by Licensee.

9.3.1. **Breach**. Licensee will have the right to terminate this Agreement in its entirety or on a Product-by-Product or country-bycountry basis upon delivery of written notice to Avalo in the event of any material breach of this Agreement by Avalo including any failure to provide the Avalo Material in accordance with this Agreement, and, <u>provided</u> that such breach has not been cured within sixty (60) days after written notice of such breach and Licensee's intention to terminate is given by Licensee to Avalo. Any such termination will become effective at the end of such sixty (60) day cure period, unless Avalo has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the sixty (60) day cure period, then, Licensee's right of termination will be suspended only if and for so long as Avalo has provided to Licensee a written plan that is reasonably calculated to effect a cure within six (6) months thereafter and such plan is acceptable to Licensee (such acceptance not to be unreasonably withheld, conditioned, or delayed), and Avalo commits to and carries out such plan as provided to Licensee.

9.3.2. **Convenience**. Upon ninety (90) days prior written notice in the case where Regulatory Approval has not been obtained for any Product in the Field in a jurisdiction in the Territory or one hundred eighty (180) days prior written notice in the case where Regulatory Approval in the Field in a jurisdiction in the Territory has been obtained for a Product, such termination to be effective at the end of such notice period, Licensee may terminate this Agreement in its entirety or on a Product-by-Product or country-by-country basis for any reason or no reason, including if Licensee decides to cease all of its Development and/or Commercialization efforts with respect to a Product in a jurisdiction.

9.4. Effects of Termination. Without limiting any legal or equitable remedies of either Party, upon termination of this Agreement for any reason: (a) all licenses granted by Avalo under this Agreement shall terminate solely with respect to the Product(s) and country(ies) subject to such termination; and (b) Licensee shall promptly transfer to Avalo copies of all Licensed Know-How in Licensee's or its Affiliate's possession that relates to the Product(s) or country(ies) subject to such termination. For clarity, in the event that this Agreement is terminated in its entirety, all Products will be deemed to be terminated Products and all countries will be deemed to be terminated countries.

9.5. <u>Rights in Bankruptcy</u>. All rights and licenses granted under or pursuant to this Agreement, including without limitation ARTICLE 2, are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "*IP*"). Upon a Party which is a licensor of rights granted under this Agreement entering into any voluntary or involuntary insolvency proceeding during the Term of this Agreement, and notwithstanding any attempted rejection of this Agreement by such Party, or any trustee, administrator or executor of such Party or an applicable bankruptcy court, the Parties agree that: the other Party, as licensee of such rights under this Agreement, shall (a) retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP and (b) retain in perpetuity all rights and licenses herein granted, <u>provided</u> that such Party continues to pay any royalties otherwise due hereunder (subject to any right of set-off hereunder), and the Party which has entered such insolvency proceeding shall have, to the extent required by applicable bankruptcy laws in order to maintain the other Party's license rights hereunder. Each Party hereby grants to the other Party and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of intellectual property, which, if not already in the other Party's possession, shall be promptly delivered to it upon the other Party's written



request therefor. The term "embodiments of intellectual property" includes all tangible, electronic or other embodiments of rights and licenses hereunder, including, without limitation, a Molecule, Product(s), all Regulatory Approval Applications and Regulatory Approvals, and all Know-How and other information related to a Molecule and Product(s), Licensed Patent Rights and Licensed Know-How. Neither Party shall interfere with the exercise by the other Party or its Affiliates of rights and licenses to IP and embodiments of intellectual property licensed hereunder in accordance with this Agreement, and each Party agrees to reasonably assist the other Party and its Affiliates to obtain the IP and embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for the other Party or its Affiliates to exercise such rights and licenses in accordance with this Agreement. The Parties agree that the terms of this Agreement are fair and reasonable, are not overly burdensome and have been negotiated in an arms-length transaction between unrelated parties with each Party represented by legal counsel. If any provision herein is deemed onerous or otherwise unenforceable by any applicable bankruptcy court, the Parties shall use good faith efforts to amend the Agreement (e.g., removing such onerous provision) so as to avoid any consequences thereof under applicable bankruptcy laws.

9.6. <u>Return of Confidential Information</u>. Except to the extent otherwise required by Applicable Law or useful or necessary to exercise any rights or perform any obligations surviving termination, upon termination of this Agreement, each Party shall promptly return to the other Party, delete or destroy all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; <u>provided</u> that such Party may keep copies of such materials in order to satisfy regulatory requirements or obligations under Applicable Law or for archival purposes only. Each Party's obligations under ARTICLE 8 terminate on the date that is five (5) years after the effective date of termination of this Agreement.

9.7. <u>Survival</u>. The provisions of ARTICLE 1 (Definitions), ARTICLE 6 (Financial Provisions), ARTICLE 8 (Confidentiality) and ARTICLE 11 (Miscellaneous Provisions) and Sections 2.2.3 (Effect of Termination on Sublicenses), 2.4 (Ownership of and Rights to Intellectual Property), 2.5 (No Other Rights), 3.6 (Disclaimers), 9.4 (Effects of Termination), 9.5 (Rights in Bankruptcy), 9.6 (Return of Confidential Information), 9.7 (Survival), 10.3 (Warranty Disclaimer), 10.4 (No Consequential Damages), and 10.5 (Indemnification and Insurance), any accrued obligation by either Party to make any payment prior to the effective date of termination, and any provision necessary to interpret or give effect to such Sections shall survive any termination of this Agreement in accordance with their respective terms. Except as set forth in this Section 9.7, upon termination or expiration of this Agreement all other rights and obligations cease. Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

## **ARTICLE 10**

## **REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION**

10.1. <u>Mutual Representations and Warranties</u>. Each Party hereby represents and warrants to the other Party, as of the Effective Date, and covenants, as applicable, that:

10.1.1. **Existence and Authority**. It is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full power and authority to enter into this Agreement and the Novation Agreement and to carry out the provisions hereof and thereof.

## 10.1.2. Authorized Execution; Binding Obligation.

(a) The execution, delivery, and performance of this Agreement and the Novation Agreement and the consummation of the transactions contemplated by this Agreement and the Novation Agreement have been duly authorized and approved by all necessary corporate or company action on its part; and

(b) This Agreement and the Novation Agreement have been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with its terms.

10.1.3. No Conflicts. The execution, delivery and performance of this Agreement and the Novation Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it or its assets may be bound.

10.1.4. All Consents and Approvals Obtained. All necessary consents, approvals and authorizations of, and all notices to, and filings by such Party with, all governmental authorities and other Persons required to be obtained or provided by such Party in connection with the execution, delivery and performance of this Agreement or the Novation Agreement have been obtained, other than Third Party consents required for the assignment of Product-related agreements as described in ARTICLE 3.

10.1.5. **Compliance with Law**. It shall at all times comply with Applicable Laws in all material respects with respect to its activities under this Agreement. Neither it nor any of its Affiliates nor any director, officer, agent, employee, consultant of, or other person associated with, or acting on behalf of, it or its Affiliates has (a) made, authorized, offered or promised to make any payment or transfer of anything of value, directly, indirectly or through a Third Party, to any foreign government official, employee or other representative (including employees of a government owned or controlled entity or public international organization and including any political party or candidate for public office), in violation of any Anti-Bribery Laws, or any law of similar effect in any jurisdiction to which such Person is subject. For the purposes of this Section 10.1.5, the acts specified include (x) the making or payment of any illegal contributions, commissions, fees, gifts, entertainment, travel or other unlawful expenses relating to political activity, (y) the direct or indirect payment, gift, offer, promise or authorized no ther unlawful expenses relating to political activity, (y) the direct or indirect payment, gift, offer, promise or authorization to make a payment, gift, offer or promise of, anything of material value to any foreign government representative and (z) the making of any bribe, illegal payoff, influence payment, kickback or other unlawful payment. "*Anti-Bribery Laws*" means the United States Foreign Corrupt Practices Act of 1977 or any other anti-bribery laws, statutes, rules or regulations of any country that may be applicable to a Party, including the United Kingdom Bribery Act 2010 and any anti-bribery and related prohibitions implemented under the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

10.2. <u>Avalo Representations and Warranties</u>. Avalo hereby represents and warrants to Licensee, as of the Effective Date, or covenants, as applicable, that:

10.2.1. **Avalo Intellectual Property; Regulatory Documentation**. Avalo Controls the Licensed Intellectual Property existing as of the Effective Date and is entitled to grant the licenses specified herein. The Licensed Patent Rights listed on <u>Schedule 1.1.38</u> constitute all of the Patent Rights Controlled by Avalo and its Affiliates as of the Effective Date that, but for the license granted by Section 2.1, would be infringed (or, in the case of patent applications, would be infringed if such patent applications were issued patents) by the Development, Manufacture or Commercialization of a Molecule or a Product, other than the MedImmune Patent Rights. The Licensed Know-How contained in the Data Room under the headings identified on <u>Schedule</u>

<u>1.1.37</u> includes, to the knowledge of Avalo, substantially all the Know-How Controlled by Avalo and its Affiliates as of the Effective Date with respect to the Molecules other than the MedImmune Know-How. Neither Avalo nor any of its Affiliates has previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Licensed Intellectual Property in a manner that conflicts with any rights purported to be granted to Licensee hereunder, and neither Avalo nor any of its Affiliates is under any obligation to make any such transfers, conveyances or encumbrances. Avalo owns the INDs with the following identifiers with respect to a Molecule or Product in existence as of the Effective Date: AOSD IND #145843 and MM IND #146653. Neither Avalo nor any of its Affiliates has granted any rights of reference under any Regulatory Documentation with respect to any Molecule or Product to any Third Party.

