# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 10-Q

for the quarterly period ended March 31, 2024 OR  TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  COMMISSION FILE NUMBER: 001-37590  AVALO THERAPEUTICS, INC. (Exact name of registrant as specified in its charter)  Delaware (State of incorporation) 540 Gaither Road, Suite 400 Rockville, Maryland 20850 (Address of principal executive offices)  Recurities registered pursuant to Section 12(b) of the Act:  Title of each class Trading Symbol Name of each exchange on which registered  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 D		QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934				
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  COMMISSION FILE NUMBER: 601-37590  AVALO THERAPEUTICS, INC. (Exact name of registrant as specified in its charter)  Delaware (State of incorporation) S40 Gaither Road, Suite 400 Rockville, Maryland 20850 (Address of principal executive offices)  Rockville, Maryland 20850 (Address of principal executive offices)  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 10 indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to submit such files). Yes 10 No 11 indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to submit such files). Yes 10 No 11 indicate by check mark whether the registrant is a large accelerated filer, a mon-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.  Large accelerated filer 11 Smaller reporting company 12 Smaller reporting company 12 Smaller reporting company 13 Smaller reporting company 14 Excelerated filer 15 Smaller reporting company 15 Smaller reporti			arterly period ended March 31, 202	4		
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Non-accelerated filer ☑ Smaller reporting company ☑ Emerging growth company ☐  If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □						
Emerging growth company   If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.		_		Accelerated filer □		
accounting standards provided pursuant to Section 13(a) of the Exchange Act. □				Smaller reporting company ☑		
indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No 🗵				ded transition period for complying with any new or revised financial		
	Indicate by c	check mark whether the registrant is a shell company (as	defined in Rule 12b-2 of the Exchang	ge Act). Yes□ No ☑		
As of May 8, 2024, the registrant had 1,034,130 shares of common stock outstanding.	As of May 8	, 2024, the registrant had 1,034,130 shares of common st	ock outstanding.			
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# AVALO THERAPEUTICS, INC.

# FORM 10-Q

# For the Quarter Ended March 31, 2024

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# PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

# **AVALO THERAPEUTICS, INC. and SUBSIDIARIES**

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

	M	arch 31, 2024	Decer	nber 31, 2023
	(	unaudited)		
Assets				
Current assets:				
Cash and cash equivalents	\$	110,177	\$	7,415
Other receivables		35		136
Prepaid expenses and other current assets		997		843
Restricted cash, current portion		4		1
Total current assets		111,213		8,395
Property and equipment, net		1,882		1,965
Goodwill		10,502		10,502
Restricted cash, net of current portion		131		131
Total assets	\$	123,728	\$	20,993
Liabilities, mezzanine equity and stockholders' (deficit) equity				
Current liabilities:				
Accounts payable	\$	916	\$	446
Accrued expenses and other current liabilities		7.383	_	4.172
Warrant liability		194,901		
Contingent consideration		12,500		_
Total current liabilities		215,700		4,618
Royalty obligation		2,000		2,000
Deferred tax liability, net		162		155
Derivative liability		5,670		5,550
Other long-term liabilities		1,281		1,366
Total liabilities		224,813		13,689
Mezzanine equity:		22 1,012		12,005
Series C Preferred Stock—\$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 22,358 and 0 shares of Series C Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively		11,457		_
Series D Preferred Stock—\$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively		_		_
Series E Preferred Stock—\$0.001 par value; 1 and 0 shares of Series E Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively		_		_
Stockholders' (deficit) equity:				
Common stock—\$0.001 par value; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023;1,034,130 and 801,746 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively		1		1
Additional paid-in capital		343,881		342,437
Accumulated deficit		(456,424)		(335,134)
Total stockholders' (deficit) equity		(112,542)		7,304
Total liabilities, mezzanine equity and stockholders' (deficit) equity	\$	123,728	\$	20,993

See accompanying notes to the unaudited condensed consolidated financial statements.

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

Three Months Ended March 31,

	March 31,			
		2024		2023
Revenues:				
Product revenue, net	\$	_	\$	475
Total revenues, net				475
Operating expenses:				
Cost of product sales		(80)		551
Research and development		2,116		6,008
Acquired in-process research and development		27,538		_
General and administrative		3,193		2,708
Total operating expenses		32,767		9,267
		(32,767)		(8,792)
Other expense:				
Excess of warrant fair value over private placement proceeds		(79,276)		_
Private placement transaction costs		(9,220)		_
Change in fair value of derivative liability		(120)		(180)
Interest income, net		100		(949)
Other expense, net		_		(26)
Total other expense, net		(88,516)		(1,155)
Loss before taxes		(121,283)		(9,947)
Income tax expense		7		8
Net loss and comprehensive loss	\$	(121,290)	\$	(9,955)
Net loss per share of common stock, basic and diluted <sup>1</sup>	\$	(141)	\$	(204)
·				