10.2.2. **In-License Agreements**. There are no agreements between Avalo or any Affiliate thereof and any Third Party licensors of either of the foregoing pursuant to which Avalo or its Affiliate has in-licensed any rights in the Licensed Intellectual Property as of the Effective Date, other than those Third Party agreements between Avalo or its Affiliate and a Third Party contractor that are included in the Data Room. Avalo and its Affiliates have, and will have throughout the Term, sufficient rights by ownership or contract to grant Licensee the rights purported to be granted under Section 2.1 to Licensed Intellectual Property.

10.2.3. **Infringement**. To the knowledge of Avalo, there is no actual or threatened infringement or misappropriation of the Licensed Intellectual Property in the Field in the Territory by any Third Party or any other infringement, misappropriation or threatened infringement or misappropriation that would adversely affect Licensee's rights under this Agreement.

10.2.4. Licensed Intellectual Property. The Licensed Patent Rights and MedImmune Patent Rights existing as of the Effective Date are subsisting and, to the knowledge of Avalo, are not invalid or unenforceable, in whole or in part and, to the knowledge of Avalo, are filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. The pending applications included in the Licensed Patent Rights and MedImmune Patent Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law and where required by such Applicable Law Avalo and its Affiliates have presented all material references, documents and information of which the inventors are aware to the relevant patent office. Each of the Licensed Patent Rights and, to the knowledge of Avalo, each of the MedImmune Patent Rights properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Patent Right is issued or such application is pending. To the knowledge of Avalo, each Person who has or has had any rights in or to any Licensed Intellectual Property or any Molecule or Product has assigned and has executed an agreement assigning its entire right, title and interest in and to such Licensed Intellectual Property, Molecule or Product. The inventions claimed by the Licensed Patent Rights (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401. There are no written claims asserted or, to Avalo's knowledge, threatened against Avalo or any of its Affiliates or judgments or settlements against or amounts with respect thereto owed by Avalo or any of its Affiliates relating to the Licensed Intellectual Property or a Molecule. No patent or patent application within the Licensed Patent Rights is the subject of any pending or, to the knowledge of Avalo, threatened interference, opposition, cancellation, protest, inventorship dispute or other challenge or adversarial

proceeding. The Licensed Know-How has been kept confidential by Avalo and its Affiliates and has been disclosed by Avalo and its Affiliates to Third Parties only under terms of confidentiality. To the knowledge of Avalo and its Affiliates, no breach of such confidentiality has been committed by any Third Party. The Licensed Intellectual Property is free of any and all liens, security interests and encumbrances, other than certain reserved nonexclusive rights for the benefit of academic or nonprofit institutions for publication, IRB, regulatory, legal, educational, patient care, and noncommercial research purposes, the nonexclusive nature of Avalo's or its Affiliates' rights to certain intellectual property rights to which ownership is otherwise retained by a Third Party contractor, and limited, non-exclusive license grants to Third Parties as set forth in those subcontract or clinical trial site contracts between Avalo (or its Affiliates) and Third Party subcontractors of Avalo or Third Party clinical trial sites, in each case included in the Data Room or established by Applicable Law. No claim or litigation has been brought or, to Avalo's knowledge, threatened by any Third Party alleging that (a) the Licensed Patent Rights are invalid, unpatentable or unenforceable, (b) the Licensed Intellectual Property or the licensing or exploiting of the Licensed Intellectual Property violates, infringes, misappropriates or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party has any right, title, or interest in, to, and under any Licensed Intellectual Property.

10.2.5. **Claims; Judgments**. There are no claims, judgments or settlements against or owed by Avalo or its Affiliates or pending or, to the knowledge of Avalo, threatened claims or litigation relating to the Licensed Intellectual Property.

10.2.6. **Disclosure**. To the knowledge of Avalo, Avalo has made available to Licensee all material information and data (including without limitation all communications with or from the FDA or any other Regulatory Authority) included in the Licensed Know-How and MedImmune Know-How of which it is aware, including that which relates to the results of Avalo's preclinical studies and clinical trials involving a Molecule, as well as all file wrappers and other documents and materials in Avalo's or its Affiliate's or their respective patent counsel's possession relating to the prosecution, defense, maintenance, validity and enforceability of the Licensed Patent Rights and MedImmune Patent Rights, other than freedom-to-operate or infringement analyses or related communications. Avalo has made available to Licensee all reports and data collections included in the Licensed Know-How containing material information about adverse safety issues (including adverse drug experiences) related to a Molecule of which Avalo has knowledge. Avalo represents that, to its knowledge, it has not failed to furnish Licensee with any material scientific or Licensed Intellectual Property-related information Controlled by Avalo and requested by Licensee that concerns a Molecule or Product. To Avalo's knowledge, there are no scientific or technical facts or scientific or technical circumstances that would reasonably be anticipated to materially adversely affect the scientific, therapeutic, or commercial potential of the Molecules or Products. Avalo does not have any knowledge of any material information regarding any Molecule or Product that would reasonably be anticipated to materially adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for any Regulatory Approval with respect to a Molecule or Product.

10.2.7. **Debarment and Compliance**. Neither Avalo, any of its Affiliates, any of their respective directors, officers, employees, or consultants, nor, to Avalo's knowledge based upon reasonable inquiry, any Third Party (and its directors, officers, employees and consultants), in each case who were responsible for the Development of the Product prior to the Effective Date: (a) is or was debarred under Section 306(a) or 306(b) of the FD&C Act; (b) has been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (i) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; or (ii) a conspiracy to commit, aid or abet the development or

approval of any drug product or regulation of any drug product; or (iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs. Avalo will promptly (and in any event, within one (1) Business Day) inform Licensee in writing if Avalo, any of its Affiliates, or any of their respective directors, officers, employees, consultants or subcontractors is the subject of any of the foregoing clauses (a) or (b) at any time during the Term. Avalo and its Affiliates have conducted and will conduct, and their respective contractors and consultants have conducted and will conduct, all Development of the Molecules and Products, in accordance with, to the extent reasonably applicable, good laboratory, manufacturing and clinical practice and Applicable Law in all material respects. Avalo and its Affiliates have employed (and, with respect to such tests and studies that Avalo will perform, will employ) Persons with reasonably appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and clinical studies with respect to the Molecules and Products.

10.2.8. **MedImmune License**. Avalo has provided Licensee with a complete and accurate copy of the MedImmune License, as such agreement is in effect as of the Effective Date, and Avalo has not materially breached and is not aware of any material breach of, the MedImmune License.

10.2.9. **No Untrue Statements of Material Fact.** To Avalo's knowledge, the representations and warranties of Avalo in this Agreement and the information, documents and materials furnished to Licensee in connection with its period of diligence prior to the Effective Date, do not, taken as a whole, (a) contain any untrue statement of a material fact or (b) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not materially misleading.

10.2.10. **No Conflict**. During the Term, neither Avalo nor any of its Affiliates will enter into any agreement that would prevent it from granting the rights purported to be granted to Licensee under this Agreement or from performing Avalo's obligations under this Agreement.

10.3. <u>Warranty Disclaimer</u>. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT OR THE NOVATION AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON- INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL. LICENSEE AGREES THAT, ASSUMING THE ACCURACY OF AVALO'S REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTION 10.1 AND SECTION 10.2, LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED INTELLECTUAL PROPERTY HAS APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF THE MOLECULES OR THE PRODUCTS AND ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

10.4. <u>No Consequential Damages</u>. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS, LOST BUSINESS, LOST OPPORTUNITY, OR LOST GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 10.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY'S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING CONFIDENTIALITY UNDER ARTICLE 8.

## 10.5. Indemnification and Insurance.

10.5.1. **Indemnification by Licensee**. Licensee shall indemnify, hold harmless, and defend Avalo, its Affiliates, and their respective directors, officers, employees and agents ("*Avalo Indemnitees*") from and against any and all damages, settlements, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorneys' fees) or judgments of any kind (collectively, "*Losses*") arising out of any Third Party claim, suit or proceeding, whether for money or equitable relief (each, a "*Third Party Claim*") against any Avalo Indemnitee to the extent arising out of or resulting from, directly or indirectly: (a) any breach of, or inaccuracy in, any representation or warranty made by Licensee in this Agreement or the Novation Agreement, or any breach or violation of any covenant or agreement of Licensee, any of its Affiliates, or any Sublicensees in or pursuant to this Agreement or the Novation Agreement, (b) the negligence, willful misconduct, or failure to comply with Applicable Law by or of Licensee, its Affiliates, any Sublicensees of any of the foregoing, or their respective directors, officers, employees and agents, or (c) the Development, Manufacturing or Commercialization of any Molecule or Product by or on behalf of Licensee, its Affiliates, or Sublicensees (including product liability or claims of intellectual property infringement or misappropriation); provided that Licensee shall not have any obligations hereunder with respect to any Losses or Third Party Claims to the extent resulting from any of the circumstances described in clause (a), (b) or (c) of Section 10.5.2.

10.5.2. **Indemnification by Avalo**. Avalo shall indemnify, hold harmless, and defend Licensee, its Affiliates and their respective directors, managers, officers, employees and agents ("*Licensee Indemnitees*") from and against any and all Losses arising out of any Third Party Claims against any Licensee Indemnitee to the extent arising out of or resulting from, directly or indirectly, (a) any breach of, or inaccuracy in, any representation or warranty made by Avalo in this Agreement, or any breach or violation of any covenant or agreement of Avalo in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of Avalo, its Affiliates, and their respective directors, officers, employees and agents, (c) the Development, Manufacture, or Commercialization of any Product by or on behalf of Avalo or its Affiliates or licensees prior to the Effective Date, or (d) any Liabilities and Obligations (as defined in the Novation Agreement) arising from performance or non-performance of the MedImmune License by or on behalf of Avalo prior to the Novation Effective Date (as defined in the Novation Agreement); provided that Avalo shall not have any obligations hereunder with respect to any Losses or Third Party Claims to the extent resulting from any of the circumstances described in clause (a) or (b) of Section 10.5.1.

10.5.3. **Indemnification Procedure**. In the event of any Third Party Claim against any Licensee Indemnitee or Avalo Indemnitee (respectively, individually, an "*Indemnitee*"), the indemnified Party shall promptly notify the other Party in writing of the claim and the indemnifying Party shall manage and control, at its sole expense, the investigation and defense of the Third Party Claim and its settlement; <u>provided</u> that the failure to so notify promptly shall not

relieve the indemnifying Party of its obligations under this Section 10.5 except to the extent of the actual prejudice suffered by such Party as a result of such failure. The Indemnitee shall reasonably cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choosing. The indemnifying Party shall not be liable for any settlements or voluntary dispositions of any Third Party Claim entered into by any Indemnitee without the indemnifying Party's written authorization, such authorization not to be unreasonably withheld. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Section 10.5.1 or Section 10.5.2 may apply, the indemnifying Party shall promptly notify the Indemnifying Party shall then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party shall be for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. The indemnifying Party shall be free to settle or enter into any voluntary disposition of any Third Party Claims subject to indemnification by it hereunder, except for any such settlement or voluntary disposition that adversely affects any Licensed Intellectual Property or imposes non-indemnified liability or admits fault or wrongdoing on the part of any Indemnitee, which will require the consent of the applicable Indemnitee(s).

#### **ARTICLE 11**

#### **MISCELLANEOUS PROVISIONS**

11.1. <u>Governing Law</u>. This Agreement shall be construed, and the respective rights of the Parties determined according to the substantive laws of the State of Delaware notwithstanding the provisions governing conflict of laws under the law of any jurisdiction to the contrary.

#### 11.2. Jurisdiction; Venue; Service of Process.

11.2.1. **Jurisdiction**. Each Party by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the state courts of the State of Delaware or the United States District Court with jurisdiction over Delaware for the purpose of any claim, controversy, action, cause of action, suit or litigation ("*Action*") between the Parties arising in whole or in part under or in connection with this Agreement, (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such Action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such Action brought in one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court and (c) hereby agrees not to commence any such Action other than before one of the above-named courts. Notwithstanding the previous sentence, a Party may commence any Action in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts or to obtain emergency or temporary injunctive relief.

11.2.2. Venue. Each Party agrees that for any Action between the Parties arising in whole or in part under or in connection with this Agreement, such Party may bring Actions only in the State of Delaware. Each Party further waives any claim and shall not assert that venue should properly lie in any other location within the selected jurisdiction.

11.2.3. Service of Process. Each Party hereby (a) consents to service of process in any Action between the Parties arising in whole or in part under or in connection with this Agreement in any manner permitted by Delaware law, (b) agrees that service of process made in accordance with clause (a) or made by registered or certified mail, return receipt requested, at its address specified pursuant to Section 11.5, shall constitute good and valid service of process in any such Action and (c) waives and agrees not to assert (by way of motion, as a defense, or otherwise) in any such Action any claim that service of process made in accordance with clause (a) or (b) does not constitute good and valid service of process.

11.3. <u>Assignment</u>. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior, written consent of the other Party. Notwithstanding the foregoing, (a) Avalo may monetize the value of its royalty stream, Milestone Payments and other payments under this Agreement by assigning to a Third Party the right to receive royalties, Milestone Payments and other payments and the right to receive royalty reports from Licensee, <u>provided</u> that Avalo gives ten (10) Business Days' prior written notice to Licensee, and (b) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of the assigning Party or pursuant to a Change of Control, <u>provided</u> that, in the case of an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by its Affiliate of this Agreement or any obligations hereunder so assigned to such assignee. Without limiting the foregoing, Avalo shall not assign any of its rights in or to the Licensed Intellectual Property to any Third Party other than a Third Party to which it is assigning this Agreement in its entirety. Any assignment in violation of this Section 11.3 will be null and void.

11.4. <u>Amendments</u>. This Agreement, the Novation Agreement, and the Schedules and Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.

11.5. <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and (a) delivered by hand, or (b) sent by internationally recognized delivery service and shall be deemed to have been properly served to the addressee upon receipt of such written communication or refusal to accept delivery, to the following addresses:

If to Avalo:	Avalo Therapeutics, Inc. 1500 Liberty Ridge Drive Suite 321 Wayne, PA 19087, U.S.A. Attn: (***)
with a copy (which shall not constitute notice) to:	Avalo Therapeutics, Inc. 1500 Liberty Ridge Drive Suite 321 Wayne, PA 19087, U.S.A. Attn: CEO
	Wyrick Robbins Yates & Ponton LLP 4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607, U.S.A. Attn: (***)
If to Licensee:	Apollo AP43 Limited 24 Hills Road Cambridge, CB2 1JP, UK
with a copy (which shall not constitute notice) to:	Ropes & Gray LLP 1900 University Avenue 6th Floor East Palo Alto, CA 94303-2284, U.S.A. Attention: (***)

Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided.

11.6. Force Majeure. The failure of either Party to timely perform any obligation under this Agreement by reason of epidemic or pandemic, earthquake, riot, civil commotion, fire, act of God, war, terrorist act, strike, flood, or governmental act or restriction, or other cause that is beyond the reasonable control of and without the fault or negligence of the respective Party (such reasons or causes being "*Force Majeure*"), shall not be deemed to be a material breach of this Agreement, but shall be excused to the extent and for the duration of such Force Majeure, and the affected Party shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and shall use its Commercially Reasonable Efforts to avoid or remove such Force Majeure. If the performance of any such obligation under this Agreement is delayed owing to Force Majeure for any continuous period of more than one hundred eighty (180) days, the Parties shall consult with respect to an equitable solution.

11.7. <u>Compliance with Export Regulations</u>. Neither Party shall export any technology licensed to it by the other Party under this Agreement except in compliance with US export laws and regulations.

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11.8. Independent Contractors. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Avalo or Licensee to act as agent for the other. Nothing in this Agreement shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

11.9. <u>Further Assurances</u>. Each Party shall execute, acknowledge or deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

11.10. No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

11.11. <u>Performance by Affiliates</u>. Avalo recognizes that Licensee may perform some or all of its obligations under this Agreement through Affiliates; <u>provided</u>, <u>however</u>, that Licensee will remain responsible for the acts and omissions of its Affiliates as if such acts omissions were those of Licensee.

11.12. <u>Construction</u>. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description that precedes such term, and will be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import regardless of whether such words are actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after the word "including" but not others). References to "Article", "Articles", "Section", "Sections", "Schedule" or "Schedule" "Exhibit" or "Exhibits" are references to the numbered Article(s), Section(s), Schedule(s) or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, (a) references to a particular law, rule or regulation mean such law, rule or regulation as in effect as of the relevant time, including all rules and regulations thereunder and any successor law, rule or regulation as the phrase "and/or"; (c) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (d) references to a particular person or entity include such person's or entity's successors and assigns to the extent not prohibited by this Agreement; (e) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative mann

11.13. <u>Headings</u>. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

11.14. <u>No Implied Waivers; Rights Cumulative</u>. No failure on the part of Avalo or Licensee to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege.

11.15. <u>Severability</u>. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

11.16. <u>No Third Party Beneficiaries</u>. No Person, other than Licensee, Avalo and their respective Affiliates and the Indemnitees under ARTICLE 10 and any permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

11.17. <u>Dispute Resolution</u>. With respect to any disputes between the Parties concerning this Agreement, the dispute shall be submitted to escalating levels of Licensee and Avalo senior management for review. If the dispute cannot be resolved despite such escalation, then the matter may be referred by either Party to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers shall be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party will be free to pursue all rights available to it under law or equity, <u>provided</u> that it has complied with this Section 11.17. Notwithstanding the foregoing, either Party may seek emergency or temporary injunctive or equitable relief in any court of competent jurisdiction.

11.18. <u>Entire Agreement</u>. This Agreement (including all exhibits and schedules hereto) and the Novation Agreement constitute the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral and written, among the Parties with respect to the subject matter hereof. This Agreement hereby supersedes the Confidentiality Agreement.

11.19. <u>Execution in Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Signatures provided by facsimile transmission, in Adobe<sup>TM</sup> Portable Document Format (PDF) sent by electronic mail, or other reasonable electronic form (e.g., DocuSign<sup>TM</sup>) shall be deemed to be original signatures.

#### (Signature page follows)

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the Effective Date.

AVALO THERAPEUTICS, INC.