 $<sup>{}^{1}\</sup>textit{Amounts for prior periods presented have been \textit{ retroactively adjusted to reflect the 1-for-240 reverse stock split effected on December 28, 2023. See \textit{Note 1 for details}.}$ 

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Preferred :	Stock	Commo	on stoc	ek		Additional paid-in	Accumulated	stoc	Total kholders'
	Shares	Amount	Shares		Amount	-	capital	deficit	(defi	cit) equity
Three Months Ended March 31, 2024		_								
Balance, December 31, 2023	_	_	801,746	\$	1	\$	342,437	\$ (335,134)	\$	7,304
Impact of reverse split fractional share round-up	_	_	60,779		_		_	_		_
Issuance of common stock pursuant to Almata Transaction	_	_	171,605		_		815	_		815
Issuance of Series C Preferred Stock pursuant to Almata Transaction	2,412	11,457			_		_	_		_
Issuance of Series C Preferred Stock in private placement	19,946				_		_	_		_
Issuance of Series D Preferred Stock in private placement	1	_								
Issuance of Series E Preferred Stock in private placement	1	_								
Stock-based compensation	_	_	_		_		629	_		629
Net loss		_			_		_	(121,290)		(121,290)
Balance, March 31, 2024	22,360 \$	11,457	1,034,130	\$	1	\$	343,881	\$ (456,424)	\$	(112,542)

_	Preferred	Stock	Comm	on stock	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares1	Amount <sup>1</sup>	capital <sup>1</sup>	deficit	deficit
Three Months Ended March 31, 2023							
Balance, December 31, 2022	_	_	39,294	<b>s</b> —	\$ 292,909	\$ (303,824)	\$ (10,915)
Issuance of shares of common stock and warrants in underwritten public offering, net	_	_	15,709	_	13,748	_	13,748
Stock-based compensation	_	_	_	_	855	_	855
Net loss	_	_	_	_	_	(9,955)	(9,955)
Balance, March 31, 2023	<b>— \$</b>		55,003	\$ —	\$ 307,512	\$ (313,779)	\$ (6,267)

<sup>&</sup>lt;sup>1</sup> Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-240 reverse stock split effected on December 28, 2023. See Note 1 for details.

See accompanying notes to the unaudited condensed consolidated financial statements.

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

(Amounts in thousands)				
		Three Months E	nded M	2023
Operating activities		2024		2023
Net loss	\$	(121,290)	\$	(9,955)
Adjustments to reconcile net loss used in operating activities:	Ψ	(121,250)	Ψ	(5,555)
Depreciation and amortization		34		33
Stock-based compensation		629		855
Acquired in-process research and development		27,538		_
Excess of warrant fair value over private placement proceeds		79,276		_
Transaction costs paid pursuant to private placement		7,013		_
Transaction costs payable upon exercise of warrants issued in private placement		1,734		_
Change in fair value of derivative liability		120		180
Accretion of debt discount		_		350
Deferred taxes		7		8
Changes in assets and liabilities:				
Other receivables		101		1,062
Inventory, net		_		1
Prepaid expenses and other assets		(154)		(337)
Lease incentive		158		_
Accounts payable		470		2,683
Deferred revenue		_		22
Accrued expenses and other liabilities		(1,652)		(4,941)
Lease liability, net		(186)		(13)
Net cash used in operating activities		(6,202)		(10,052)
Investing activities				
Cash assumed from Almata Transaction		356		
Leasehold improvements		_		(158)
Disposal of property and equipment		<u> </u>		25
Net cash provided by (used in) investing activities		356		(133)
Financing activities				
Proceeds from private placement investment, gross		115,625		_
Transaction costs paid pursuant to private placement		(7,013)		_
Proceeds from issuance of common stock and pre-funded warrants in underwritten public offering, net				13,748
Net cash provided by financing activities		108,612		13,748
Increase in cash, cash equivalents and restricted cash		102,766		3,563
Cash, cash equivalents, and restricted cash at beginning of period		7,546		13,318
Cash, cash equivalents, and restricted cash at end of period	\$	110,312	\$	16,881
Supplemental disclosures of cash flow information				
Cash paid for interest	\$		\$	704
Supplemental disclosures of non-cash activities				
Issuance of common stock and Series C Preferred Stock pursuant to Almata Transaction	\$	12,727	\$	_

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

		March 31,		
	2024			2023
Cash and cash equivalents	\$	10,177	\$	16,687
Restricted cash, current		4		63
Restricted cash, non-current		131		131
Total cash, cash equivalents and restricted cash	\$	10,312		16,881

See accompanying notes to the unaudited condensed consolidated financial statements.