By:/s/ Garry Neil, M.D.Name:Dr. Garry Neil, M.D.Title:Chief Executive Officer

APOLLO AP43 LIMITED

By:

Name:

Title:

/s/ Richard Mason Dr. Richard Mason Chief Executive Officer

[Signature Page to License Agreement]

Exhibit 10.3

# PURCHASE AGREEMENT BY AND AMONG AVALO THERAPEUTICS, INC., AND ES THERAPEUTICS, LLC

# DATED AS OF NOVEMBER 4, 2022

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#### PURCHASE AGREEMENT

This PURCHASE AGREEMENT, dated as of November 4, 2022 (this "*Agreement*"), is made and entered into by and among Avalo Therapeutics, Inc., a Delaware corporation ("*Seller*"), and ES Therapeutics, LLC, a Delaware limited liability company (the "*Buyer*"). Terms with initial capitalized letters not otherwise defined in this Agreement have the meaning ascribed to them in <u>Section 8.1</u>.

#### RECITALS:

1. Pursuant to the Asset Purchase Agreement, dated August 14, 2017, by and between Janssen Pharmaceuticals, Inc. ("*Janssen*") and the Seller, formerly known as Cerecor Inc. (the "*Janssen Agreement*"), the Seller is entitled to receive a Milestone Payment (as defined in the Janssen Agreement) (the "*Janssen Milestone Payment*") upon the filing and acceptance of an new drug application for, or other equivalent application to sell, a pharmaceutical product containing the Compound (as defined in the Janssen Agreement) in the United States by Janssen.

2. Pursuant to the License Agreement, dated July 29, 2022, by and between Apollo AP43 Limited ("*Apollo*") and the Seller (the "*Apollo Agreement*"), the Seller is entitled to receive a Milestone Payment (as defined in the Apollo Agreement) (the "*Apollo Milestone Payment*") upon the achievement of any Milestone Event (as defined in the Apollo Agreement), and a royalty payment equal to the applicable percentage of Annual Net Sales (as defined and as set forth in the Apollo Agreement) (the "*Apollo Royalty Payment*") of a product containing the Molecule (as defined in the Apollo Agreement), alone or in combination with one or more other active pharmaceutical ingredients.

3. Pursuant to the Assignment of License Agreement, dated August 8, 2019, by and between the Seller, Buyer and Armistice Capital Master Fund Ltd. (the "*ES License Agreement*"), the Seller transferred to the Buyer all of the Seller's rights and interests in a License Agreement, dated February 18, 2015, by and between Seller, formerly known as Cerecor Inc., and Eli Lilly and Company, for and in consideration of a series of payments owed by Buyer to Seller (the "*ES License Payments*"), of which such payments have not been paid in full by Buyer as of the date hereof.

4. The Seller desires to sell, assign, transfer, and convey the Payment Rights described below, and the Buyer desires to purchase, acquire, accept and assume from the Seller, the Payment Rights described below, upon and subject to the terms and conditions set forth in this Agreement.

5. In addition to the sale, assignment, transfer, and conveyance of the Payment Rights, Seller desires to waive any further obligations for future payments owed by Buyer to Seller under the ES License Agreement.

THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Seller and the Buyer hereby agree as follows:



#### ARTICLE 1

#### PURCHASE, SALE AND ASSIGNMENT OF THE AGREEMENTS

#### Section 1.1 Purchase, Sale and Assignment; Waiver of Payment Rights.

(a) Upon the terms and subject to the conditions of this Agreement, at the Closing, the Seller shall sell, transfer, assign and convey to the Buyer, and the Buyer shall purchase, acquire and accept from the Seller, the Seller's right to receive the Janssen Milestone Payment, as defined and set forth in the Janssen Agreement, arising on or after a Milestone Event (as defined in the Janssen Agreement) (collectively, the "Janssen Payment Rights").

(b) Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller shall sell, transfer, assign and convey to the Buyer, and the Buyer shall purchase, acquire and accept from the Seller, the Seller's right to receive the Milestone Payment and all royalty payments, as defined and set forth in the Apollo Agreement, arising on and after a Milestone Event and during the Royalty Term (both as defined by the Apollo Agreement (collectively, the "*Apollo Payment Rights*," and together with the Janssen Payment Rights, the "*Payment Rights*").

(c) Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller shall waive any and all right, title and interest in and to the ES License Payments, and Buyer shall have no further obligation to make the ES License Payments that are currently outstanding and owed to Seller in accordance with the ES License Agreement as of Closing.

Section 1.2 <u>Purchase Price</u>. The purchase price to be paid to the Seller for the sale, transfer, assignment and conveyance of the Seller's right, title and interest in and to the Payment Rights to the Buyer is collectively Five Million Dollars (\$5,000,000.00) (the "*Purchase Price*").

Section 1.3 <u>Sale</u>. It is the intention of the parties hereto that the sale, transfer, assignment and conveyance contemplated by this Agreement shall constitute a sale of the Payment Rights from the Seller to Buyer and not a financing transaction, borrowing or loan; and accordingly, the Seller and the Buyer will treat the sale, transfer, assignment and conveyance of the Payment Rights as sales of "accounts" in accordance with the UCC for accounting purposes.

#### ARTICLE 2

#### CLOSING

Section 2.1 <u>Closing</u>. The Closing shall take place remotely by exchange of electronic copies of the agreements, documents, certificates and other instruments set forth in this <u>Agreement</u> on the first Business Day following satisfaction of all Closing conditions (other than those that by their terms are to be satisfied or taken at the Closing) set forth in this <u>Article 2</u>.

Section 2.2 <u>Payment of Purchase Price</u>. At the Closing, the Buyer shall deliver (or cause to be delivered) payment of the Purchase Price to Seller, by wire transfer of immediately available funds to an account specified by the Seller in writing at least two Business Days prior to the Closing Date.

Section 2.3 <u>Conditions to the Buyer's Obligations</u>. The obligations of the Buyer to consummate the transactions contemplated hereunder on the Closing Date are subject to the

satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) The representations and warranties of Seller contained in <u>Section 3.1</u> must be true and correct in all material respects as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date), and the Buyer must have received a certificate executed by an authorized person of Seller on the Closing Date certifying on behalf of such Seller to the effect of the foregoing.

(b) There must not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(c) There must not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person challenging or seeking to make illegal, to delay materially or otherwise restrain or prohibit the consummation of the transactions contemplated hereby.

(d) At the Closing the Seller must have delivered to the Buyer a duly executed bill of sale, assignment, and assumption agreement evidencing the sale, transfer, assignment and conveyance of the Payment Rights, in substantially the form attached hereto as Exhibit  $\underline{A}$  (the "*Conveyance Agreement*").

(e) At the Closing, the Seller must have delivered to the Buyer a duly executed consent from Janssen (or its Affiliate with rights to consent on its behalf) consenting to the sale of the Janssen Payment Rights pursuant to this Agreement (the "Janssen Consent").

(f) At the Closing the Seller must have received a fairness opinion from a financial advisor chosen at Seller's sole discretion and in form and substance satisfactory to Seller in connection with this Agreement and the transactions contemplated hereby, stating, among other things, that the Purchase Price to be paid hereunder is fair, from a financial perspective, to the stockholders of the Seller.

(g) At the Closing, the Seller shall have delivered to the Buyer a certificate of an authorized person of such Seller, dated as of the Closing Date, (i) certifying as to the incumbency of the authorized person of such Seller executing this Agreement, (ii) containing copies of the resolutions or written consents of such Seller authorizing the execution, delivery, and performance of this Agreement and certifying that such resolutions are in full force and effect.

(h) At the Closing, all Liens of Seller's lenders relating to the Payment Rights, including the Venture Loan and Security Agreement, dated June 4, 2021, by and between Horizon Technology Finance Corporation, Powerscourt Investments XXV, LP, Seller (formerly known as Cerecor Inc.), and each subsidiary listed on Schedule 1 attached thereto, shall be released and there shall be no Lien with respect to the Payment Rights except those, if any, which will arise as a result of Buyer's actions in the consummation of the Closing and those in favor of Buyer.

Section 2.4 <u>Conditions to Seller's Obligations</u>. The obligations of the Seller to consummate the transactions contemplated hereunder on the Closing Date are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) The representations and warranties of the Buyer contained in <u>Section 3.2</u> must be true and correct in all material respects as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date), and the Seller must have received a certificate executed by a duly authorized officer of the Buyer on the Closing Date certifying on behalf of the Buyer to the effect of the foregoing.

(b) There must not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(c) There must not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person challenging or seeking to make illegal, to delay materially or otherwise to restrain or prohibit the consummation of the transactions contemplated hereby.

(d) At the Closing, the Buyer must have delivered to the Seller a counterpart signature page to the Conveyance Agreement, duly executed by Buyer.

(e) At the Closing the Seller must have received a fairness opinion from a financial advisor chosen at Seller's sole discretion and in form and substance satisfactory to Seller in connection with this Agreement and the transactions contemplated hereby, stating, among other things, that the Purchase Price to be paid hereunder is fair, from a financial perspective, to the stockholders of the Seller.

(f) At the Closing, the Buyer must have delivered to the Seller a certificate of an authorized person of Buyer, dated as of the Closing Date, certifying as to (i) the incumbency of the officers executing this Agreement on behalf of the Buyer (ii) containing copies of the resolutions or written consents of the Buyer authorizing the execution, delivery, and performance of this Agreement and certifying that such resolutions are in full force and effect.

(g) At the Closing, all Liens of Seller's lenders relating to the Payment Rights, including the Venture Loan and Security Agreement, dated June 4, 2021, by and between Horizon Technology Finance Corporation, Powerscourt Investments XXV, LP, Seller (formerly known as Cerecor Inc.), and each subsidiary listed on Schedule 1 attached thereto, shall be released and there shall be no Lien with respect to the Payment Rights except those, if any, which will arise as a result of Buyer's actions in the consummation of the Closing and those in favor of Buyer.

## ARTICLE 3

#### REPRESENTATIONS AND WARRANTIES

Section 3.1 <u>Seller's Representations and Warranties</u>. Seller represents and warrants to the Buyer as of the date hereof as follows:

(a) <u>Existence: Good Standing</u>. Seller is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. Seller is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the nature of the business conducted by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a material adverse effect

on the Payment Rights, or Seller's ability to enter into and to perform its obligations under this Agreement.

(b) <u>Authorization</u>. Seller has all requisite entity power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary entity action on the part of Seller.

(c) <u>Enforceability</u>. This Agreement has been duly executed and delivered by an authorized person of Seller and constitutes the valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) <u>No Conflicts</u>. The execution, delivery and performance by Seller of this Agreement and the consummation of the transactions contemplated hereby do not and will not (i) contravene or conflict with the certificate of incorporation of Seller, (ii) contravene or conflict with or constitute a material default under any law or Judgment binding upon or applicable to Seller, (iii) contravene or conflict with or constitute a default under the Janssen Agreement or Apollo Agreement, as applicable, or (iv) except as would not reasonably be expected to result in a material adverse effect on Seller's ability to perform its obligations under this Agreement, contravene or conflict with or constitute a material default under any other material contract binding upon Seller.

(e) <u>Consents</u>. Except for the consents that have been obtained and the notices delivered on or prior to the Closing or filings required by the federal securities laws or stock exchange rules, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by Seller in connection with (i) the execution and delivery by Seller of this Agreement, (ii) the performance by Seller of its obligations under this Agreement or (iii) the consummation by Seller of any of the transactions contemplated by this Agreement.

(f) <u>No Litigation</u>. There is no action, suit, investigation or proceeding pending before any Governmental Entity or, to the Knowledge of the Seller, threatened to which Seller is a party that, individually or in the aggregate would, if determined adversely, reasonably be expected to prevent or adversely affect (i) the ability of Seller to enter into and to perform its obligations under this Agreement, or (ii) Seller's rights under the Apollo Agreement or Janssen Agreement, as applicable. To the Knowledge of the Seller, no event has occurred or circumstance exists that is reasonably likely to give rise to or serve as a basis for the commencement of any such action, suit, investigation or proceeding.

(g) <u>Compliance with Laws</u>. Seller is not in violation of, and to the Knowledge of the Seller, Seller is not under investigation with respect to, nor has Seller been threatened in writing to be charged with or given written notice of any violation of, any law or Judgment applicable to the Seller, which violation would reasonably be expected to adversely affect Seller's rights in respect of the Payment Rights.

(h) <u>Delivery of Apollo Agreement and Janssen Agreement</u>. Seller has delivered a true, correct, and complete copy of the Apollo Agreement and the Janssen Agreement to Buyer, together with all exhibits, schedules and other attachments thereto and all amendments and modifications thereto as of the Closing Date.

(i) <u>Validity and Enforceability of Agreements; Waiver</u>. The Apollo Agreement and Janssen Agreement are valid and binding obligations of Seller. The Apollo

Agreement and Janssen Agreement are enforceable against Seller and, to the Knowledge of the Seller, Apollo and Janssen, respectively, in each case in accordance with the Apollo Agreement and Janssen Agreement terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law). Seller has not received any written notice in connection with the Apollo Agreement or the Janssen Agreement challenging the validity, enforceability or interpretation of any provision of such agreement, including the obligation to pay any portion of the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment.

(j) Notices. Seller has made available to the Buyer (i) all material written notices since July 29, 2022, from Apollo or any of its Affiliates to Seller (or any of its Affiliates) pursuant to or relating to the Apollo Agreement, and (ii) all material written notices since July 29, 2022, from Seller or any of its Affiliates to Apollo or any of its Affiliates pursuant to or relating to the Apollo Agreement. Seller has made available to the Buyer (i) all material written notices since August 14, 2017, from Janssen or any of its Affiliates to Seller (or any of its Affiliates) pursuant to or relating to the Janssen Agreement, and (ii) all material written notices since August 14, 2017, from Seller or any of its Affiliates to Janssen or any of its Affiliates pursuant to or relating to the Janssen Agreement.

(k) <u>No Liens or Assignments by Seller; Title</u>. Except as contemplated by this Agreement, Seller has not conveyed, assigned or otherwise transferred or granted any Liens (other than Permitted Liens) upon all or any portion of its right, title and interest in and to the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment.

(1) <u>No Termination</u>. Seller has not (i) given Apollo or Janssen any written notice of termination of the Apollo Agreement or the Janssen Agreement (whether in whole or in part), respectively, or any written notice expressing any intention or desire to terminate the Apollo Agreement or the Janssen Agreement, or (ii) received any written notice of termination of the Apollo Agreement or Janssen Agreement (whether in whole or in part) or any written notice expressing any intention or desire to terminate the Janssen Agreement. To the Knowledge of the Seller, no event has occurred and is continuing that would give any party to the Apollo Agreement or the Janssen Agreement or Janssen Agreement or

(m) <u>No Breaches or Defaults</u>. There is and has been no material breach or default under the Apollo Agreement or Janssen Agreement either by Seller (or any predecessor thereof) or, to the Knowledge of the Seller, by Apollo or Janssen (or any predecessor thereof).

(n) Intellectual Property Challenges. Seller has not received any written notice from Apollo or Janssen of any claim by any Person regarding a challenge of inventorship or ownership of, the rights of Apollo or Janssen in and to, or the patentability, validity or enforceability of, any material patent related to the Molecule (as defined in the Apollo Agreement) or the Compound (as defined in the Janssen Agreement) (collectively, the "*Products*"), or asserting that the development, manufacture, importation, sale, offer for sale or use of the Products infringe any patent.

(o) <u>Brokers' Fees</u>. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Seller who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 3.2 <u>Buyer's Representations and Warranties</u>. The Buyer represents and warrants to the Seller that as of the date hereof:

(a) <u>Existence: Good Standing</u>. The Buyer is a limited liability company organized, validly existing and in good standing under the laws of the State of Delaware.

(b) <u>Authorization</u>. The Buyer has the requisite limited liability company right, power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary action on the part of the Buyer.

(c) <u>Enforceability</u>. This Agreement has been duly executed and delivered by an authorized person of the Buyer and constitutes the valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) <u>No Conflicts</u>. The execution, delivery and performance by the Buyer of this Agreement does not and will not (i) contravene or conflict with the organizational documents of the Buyer, (ii) contravene or conflict with or constitute a default under any material provision of any law binding upon or applicable to the Buyer or (iii) contravene or conflict with or constitute a default under any material contract or other material agreement or Judgment binding upon or applicable to the Buyer.

(e) <u>Consents</u>. No consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Buyer in connection with (i) the execution and delivery by the Buyer of this Agreement, (ii) the performance by the Buyer of its obligations under this Agreement, or (iii) the consummation by the Buyer of any of the transactions contemplated by this Agreement.

(f) <u>No Litigation</u>. There is no action, suit, investigation or proceeding pending or, to the knowledge of the Buyer, threatened before any Governmental Entity to which the Buyer is a party that would, if determined adversely, reasonably be expected to prevent or materially and adversely affect the ability of the Buyer to perform its obligations under this Agreement.

(g) <u>Financing</u>. The Buyer has sufficient cash on hand to pay the entire Purchase Price. The Buyer acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

(h) <u>Brokers' Fees</u>. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Buyer who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(i) <u>Investigation by the Buyer</u>. The Buyer has conducted its own independent investigation, verification, review, and analysis of the Payment Rights and prospects for the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment. In entering into this Agreement, the Buyer acknowledges that it has relied solely on the aforementioned investigation, verification, review, and analysis and not on any factual representation, warranty, inducement, promise, understanding, omission, condition or opinion of the Seller or any of its Affiliates or respective Representatives.

Section 3.3 No Implied Representations and Warranties.

(a) Except as expressly set forth in <u>Section 3.1</u>, Seller makes (and the Buyer acknowledges that Seller makes) no representation or warranty, expressed or implied, at law or in equity, in respect of the Apollo Agreement and the Janssen Agreement, any payments owed or owing, or that might become due, under the Apollo Agreement and the Janssen Agreement, any projections for receiving the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment owed or owing, or that might become due, thereunder, or the transactions contemplated hereby, including with respect to merchantability or fitness for any particular purpose or any other representation or warranties, and any such other representations or warranties are hereby expressly disclaimed.

(b) Except as expressly set forth in <u>Section 3.2</u>, the Buyer makes (and the Seller acknowledges that the Buyer makes) no representation or warranty, expressed or implied, at law or in equity, and any such other representations or warranties are hereby expressly disclaimed.