# Notes to Unaudited Condensed Consolidated Financial Statements

#### 1. Business

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

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

On March 27, 2024, the Company acquired AVTX-009, a Phase 2-ready anti-IL-1β mAb, through a merger with AlmataBio, Inc. ("AlmataBio") with and into its wholly owned subsidiary (the "Almata Transaction"). Additionally, on March 28, 2024, the Company closed a private placement investment for up to \$185 million in gross proceeds, including initial upfront gross investment of \$115.6 million. The upfront net proceeds were approximately \$108.1 million after deducting transaction costs. The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of warrants issued in the financing.

#### Liquidity

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

For the three months ended March 31, 2024, Avalo generated a net loss of \$121.3 million and negative cash flows from operations of \$6.2 million. As of March 31, 2024, Avalo had \$110.2 million in cash and cash equivalents. In March 2024, the Company closed a private placement investment for up to \$85 million in gross proceeds, including an initial upfront gross investment of \$115.6 million. Net proceeds were \$108.1 million after deducting transaction costs. The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of warrants issued in the financing.

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

# 2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

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

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

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

On December 28, 2023, Avalo effected a 1-for-240 reverse stock split of the outstanding shares of the Company's common stock and began trading on a split-adjusted basis on December 29, 2023. The Company retroactively applied the reverse stock split to common share and per share amounts for periods prior to December 28, 2023, including the unaudited consolidated financial statements for the quarter ended March 31, 2023. Additionally, pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under all of the Company's outstanding options and warrants, and the number of shares authorized for issuance pursuant to the Company's equity incentive plans have been reduced proportionately. Avalo retroactively applied such adjustments in the notes to consolidated financial statements for periods presented prior to December 28, 2023, including the quarter ended March 31, 2023. The reverse stock split did not reduce the number of authorized shares of common and preferred stock and did not alter the par value.

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

#### Significant Accounting Policies

During the three months ended March 31, 2024, there were no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 29, 2024, except for the policies related to asset acquisitions and warrant liability as described below.

# Asset Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

# Warrant Liability

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded on the consolidated statement of operations. The assessment of whether the warrants are accounted for as equity-classified or liability-classified instruments is re-evaluated on a periodic basis.

#### 3. Asset Acquisition

#### Almata Transaction

On March 27, 2024, the Company acquired AVTX-009, a Phase 2-ready anti-IL-1 $\beta$  mAb, through a merger with AlmataBio with and into its wholly owned subsidiary. The Company's acquisition of AlmataBio was structured as a stock-for-stock transaction whereby all outstanding equity interests in AlmataBio were exchanged in a merger for a combination of the Company's common stock and shares of the Company's Series C Preferred Stock, resulting in the issuance of 171,605 shares of Company common stock and 2,412 shares of Series C Preferred Stock. Subject to Company stockholder approval, each share of Company Series C Preferred Stock (i) issued to former AlmataBio stockholders and ii) pursuant to the private placement investment will automatically convert to 1,000 shares of common stock, subject to certain beneficial ownership limitations. The Series C Preferred Stock holds no voting rights.

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

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

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

	Three	Months Ended March 31, 2024
Stock consideration <sup>1</sup>	\$	12,272
Milestone payment due upon close of private placement investmen€		7,500
Milestone payment due upon first patient dosed in a Phase 2 triaf		5,000
Transaction costs		2,402
Total GAAP Purchase Price at Close	\$	27,174
Acquired IPR&D	\$	27,538
Cash		356
Accrued expenses and other current liabilities		(720)
Total net assets acquired and liabilities assumed	\$	27,174

<sup>&</sup>lt;sup>1</sup> Equal to the aggregate common shares issued of 171,605 and the aggregate preferred shares issued of 2,412 (as-converted to 2,412,000 shares of common stock), multiplied by the Company's closing stock price of \$4.75 on March 27, 2024.

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

# 4. Revenue

The Company's license and supply agreement for Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, ended on September 30, 2023, and therefore there was no net product revenues for the three months ended March 31, 2024. Avalo considered Millipred® a non-core asset. Historically, the Company sold Millipred® in the United States primarily through wholesale distributors, who accounted for substantially all of the Company's net product revenues and trade receivables. For the three months ended March 31, 2023, the Company recognized net product revenue of \$0.5 million.

The Company will continue to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized. Pursuant the Millipred® license and supply agreement, Avalo was required to pay the supplier fifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a \$0.5 million quarterly minimum payment dependent on Avalo reaching certain net profit amounts as stipulated in the agreement. The profit share commenced on July 1, 2021 and ended on September 30, 2023. Within twenty-five months of September 30, 2023, the net profit share is subject to a reconciliation process where estimated deductions to arrive at net profit will be trued-up to actuals and could result in Avalo owing additional amounts to the supplier or vice versa, which would be recognized in cost of product sales.