#### **ARTICLE 4**

#### COVENANTS

Section 4.1 <u>Disclosures</u>. Neither the Buyer nor the Seller may issue a press release or other public announcement, or otherwise make any public disclosure with respect to this Agreement or the subject matter hereof, without the prior written consent of the other party hereto (which consent may not be unreasonably withheld or delayed), except as may be required by applicable law or stock exchange rule (in which case the party hereto required to make the press release or other public announcement or disclosure shall allow the other parties hereto reasonable time to comment on such press release or other public announcement or disclosure in advance of such issuance, to the extent practicable); except that no review or consent is required in respect of disclosures by any party of the Agreement and the transaction in such party's periodic reports filed with the U.S. Securities and Exchange Commission or if the disclosures were previously approved pursuant to this <u>Section 4.1</u>; it being understood that Seller is a public company and this Agreement may be filed as an exhibit to a Form 8-K or other filing by Seller. Either party may disclose the terms of this Agreement to its current and potential shareholders, members, and their Affiliates and Representatives in accordance with <u>Article 5</u> below. Buyer acknowledges that Seller's securities are publicly traded. Buyer agrees that so long as it possesses any Confidential Information (as defined below) about Seller that may be considered "material non-public information" for purposes of the U.S. federal securities laws, Buyer and its Representatives and Affiliates, shall not purchase, sell or otherwise trade in, directly or indirectly, publicly or privately, Seller's securities.

Section 4.2 <u>Efforts to Consummate Transactions</u>. Subject to the terms and conditions of this Agreement, Seller and the Buyer shall use its commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things reasonably necessary under applicable law to consummate the transactions contemplated by this Agreement.

Section 4.3 <u>Further Assurances</u>. After the Closing, the Seller and the Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to the transactions contemplated by this Agreement.

#### ARTICLE 5

#### CONFIDENTIALITY

#### Section 5.1 Confidentiality.

(a) Except as specifically provided herein or as necessary for the proper exercise of its rights and obligations under this Agreement, the Janssen Agreement, the Apollo Agreement, or as required under any applicable law or as reasonably necessary (as determined by the Person required to defend the claim) for the Buyer or Seller to defend any claim with any Governmental Entity, each party shall keep confidential, use at least the same standard of care as it uses to protect its own proprietary or confidential information (but in no event less than reasonable care), and not disclose to any Person (other than its Affiliates and its Affiliates' Representatives), and shall cause its Affiliates and its Affiliates' Representatives to keep confidential and not disclose to any Person, all Confidential Information.

(b) "Confidential Information" means all information of either Buyer or Seller concerning, or relating to, this Agreement, the Janssen Agreement, or the Apollo Agreement, including (i) any license, sublicense or other agreements involving or relating to the, Apollo Milestone Payment, Apollo Royalty Payment, Janssen Milestone Payment, or the intellectual property, compounds or products giving rise to the Apollo Milestone Payment, notices, correspondence or other information furnished pursuant to or in contemplation of this Agreement and any other reports, notices, correspondence or documents relating to this Agreement, the Janssen Agreement, the Apollo Agreement, or the intellectual property, compounds or products giving rise to the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment, including the Products, (iii) any inventions, devices, improvements, formulations, discoveries, compositions, ingredients, patent applications, know-how, processes, trial results, research, developments or any other intellectual property, trade secrets or information involving or relating to the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment, compounds or products giving rise to the Apollo Royalty Payment, Janssen Milestone Payment, or the intellectual property, compounds or products, (iii) any inventions, devices, improvements or any other intellectual property, trade secrets or information involving or relating to the Apollo Milestone Payment, Apollo Royalty Payment, or Janssen Milestone Payment, including the Products; (iv) creative properties, technology, intellectual property assets, financial or business plans and affairs, financial statements, internal management tools and systems, products and product development plans, marketing plans, customers, clients and contracts; (v) information and materials designated by either Party as confidential either orally or by means of appropriate markings; or (vi) information a

(c) Notwithstanding the foregoing, "Confidential Information" does not include any information that the party receiving such information can demonstrate by competent written evidence (i) was at the time of disclosure to it (or thereafter becomes, without breach of this Agreement by such party or its Affiliates) a part of the public domain by publication or otherwise; (ii) was already properly and lawfully in its possession at the time it was received from the other party; (iii) was lawfully received from a third party who, to the knowledge of such party, was under no legal, contractual, or fiduciary obligation of confidentiality to the disclosing party with respect thereto; (iv) is independently invented, discovered or developed by the receiving party without use or reference to such information, or (v) is published in the public domain with the mutual agreement of the parties.

(d) Notwithstanding anything herein to the contrary, nothing in this <u>Section 5.1</u> restricts the Buyer or Seller from disclosing the existence of this Agreement, the Purchase Price, or other material information about this Agreement and the nature thereof to any

of Buyer's or such Seller's respective Representative, equityholders, investors, bondholders, and prospective equityholders and investors in connection with the transactions contemplated hereby and any ordinary-course fundraising, reporting, and other activities so long as such Persons are informed of the confidential nature of such Confidential Information and are directed to comply with the confidentiality obligations hereunder.

Section 5.2 <u>Authorized Disclosure</u>. Any party or its Affiliates may disclose Confidential Information to the extent such disclosure is reasonably necessary in the following situations:

(a) prosecuting or defending litigation;

(b) complying with applicable laws and regulations, including regulations promulgated by a stock market or securities exchanges;

- (c) complying with a valid order of a court of competent jurisdiction or other Governmental Entity;
- (d) for regulatory, tax or customs purposes;
- (e) in connection with a routine examination by a regulatory authority having or asserting jurisdiction over it; and

(f) for audit purposes, provided that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure.

Section 5.3 <u>Janssen Agreement Confidentiality</u>. Anything in this Agreement to the contrary notwithstanding, as a condition to inducing Janssen to provide the Janssen Consent, Buyer agrees to comply with the provisions of Section 5.1(a) of the Janssen Agreement as though Buyer were "Seller" as used in Section 5.1(a) of the Janssen Agreement.

## ARTICLE 6

#### INDEMNIFICATION

Section 6.1 <u>Survival of Representations, Warranties and Covenants</u>. The representations and warranties of the parties contained herein shall survive for twelve (12) months after the Closing Date. All covenants and agreements which by their terms survive, or otherwise contemplate performance after, the Closing Date shall survive for the period in which they are required to be performed.

Section 6.2 <u>Obligation of Seller to Indemnify – Third Party Claims</u>. From and after the Closing, and subject to the limitations set forth in this <u>Article 6</u>, the Seller shall indemnify, defend and hold harmless the Buyer, its Affiliates and their respective employees, officers, directors, managers, members, shareholders, Representatives, agents and successors and assigns (each, a "*Buyer Indemnified Party*") from and against any and all Losses incurred by any of them, to the extent arising or resulting from any action, suit, investigation or proceeding threatened or asserted by a Person or any Governmental Entity related in any way to the transactions contemplated hereunder.

Section 6.3 <u>Obligation of Seller to Indemnify – Other Claims</u> From and after the Closing, and subject to the limitations set forth in this <u>Article 6</u>, the Seller shall indemnify, defend and hold harmless the Buyer Indemnified Parties from and against any and all Losses incurred by any of them, to the extent arising or resulting from any of the following:

(a) any misrepresentation, breach of or inaccuracy in any representation or warranty made by Seller in this Agreement;

(b) any breach or failure by Seller to perform or observe, or to have performed or observed, any covenant, agreement or condition to be performed or observed by it under this Agreement; and

(c) Fraud of Seller in connection with this Agreement.

Section 6.4 Limitations.

(a) A Buyer Indemnified Party will not be entitled to any indemnification by the Seller under this Article 6 (including Section 6.2) to the extent it is determined by a court of competent jurisdiction that the Losses arose out of the Buyer Indemnified Party's gross negligence or fraud committed in connection with the parties' entry into this Agreement and the transactions contemplated hereunder; provided, however, this Section 6.4(a) shall only apply to the extent the conduct constituting gross negligence or fraud by the Buyer Indemnified Party occurred solely on or after September 21, 2022.

(b) Notwithstanding anything to the contrary herein, in no event shall the maximum aggregate liability of such Seller under this Agreement for any Losses arising under or pursuant to this <u>Article 6</u>, or for any claims made by Buyer pursuant to this <u>Article 6</u> (including, without limitation, with respect to breaches of the Seller Fundamental Representations or any action, suit, investigation or proceeding threatened or asserted by a Person or any Governmental Entity related in any way to the transactions contemplated hereunder) exceed the Purchase Price, and the Seller will have no liability for such Losses in excess of the Purchase Price actually received by Seller.

Section 6.5 Procedures Relating to Indemnification for Third Party Claims.

(a) <u>Notice of Third Party Claim</u>. In order for a Buyer Indemnified Party to be entitled to any indemnification under this <u>Article 6</u> in respect of Losses arising out of or involving a claim or demand made by any Person other than Buyer against a Buyer Indemnified Party (a "*Third Party Claim*"), the Buyer Indemnified Party must notify the Seller (the "*Indemnifying Party*") promptly in writing (including in such notice a brief description of the Third Party Claim, including damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Buyer Indemnified Party); provided, however, that the failure to promptly provide such notice shall not affect the indemnification provided under this <u>Article 6</u> except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure. Thereafter, the Buyer Indemnified Party shall deliver to the Indemnifying Party, promptly after the Buyer Indemnified Party's receipt thereof, copies of all material documents (including court papers) received by the Buyer Indemnified Party Claim.