<sup>&</sup>lt;sup>2</sup> Avalo deemed these milestones probable and estimable as of the transaction close date and therefore included them as part of the GAAP purchase price at close. The first milestone payment due upon the close of the private placement investment was met on March 28, 2024 and was paid on April 1, 2024.

Aytu BioScience, Inc. ("Aytu"), to which the Company sold its rights, title, and interests in assets relating to certain commercialized products in 2019 (the "Aytu Transaction"), managed Millipred® commercial operations until August 31, 2021 pursuant to transition service agreements, which included managing the third-party logistics provider. As a result, Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred® from the second quarter of 2020 through the third quarter of 2021. The transition services agreement allows Aytu to withhold up to \$1.0 million until December of 2024. In the second quarter of 2022, Avalo fully reserved the receivable as a result of Aytu's conclusion within its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 that substantial doubt existed with respect to its ability to continue as a going concern within one year after the date those financial statements were issued. As of March 31, 2024, the total receivable balance was approximately \$0.6 million and remains fully reserved as of March 31, 2024. We will continue to reassess its collectability each reporting period.

#### 5. Net Loss Per Share

The Company had two classes of stock outstanding during the three months ended March 31, 2024, common stock and preferred stock, and had only common stock outstanding during the three months ended March 31, 2023. The Company computes net loss per share using the two-class method, as the Series C Preferred Stock participates in distributions with the Company's common stock. The two-class method of computing net loss per share is an earnings allocation formula that determines net loss for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. As the Company is in a net loss position for the three months ended March 31, 2024, the two-class method of computing net loss per share results in no allocation of undistributed losses to participating securities.

Basic net loss per share for common stock is computed by dividing the sum of distributed earnings by the weighted average number of shares outstanding for the period. The weighted average number of common shares outstanding as of March 31, 2023 includes the weighted average effect of pre-funded warrants, the exercise of which required nominal consideration for the delivery of the shares of common stock. There were no pre-funded warrants outstanding as of March 31, 2024.

Diluted net loss per share may include the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive, and (iii) preferred stock under the if-converted method. Because the impact of these items is anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses.

The following tables set forth the computation of basic and diluted net loss per share of common stock for the three months ended March 31, 2024 and March 31, 2023 (in thousands, except share amounts):

	Three Months Ended March 31, 2024		
	Common stock		
Net loss	\$ (121,290)		
Weighted average shares	859,381		
Basic and diluted net loss per share	\$ (141)		

As the Company is in a net loss position as of March 31, 2024, the two-class method of computing net loss per share results in no allocation of undistributed losses to participating securities. As such, there is no allocation of undistributed losses to the Series C Preferred Stock outstanding for the three months ended March 31, 2024, and therefore the preferred stock is not reflected in the above table.

	 Three Months Ended March 31, 2023
	Common stock
Net loss	\$ (9,955)
Weighted average shares	 48,845
Basic and diluted net loss per share	\$ (204)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three months ended March 31, 2024 and 2023, as they could have been anti-dilutive:

	Three Mont	hs Ended
	March	31,
	2024	2023
Stock options	7,543	7,558
Warrants on common stock <sup>1</sup>	11,969,063	17,254
Series C Preferred Stock (as-converted to common stock) <sup>2</sup>	22,357,897	_

<sup>&</sup>lt;sup>1</sup> The weighted average number of common shares outstanding for the three months ended March 31, 2023 includes the weighted average outstanding pre-funded warrants for the period because their exercise price was nominal. There were no pre-funded warrants outstanding as of March 31, 2024.

# 6. Fair Value Measurements

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

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

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

<sup>&</sup>lt;sup>2</sup> Subject to stockholder approval, each share of the Company's Series C Preferred Stock will automatically convert to 1,000 shares of common stock, subject to certain beneficial ownership limitations.

March 31, 2024

	Fair Value Measurements Using						
	Quoted prices in active markets for identical assets	Significant other observable inputs (Level 2)		Significa	ant unobservable inputs		
	 (Level 1)				(Level 3)		
Assets							
Investments in money market funds*	\$ 104,776	\$	_	\$	_		
Liabilities							
Derivative liability	\$ _	\$	_	\$	5,670		
Warrant liability	\$ _	\$	_		194,901		

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

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

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

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

# Level 3 Valuation

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability and derivative liability for the three months ended March 31, 2024:

	Warrant liability		Derivative liability		Total
Balance at December 31, 2023	\$	_	\$	5,550	\$ 5,550
Initial valuation of warrant liability		194,901		_	194,901
Change in fair value		_		120	120
Balance at March 31, 2024	\$	194,901	\$	5,670	\$ 200,571

	Warrant liabili	ty	Derivative liability		Total
Balance at December 31, 2022	\$	_	\$	4,830	\$ 4,830
Initial valuation of warrant liability		_		_	_
Change in fair value		_		180	180
Balance at March 31, 2023	\$	_	\$	5,010	\$ 5,010

# Warrant liability

On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received (i)19,946 shares of non-voting convertible preferred stock (the "Series C Preferred Stock") and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into). Refer to Note 10 - Capital Structure and sub-header "Q1 2024 Financing" for more information regarding the warrants.

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

The Company's warrant liability is measured at fair value each reporting period utilizing the Black-Scholes option pricing model, which requires assumptions including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, are subjective and require judgment to develop. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our warrant liability could be materially different.

The closing stock price of Avalo's common stock on March 28, 2024, which was the date the transaction closed, as well as the last trading day of the first quarter of 2024, was the main driver of the fair value of the warrant liability. Future increases or decreases to the stock price at each reporting period will drive increases or decreases, respectively, to the fair value of the warrant liability. The expected term was estimated based on when the Company expects the first patient dosed in a Phase 2 trial of AVTX-009 in hidradenitis suppurativa (the "Dosing Date"), to occur. If the Dosing Date occurs earlier or later than expected, then the expected term will decrease or increase, respectively, which may decrease or increase, respectively, the value of the warrant liability. Expected volatility is based on a blend between the Company's historical volatility and the volatility of comparable peer companies. The risk-free interest rate was based on the implied yield available on U.S. treasury securities with a maturity equivalent to the expected term. The warrant liability was classified as a Level 3 instrument as its value was based on unobservable market inputs. The inputs utilized include the following:

	As of Ma	rch 31, 2024
Common stock price	\$	21.75
Expected term (in years)		0.5
Expected volatility		109 %
Risk-free rate		5.35 %
Exercise price	\$	5.796933
Dividend yield rate		— %

The initial measurement of the warrant liability of \$194.9 million exceeded the proceeds received from the private placement investment of \$15.6 million, which resulted in a \$79.3 million loss recognized in other expense, net. Subsequently, the warrants are carried at fair value with changes in fair value recognized in the Company's consolidated statements of operations and comprehensive loss until either exercised or expired.

# Derivative liability

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

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

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

The fair value of the derivative liability as of the transaction date was approximately \$4.8 million, of which \$3.5 million was attributable to the AVTX-501 Milestone and \$1.3 million was attributable to the AVTX-007 Milestones and Royalties. Subsequent to the transaction date, at each reporting period, the derivative liability is remeasured at fair value. As of March 31, 2024, the fair value of the derivative liability was \$5.7 million, of which \$3.8 million was attributable to the AVTX-501 Milestone and \$1.9 million was attributable to the AVTX-007 Milestones and Royalties. For the three months ended March 31, 2024, the \$0.1 million change in fair value was recognized in other expense, net in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss.

The fair value of the AVTX-501 Milestone was primarily driven by an approximate 23% probability of success to reach the milestone in approximately 3.6 years. The fair value of AVTX-007 Milestones and Royalties was primarily driven by an approximate 17% probability of success, time to commercialization of approximately 4.6 years, and sales forecasts with peak annual net sales reaching \$300 million. As discussed above, these unobservable inputs were estimated by Avalo based on limited publicly available information and therefore could differ from Janssen and Apollo's internal development plans. Any changes to these inputs may result in significant changes to the fair value measurement. Notably, the probability of success is the largest driver of the fair value and therefore changes to such input would likely result in significant changes to such fair value.

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

No changes in valuation techniques or inputs occurred during the three months ended March 31, 2024 and 2023. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three months ended March 31, 2024 and 2023.

# 7. Leases

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

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

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

The weighted average remaining term of the operating leases at March 31, 2024 was 4.4 years.

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

As of			
M	arch 31, 2024	]	December 31, 2023
\$ 1,280		\$	1,329
\$	545	\$	537
	1,281		1,366
\$	1,826	\$	1,903
	\$ \$ \$	March 31, 2024 \$ 1,280 \$ 545 1,281	March 31, 2024 \$ 1,280 \$ \$ 545 \$ 1,281

As of

The operating lease right-of-use ("ROU") assets are included in property and equipment, net and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our unaudited condensed consolidated balance sheets. The Company utilized a weighted average discount rate of 9.1% to determine the present value of the lease payments.

The components of lease expense for the three months ended March 31, 2024 and 2023 were as follows (in thousands):

	i nree Months Ended March 31,			
	2024			
Operating lease cost*	\$ 108	\$	120	

<sup>\*</sup>Includes short-term leases, which are immaterial.