#### (b) Defense of Third Party Claims.

(i) The Indemnifying Party shall be entitled to participate in the defense of the Third Party Claim and, if it so chooses, to assume the defense thereof, at its own expense, with counsel selected by the Indemnifying Party (so long as the Buyer

Indemnified Party does not reasonably object to such counsel) if: (A) such Third Party Claim does not relate to or arise in connection with any criminal action; (B) the Indemnifying Party makes reasonably adequate provision to satisfy the Buyer Indemnified Party of the Indemnifying Party's ability to defend, satisfy and discharge such Third Party Claim; (C) no defense exists for the Buyer Indemnified Party that is not available to the Indemnifying Party; and (D) if the named parties to such Third Party Claim (including impleaded parties) include both the Indemnifying Party and the Buyer Indemnified Party, representation of both parties by the same counsel would not be inappropriate due to actual or potential differing interests between them (as determined by the Buyer Indemnified Party in its reasonable discretion) (collectively, the "*Defense Conditions*").

(ii) If the Indemnifying Party elects to assume the defense of any Third Party Claim, the Indemnifying Party shall not be liable to the Buyer Indemnified Party for legal expenses subsequently incurred by the Buyer Indemnified Party in connection with the defense thereof; except that if (A) the Indemnifying Party fails to take reasonable steps necessary to defend diligently such Third Party Claim within ten (10) Business Days after receiving written notice from the Buyer Indemnified Party that the Buyer Indemnified Party believes the Indemnifying Party has failed to take such steps, or (B) if any of the Defense Conditions cease to be satisfied for any reason, the Buyer Indemnified Party may assume its own defense, and the Indemnifying Party will be liable for all reasonable costs or expenses paid or incurred in connection therewith to the extent the cost or expense is a result of or arises from a matter to which the Buyer Indemnified Party will have the right to compromise or settle such Third Party Claim with the consent of the Indemnifying Party (which consent may not be unreasonably withheld or delayed). If settled with such consent, or if there is a final judgment against the Buyer Indemnified Party, the Indemnifying Party agrees to settlement is a result of, or arises from, a matter to which the Buyer Indemnified Party is entitled to indemnified Party from and against any Loss by reason of such settlement or judgment to the extent the judgment or settlement is a result of, or arises from, a matter to which the Buyer Indemnified Party is entitled to indemnified Party from and against any Loss by reason of such settlement or judgment to the extent the judgment or settlement is a result of, or arises from, a matter to which the Buyer Indemnified Party is entitled to indemnification under <u>Article 6</u>, subject in all respects to the limitations set forth in <u>Section 6.3</u>.

(iii) In the event the Indemnifying Party has assumed control of the defense of the Third Party Claim, the Indemnifying Party shall permit the Buyer Indemnified Party to participate in, but not control, the defense of any such action or suit through counsel chosen by the Buyer Indemnified Party; unless the Indemnifying Party does not reasonably object to such counsel, and the Buyer Indemnified Party must bear responsibility for the fees and expenses of such counsel. The Indemnifying Party will be liable for the fees and expenses of counsel employed by the Buyer Indemnified Party in the defense of a Third Party Claim that results in an indemnification obligation under <u>Article 6</u> for any period during which the Indemnifying Party has not assumed the defense thereof (other than during the period prior to the time the Buyer Indemnified Party notifies the Indemnifying Party of such Third Party Claim).

(c) <u>Cooperation</u>. The parties hereto shall reasonably cooperate in the defense or prosecution of any Third Party Claim, with such cooperation to include (i) the retention of and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) the making available of employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder. If the Indemnifying Party has assumed the defense of a Third Party Claim, the Buyer Indemnified Party shall agree to any settlement, compromise or discharge of such Third Party Claim that the Indemnifying Party may recommend and that by its terms obligates the Indemnifying Party to pay the full amount of the Liability (if any) in connection with such Third

Party Claim and which (i) does not include a statement as, to or admission of, fault, culpability or a failure to act by or on behalf of any such Buyer Indemnified Party, (ii) includes an unconditional release of such Buyer Indemnified Party from all Liability on claims that are the subject matter of such Third Party Claim and (iii) does not provide for injunctive relief or other relief relating to such Buyer Indemnified Party other than monetary damages. The foregoing obligations to cooperate is limited to the extent to which such cooperation does not jeopardize, undermine, or otherwise waive any rights, defenses, or privileges in respect of claims or disputes between the Buyer and Seller.

Section 6.6 <u>Procedures Relating to Indemnification for Other Claims</u>. In order for a Buyer Indemnified Party to be entitled to any indemnification under this <u>Article 6</u> in respect of Losses that do not arise out of or involve a Third Party Claim, the Buyer Indemnified Party must notify the Indemnifying Party promptly in writing (including in such notice a brief description of the claim for indemnification and the Loss, including damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Buyer Indemnified Party), but the failure to promptly provide such notice will not affect the indemnification provided under this <u>Article 6</u> except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure.

Section 6.7 <u>Buyer Tax Indemnity</u>. In connection with the Closing and from time to time thereafter upon reasonable request by Janssen, Buyer shall provide Janssen an Internal Revenue Service Form W-9 certifying under penalties of perjury that Buyer is neither subject to backup withholding nor subject to U.S. nonresident withholding tax. From and after the Closing, if any withholding Tax is found to be due in respect of the Janssen Milestone Payment and Janssen has not withheld such amount in accordance with applicable law, (a) Buyer shall be responsible to pay such tax to the appropriate taxing authority, and (b) Buyer shall indemnify, defend, and hold harmless Seller and its Affiliates (other than Buyer and its Affiliates) and their respective employees, officers, directors, managers, members, shareholders, Representatives, agents, and successors and assigns from and against any Losses arising out of, resulting from, or in connection with Seller's obligations to indemnify and hold harmless Janssen from and against any Losses arising from Janssen's not making such required withholding of taxes in respect of the Janssen Milestone Payment.

Section 6.8 <u>Exclusive Remedy</u>. Other than for claims for equitable relief, including the seeking of specific performance in accordance with <u>Section 8.13</u>, the parties hereto acknowledge and agree that, from and after the Closing Date, this <u>Article 6</u> will provide such parties' sole and exclusive remedy with respect to any matter or claim arising out of, relating to, or in connection with, this Agreement and the transactions contemplated hereby.

#### ARTICLE 7

#### TERMINATION

Section 7.1 <u>Termination</u>. This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of Seller and Buyer;

(b) by Buyer or Seller by written notice to the other party if the notifying party is not then in material breach of any provision of this Agreement and there has been a material breach, inaccuracy in or failure to perform any representation, warranty, covenant or

agreement made by the other party pursuant to this Agreement that would give rise to the failure of any of the conditions specified in <u>Section</u> <u>2.3</u> or <u>Section 2.4</u> and such breach, inaccuracy or failure is not cured or waived within sixty days after written notice thereof from the non-breaching party;

(c) by Buyer or Seller if the Closing has not occurred on or before 60 days following the date of this Agreement, unless extended by mutual written agreement of the parties; provided, however, that the right to terminate this Agreement pursuant to this <u>Section</u> <u>7.1(c)</u> shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in this Agreement has been the cause of, or resulted in, the failure of the Closing to occur on or before such date; or

(d) by Buyer or Seller in the event that:

(i) there is any law that makes consummation of the transactions contemplated by this Agreement illegal or otherwise prohibited; or

(ii) any Governmental Entity issues a Judgment restraining or enjoining the transactions contemplated by this Agreement, and such Judgment becomes final and non-appealable.

Section 7.2 <u>Effect of Termination</u>. In the event of the termination of this Agreement in accordance with this Agreement, this Agreement will forthwith become void and there shall be no liability on the part of any party hereto except:

- (a) as set forth in this <u>Article 7</u>; and
- (b) that nothing herein shall relieve any party hereto from liability for any intentional breach of any provision hereof.

#### ARTICLE 8

#### MISCELLANEOUS

Section 8.1 <u>Definitions</u>. As used in this Agreement, the following terms shall have the following meanings:

"Affiliate" means, with respect to any particular Person, any other Person directly or indirectly controlling, controlled by or under common control with such particular Person. Buyer's Affiliates include Armistice Capital, LLC, Armistice Master Fund Ltd., and their respective officers, directors, and employees.

"Agreement" is defined in the preamble.

"Ancillary Agreements" means the Conveyance Agreement, the Agreement, and the Janssen Consent.

"Apollo" is defined in the recitals.

"Apollo Agreement" is defined in the recitals.

"Apollo Milestone Payment" is defined in the recitals.

"Apollo Payment Rights" is defined in Section 1.1(b).

"Apollo Royalty Payment" is defined in the recitals.

"Bankruptcy Laws" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors' rights generally.

"Business Day" means any day other than (i) a Saturday or Sunday or (ii) a day on which banking institutions located in Delaware are permitted or required by applicable law or regulation to remain closed.

"Buyer" is defined in the preamble.

"Cap" is defined in <u>Section 6.3(a)</u>.

"*Closing*" means the closing of the sale, transfer, assignment and conveyance of the Payment Rights hereunder in accordance with <u>Section 1.1</u> hereof.

"Closing Date" means the date on which the Closing occurs.

"Conveyance Agreement" is defined in Section 2.3(d).