The following table shows a maturity analysis of the operating lease liabilities as of March 31, 2024 (in thousands):

	τ	Indiscounted Cash Flows
April 1, 2024 through December 31, 2024	\$	407
2025		553
2026		563
2027		259
2028		201
2029		207
Thereafter		17
Total lease payments	\$	2,207
Less implied interest		(381)
Total	\$	1,826

# 8. Accrued Expenses and Other Current Liabilities

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

	As of			
	March 31, 2024			December 31, 2023
Research and development	\$	329	\$	352
Compensation and benefits		752		580
General and administrative (including asset acquisition related transaction costs)		1,934		830
Private placement investment transaction costs		2,034		_
Commercial operations		1,789		1,873
Lease liability, current		545		537
Total accrued expenses and other current liabilities	\$	7,383	\$	4,172

# 9. Notes Payable

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

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

On June 4, 2021, pursuant to the Loan Agreement, the Company issued warrants to the Lenders to purchase 148 shares of the Company's common stock with an exercise price of \$7,488 per share (the "Warrants"). The Warrants are exercisable for ten years from the date of issuance. Pursuant to the Payoff Letter, Avalo's obligations under the Warrants shall survive pursuant to the original terms at issuance. The Warrants, which met equity classification, were recognized as a component of permanent stockholders' (deficit) equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Company recognized debt issuance costs and the amount allocated to the warrants as a debt discount on the date of issuance and amortized these costs to interest expense using the effective interest method over the original term of the loan. As a result of the payoff in the third quarter of 2023, the Company accelerated the remaining \$0.9 million amortization of the debt discount, which was recognized as interest expense in the third quarter of 2023.

# 10. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock, common stock and preferred stock. At March 31, 2024, the total number of shares of capital stock the Company was authorized to issue was 205,000,000, of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of \$0.001 per share.

#### Almata Transaction

On March 27, 2024, the Company acquired AlmataBio in which the former AlmataBio stockholders received (i) 171,605 shares of the Company's common stock and (ii) 2,412 shares of the Company's Series C Preferred Stock. Subject to the Requisite Stockholder Approval, the date Company shareholders approve the issuance of common stock for conversion of Series C Preferred Stock and for exercise of warrants, each share of the Series C Preferred Stock issued to former AlmataBio stockholders will automatically convert to 1,000 shares of common stock, subject to certain beneficial ownership limitations. The Series C Preferred Stock holds no voting rights. Refer to Note 3 - Asset Acquisition for more information regarding the acquisition and refer to sub-header "Series C Preferred Stock" within the "Q1 2024 Financing" section below for more information regarding the Series C Preferred Stock issued pursuant to the Almata Transaction.

# Q1 2024 Financing

On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received (i)19,946 shares of non-voting convertible preferred stock, the Series C Preferred Stock, and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into), resulting in upfront gross proceeds of \$115.6 million. Net proceeds were \$108.1 million after deducting transaction costs. The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of the warrants.

Warrants on common stock or Series C Preferred Stock issued in Q1 2024 Financing

The warrants are exercisable via gross physical settlement for \$5.796933 per underlying share of common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into). The warrants will become exercisable on (i) March 28, 2024, if exercised for shares of Series C Preferred Stock, or (ii) upon receipt of Requisite Stockholder Approval if exercised for shares of common stock. The warrants will expire on the earlier of (y) the fifth anniversary of the date of issuance or (z) the Dosing Date (as defined in Note 6 - Fair Value Measurements), provided that if the Requisite Stockholder Approval has not been received by the Dosing Date, then the warrants will expire on the earlier of the (A) the fifth anniversary of the date of issuance or (B) thirty-first day following receipt of the Requisite Stockholder Approval. The warrants include anti-dilution protection provisions.

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

No warrants were exercised for the quarterly period ended on March 31, 2024.

Upon exercise of the warrants, the Company will pay an additional amount of transaction costs to a third-party financial institution, based on 2.5% gross proceeds received from the exercise. As the warrants are in the money as of the quarterly period ended March 31, 2024, the Company has recognized \$1.7 million for transaction costs within other expense, net. The Company also incurred an additional \$7.5 million of transaction costs related to the private placement investment which were expensed within other expense, net.

Series C Preferred Stock issued in the Almata Transaction and Q1 2024 Financing

As of March 31, 2024, the Company had 5,000,000 shares of Preferred Stock authorized, of which 34,326 have been designated as Series C Preferred Stock. As of March 31, 2024, there were 22,358 shares of Series C Preferred Stock outstanding, with a par value of \$0.001 per share. The Series C Preferred Stock have no voting rights, no liquidation preference, and are not redeemable. In the event of any liquidation, dissolution or winding up of the Company, Series C Preferred Stock are entitled to be paid out of the assets with the Company legally available for distribution to its stockholders on an as-converted and pari-passu basis with common stock. The Series C Preferred Stock is subject to broad-based weighted average anti-dilution protection for certain issuances of common stock and securities convertible into common stock. The Series C Preferred Stock are entitled to receive dividends equal to and in the same form, and in the same manner, based on the then-current conversion ratio as dividends actually paid on shares of the common stock, when, as and if such dividends are paid on shares of the common stock. Upon Requisite Stockholder Approval, each share of Series C Preferred Stock (i) issued to the former AlmataBio stockholders (as discussed above) and (ii) pursuant to the private placement investment will automatically convert to 1,000 shares of common stock, subject to certain beneficial ownership limitations.

The Series C Preferred Stock is contingently redeemable outside the control of the Company such that the Series C Preferred Stock is recognized outside of permanent equity. The carrying value of Series C Preferred Stock issued to the former AlmataBio stockholders pursuant to the Almata Transaction of \$11.5 million is recognized outside of stockholder's (deficit) equity on the Company's unaudited consolidated balance sheet. No amounts were allocated to the Series C Preferred Stock issued pursuant to the Q1 2024 Financing because the initial fair value of the warrants exceeded gross proceeds received for the issuance of the private placement bundle that included both Series C Preferred Stock and warrants. The Series C Preferred Stock is not remeasured to redemption value until the shares are probable of becoming redeemable for cash. As of March 31, 2024, the Company expects to have sufficient authorized and unissued shares to settle the Series C Preferred Stock upon Requisite Stockholder Approval, and therefore it is not probable that the Series C Preferred Stock would be redeemable for cash as of the balance sheet date.

As of March 31, 2024, no Series C Preferred Stock were converted to common stock.

Series D and Series E Preferred Stock issued in the Q1 2024 Financing

As a condition to the Q1 2024 Financing, a single Series D Preferred Stock and a single Series E Preferred Stock were issued to two institutional investors that participated in the private placement. Both the Series D and the Series E Preferred Stock have a par value and liquidation preference of \$0.001 per share. The Series D and Series E Preferred Stock do not have voting rights, are not entitled to dividends, and are not convertible into common stock. The holders of the Series D and Series E Preferred Stock have the option to require the Company to redeem their shares at a price equal to the par value at any time. The Company retains the right to redeem the Series D and Series E Preferred Stock at a price equal to the par value if the holder owns less than a certain threshold of the Company's outstanding common stock. While the Series D and Series E Preferred Stock do not provide the holders with substantive economics, the Series D and Series E Preferred Stock were issued solely to allow for the institutional investors to appoint a director to the Company's board of directors.

# **Common Stock Warrants**

At March 31, 2024, the following common stock warrants were outstanding:

Number of common shares	Exercise price	Expiration
underlying warrants	per share	date
1,389	\$ 36,000	June 2024
148	\$ 7,488	June 2031
11,967,526	\$ 5.80 (1)	(1)
11,969,063		

<sup>(1)</sup> The warrants will become exercisable (i) on March 28, 2024, if exercised for shares of Series C Preferred Stock, or (ii) upon receipt of Requisite Stockholder Approval, the date Company shareholders approve the issuance of common stock for conversion of Series C Preferred Stock and for exercise of warrants, if exercised for shares of common stock. The warrants will expire on the earlier of (y) the fifth anniversary of the date of issuance or (z) the thirty-first day following the Dosing Date, provided that if the Requisite Stockholder Approval has not been received by the Dosing Date, then the warrants will expire on the earlier of the (A) the fifth anniversary of the date of issuance or (B) thirty-first day following receipt of the Requisite Stockholder Approval. The warrants include anti-dilution protection provisions.

# 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, 2024, pursuant to the terms of the 2016 Third Amended Plan, an additional 32,070 shares were made available for issuance. As of March 31, 2024, there were32,520 shares available for future issuance under the 2016 Third Amended Plan.

Option grants expire after ten years. Employee options typically vest over four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. 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 and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the three months ended March 31, 2024 and 2023 was as follows (in thousands):

	Three Months Ended March 31,			
	2024			
Research and development	\$ 269	\$	326	
General and administrative	360		529	
Total stock-based compensation	\$ 629	\$	855	

# 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 periods. A summary of option activity for the three months ended March 31, 2024 is as follows:

	Options Outstanding													
	Number of shares		Weighted average exercise price per share										eighted average grant te fair value per share	Weighted average remaining contractual term (in years)
Balance at December 31, 2023	7,211	\$	3,192	\$	1,930	8.3								
Granted	_	\$	_	\$	_									
Forfeited	(13)	\$	660	\$	473									
Expired	(3)	\$	11,232	\$	6,444									
Balance at March 31, 2024	7,195	\$	3,192	\$	1,936	8.0								
Exercisable at March 31, 2024	4,058	\$	4,791	\$	2,803	7.4								

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2024, the aggregate intrinsic value of options outstanding was minimal. There were 545 options that vested during the three months ended March 31, 2024 with a weighted average exercise price of \$1,598 per share. The total grant date fair value of shares which vested during the three months ended March 31, 2024 was \$0.6 million.

The Company recognized stock-based compensation expense of \$0.6 million related to stock options with service-based vesting conditions for the three months ended March 31, 2024. At March 31, 2024, there was \$2.2 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 1.4 years.

# Stock-based compensation assumptions

There were no stock options granted in the three months ended March 31, 2024.