"*Fraud*" means actual fraud with the intent to deceive under Delaware common law (and not equitable fraud, negligent misrepresentation or omission or any fraud based on recklessness or negligence) with respect to any representation or warranty set forth in this Agreement.

"Governmental Entity" means any United States or foreign federal, state, local or municipal (i) governmental or quasi-governmental entity of any nature (including any governmental agency, branch, department, authority, instrumentality or court or other tribunal) or (ii) body exercising or entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority, or power of any nature, including any arbitral tribunal.

"Janssen" is defined in the recitals.

"Janssen Agreement" is defined in the recitals.

"Janssen Consent" is defined in Section 2.3(e).

"Janssen Milestone Payment" is defined in the recitals.

"Janssen Payment Rights" is defined in Section 1.1(a).

"Judgment" means any judgment, order, writ, ruling, assessment, injunction, citation, award or decree of any nature.

"Knowledge of the Seller," means the actual knowledge of Garry Neil, M.D., and Chris Sullivan.

"Lien" means any mortgage, lien, title defect, pledge, charge, adverse claim, security interest, encumbrance or restriction of any kind, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind.

"Loss" and "Losses" means losses, liabilities, expenses (including reasonable attorneys' fees and expenses) and damages, but excluding punitive, special, indirect, exemplary and consequential damages, lost profits, "diminution in value" and any damages based on any type of "multiple of earnings," "multiple of cash flow" or other similar valuation methodology.

"Payment Rights" is defined in Section 1.1(b).

"*Permitted Liens*" means any (i) mechanic's, materialmen's, and similar liens for amounts not yet due and payable or (ii) statutory liens for taxes not yet due and payable or for taxes that the taxpayer is contesting in good faith.

"*Person*" means any individual, firm, corporation, company, partnership, limited liability company, trust, joint venture, association, estate, trust, Governmental Entity or other entity, enterprise, association or organization.

"Products" is defined in Section 3.1(n).

"Purchase Price" is defined in Section 1.2.

*"Representative"* means, with respect to any Person, (i) any direct or indirect stockholder, member or partner of such Person and (ii) any manager, director, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, bankers, financial advisors and actual and potential lenders and investors) of such Person.

"Seller" is defined in the preamble.

"Seller Fundamental Representations" means the representations and warranties set forth in <u>Section 3.1(a)</u> (Existence; Good Standing), <u>Section 3.1(b)</u> (Authorization), <u>Section 3.1(c)</u> (Enforceability); <u>Section 3.1(k)</u> (No Liens or Assignments by Seller; Title); and <u>Section 3.1(o)</u> (Brokers' Fees).

"UCC" means the Delaware Uniform Commercial Code, as amended (6 Del. C. §1-101).

Section 8.2 <u>Certain Interpretations</u>. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) "either" and "or" are not exclusive and "include," "includes" and "including" are not limiting and will be deemed to be followed by the words "without limitation;"

(b) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if,"

(c) "hereof," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

(d) references to a Person are also to its permitted successors and assigns;

(e) definitions are applicable to the singular as well as the plural forms of such terms;

(f) unless otherwise indicated, references to an "Article", "Section" or "Exhibit" refer to an Article or Section of, or an Exhibit to, this Agreement;

(g) references to "\$" or otherwise to dollar amounts refer to the lawful currency of the United States;

(h) references to an agreement or other document include references to any annexes, exhibits and schedules attached thereto excluding any amendments, restatements, reformations, supplements or other modifications after the date hereof; and

(i) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

Section 8.3 <u>Headings</u>. The table of contents and the descriptive headings of the several Articles and Sections of this Agreement and the Exhibits are for convenience only, do not constitute a part of this Agreement and do not control or affect, in any way, the meaning or interpretation of this Agreement.

Section 8.4 <u>Notices</u>. All notices and other communications under this Agreement must be in writing and must be by email with PDF attachment, courier service or personal delivery to the following addresses, or to such other addresses as shall be designated from time to time by a party hereto in accordance with this <u>Section 8.4</u>:

If to the Seller, to it at:

Avalo Therapeutics, Inc. 540 Gaither Road, Suite 400 Rockville, MD 20850 Attn: Garry Neil, M.D. Telephone: 410-522-8707 Email:

with a copy to (which shall not constitute notice):

Wyrick Robbins Yates & Ponton LLP 4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607 Attn: David Creekman; Andrew Gibbons Telephone: (919) 781-4000 Email:

If to the Buyer, to it at:

ES Therapeutics, LLC 251 Little Falls Drive Wilmington, DE 19808 Attn: Steven Boyd Telephone: Email:

All notices and communications under this Agreement will be deemed to have been duly given (i) when delivered by hand, if personally delivered, (ii) when received by a recipient, if sent by email, or (iii) one Business Day following sending within the United States by overnight delivery via commercial one-day overnight courier service.

Section 8.5 <u>Expenses</u>. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby will be paid by the party hereto incurring such fees, costs and expenses.

Section 8.6 <u>Assignment</u>. This Agreement is binding upon, inures to the benefit of and is enforceable by, the parties hereto and their respective permitted successors and assigns.

Section 8.7 Amendment and Waiver.

(a) This Agreement may be amended, modified or supplemented only in a writing signed by each of the parties hereto. Any provision of this Agreement may be waived only in a writing signed by the party hereto granting such waiver.

(b) No failure or delay on the part of any party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto will be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 8.8 <u>Entire Agreement</u>. This Agreement, the Ancillary Agreements, and the Exhibits annexed hereto constitute the entire understanding between the parties hereto with respect to the subject matter hereof and supersede all other understandings and negotiations with respect thereto.

Section 8.9 <u>No Third-Party Beneficiaries</u>. This Agreement is for the sole benefit of the Seller and the Buyer and their permitted successors and assigns, and nothing herein expressed or implied will give or be construed to give to any Person, other than the parties hereto and such successors and assigns, any legal or equitable rights hereunder.

Section 8.10 <u>Governing Law</u>. This Agreement is governed by, and must be construed in accordance with, the laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

Section 8.11 JURISDICTION; VENUE; WAIVER OF JURY TRIAL.

(a) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS RESPECTIVE PROPERTY AND ASSETS, TO THE EXCLUSIVE JURISDICTION OF ANY DELAWARE STATE COURT OR FEDERAL COURT OF THE UNITED STATES OF AMERICA SITTING IN NEW CASTLE COUNTY, DELAWARE, AND ANY APPELLATE COURT THEREOF, IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT IN RESPECT THEREOF, AND THE BUYER AND SELLER HEREBY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN ANY SUCH DELAWARE STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. THE BUYER AND THE SELLER HEREBY AGREE THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING WILL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY APPLICABLE LAW. EACH OF THE BUYER AND THE SELLER HEREBY SUBMITS TO THE EXCLUSIVE PERSONAL JURISDICTION AND VENUE OF SUCH DELAWARE STATE AND FEDERAL COURTS. THE BUYER AND THE SELLER AGREE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THAT PROCESS MAY BE SERVED ON THE BUYER OR THE SELLER IN THE SAME MANNER THAT NOTICES MAY BE GIVEN PURSUANT TO <u>SECTION 8.4</u> HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT IN ANY DELAWARE STATE OR FEDERAL COURT. EACH OF THE BUYER AND SELLER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(c) EACH OF THE PARTIES TO THIS AGREEMENT HEREBY IRREVOCABLY WAIVES ALL RIGHT TO A TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

Section 8.12 <u>Severability</u>. If any term or provision of this Agreement for any reason is held to be invalid, illegal or unenforceable in any situation in any jurisdiction, then, to the extent that the economic and legal substance of the transactions contemplated hereby is not affected in a manner that is materially adverse to either party hereto, all other terms and provisions of this Agreement will nevertheless remain in full force and effect and the enforceability and validity of the offending term or provision shall not be affected in any other situation or jurisdiction.

Section 8.13 <u>Specific Performance</u>. Each of the parties acknowledges and agrees that the other party may be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, each of the parties agrees that, without posting bond or other undertaking, the other party will be entitled to seek an injunction or injunctions to prevent breaches or violations of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action, suit or other proceeding instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which it may be entitled, at law or in equity.

Section 8.14 <u>Counterparts</u>. This Agreement may be executed either by manual signature or a facsimile or other electronic version of a manual signature in any number of counterparts and may be delivered via electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com), each such counterpart considered an original and, when taken together, all counterparts shall be deemed one document.

## [Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Purchase Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

# BUYER:ES THERAPEUTICS, LLCBy:/s/ Steven BoydName:Steven BoydIts:Managing Member

# [SIGNATURE PAGE TO THE PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the parties hereto have caused this Purchase Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

## **SELLER:**

# AVALO THERAPEUTICS, INC.

By:	/s/ Garry Neil, M.D.
Name:	Garry Neil, M.D.
Its:	Chief Executive Officer

# [SIGNATURE PAGE TO THE PURCHASE AGREEMENT]

# Exhibit A

# FORM OF CONVEYANCE AGREEMENT

Exhibit A

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

Date: November 7, 2022

/s/ Garry Neil, M.D.

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

#### 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: November 7, 2022

/s/ Christopher Sullivan

Christopher Sullivan Chief Financial Officer (Registrant's principal financial officer)

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

In connection with the Quarterly Report of Avalo Therapeutics, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 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: November 7, 2022

/s/ Garry Neil, M.D.

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

Date: November 7, 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.