# Stock options with market-based vesting conditions

As of March 31, 2024, there were 348 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 \$9,488 and a weighted average remaining contractual term of 0.2 years. There were no stock options with market-based vesting conditions granted, exercised, or forfeited for the three months ended March 31, 2024.

# 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 174 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, (ii) 174 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. On January 1, 2024, the number of shares available for issuance under the ESPP increased by 174. As of March 31, 2024, 958 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized minimal stock-based compensation expense for the three months ended March 31, 2024.

# 12. Income Taxes

The Company recognized minimal income tax expense for the three months ended March 31, 2024 and 2023 due to the significant valuation allowance against the Company's deferred tax assets and the current and prior period losses.

# 13. Commitments and Contingencies

# Litigation

# Litigation - General

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

# Dispute Notice Settlement

On August 14, 2023, the Company received a notice from Apollo AP43 Limited alleging that the Company was in breach of the license agreement between them dated July 29, 2022 by virtue of owing \$0.8 million to a service provider under the terms of that license. On January 25, 2024, the Company and Apollo entered into a settlement and release agreement, pursuant to which Avalo agreed to pay Apollo \$0.2 million to settle the dispute and Apollo released Avalo from any and all liabilities or claims relating to the dispute that Apollo may have against Avalo from the date of the license agreement through the date of the settlement and release agreement. The Company recognized the \$0.2 million settlement within accrued expenses and other current liabilities as of December 2023 and made the \$0.2 million settlement payment in the first quarter of 2024.

# Possible Future Milestone Payments for In-Licensed Compounds

#### General

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

#### AVTX-009 Agreements

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

Avalo is required to pay up to \$70 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay sales-based milestones aggregating up to \$720 million. Additionally, Avalo is required to pay royalties during a country-by-country royalty term equal to a mid-single digit-to-low double digit of Avalo or its sublicensees' annual net sales.

No expense related to these AVTX-009 agreements was recognized in the three months ended March 31, 2024. There has been no cumulative expense recognized as of March 31, 2024 related to the milestones under these AVTX-009 agreements. The Company will continue to monitor the milestones at each reporting period.

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

# 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 of \$0.0 million, which we recognized within research and development expenses in 2021. The Company is also required to pay KKC up to an aggregate of \$112.5 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to 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 any 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). In addition to the KKC License Agreement, Avalo is subject to additional royalties upon commercialization of up to an amount of less than 10% of net sales.

No expense related to the KKC License Agreement was recognized in the three months ended March 31, 2024. There has beem cumulative expense recognized as of March 31, 2024 related to the milestones under the KKC License Agreement. The Company will continue to monitor the 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 Sanford Burnham Prebys License Agreement, the Company incurred an upfront license fee of \$0.4 million, as well as patent costs of \$0.5 million, which we recognized within research and development expenses and within general and administrative expenses, respectively, in 2021. The Company is required to pay Sanford Burnham Prebys up to an aggregate of \$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 material expense related to the Sanford Burnham Prebys License Agreement was recognized in the three months ended March 31, 2024. There has been cumulative expense recognized as of March 31, 2024 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 an aggregate of \$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 any sublicensing of its rights under the Astellas license agreement, subject to certain exclusions. Upon commercialization, the Company is required to pay Astellas royalties during a country-by-country royalty term equal to a tiered mid-to-high single digit percentage of annual net sales. Avalo is fully responsible for the development and commercialization of the program.

No expense related to this license agreement was recognized in the three months ended March 31, 2024. There has been \$0.5 million of cumulative expense recognized as of March 31, 2024 related to the milestones under this license agreement. The Company will continue to monitor the remaining 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. in 2013.

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

The Company had not recognized any milestones as of March 31, 2024.

# AVTX-406 License Assignment

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

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

The Company had not recognized any milestones as of March 31, 2024.

# AVTX-800 Series Asset Sale

On October 27, 2023, the Company sold its rights, title and interests in assets relating to the 800 Series to AUG.

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

The Company had not recognized any revenue related to the milestones as of March 31, 2024.

# **Acquisition Related and Other Contingent Liabilities**

# Almata Transaction Possible Future Milestone Payments

On March 27, 2024, the Company acquired AVTX-009 through its acquisition of AlmataBio. The Company agreed to an aggregate milestone payment of \$7.5 million in cash due upon the closing of the private placement investment (which closed on March 28, 2024), a second aggregate milestone payment of \$5.0 million due upon the first patient being dosed in a Phase 2 trial for the indication of hidradenitis suppurative and a third aggregate milestone payment of \$15.0 million due upon the first patient being dosed in a Phase 3 trial (regardless of indication). The former Almata stockholders have the option to elect to have the second and third milestone payments be paid in cash, shares of Avalo common stock or a combination thereof.

The Company recognized the \$7.5 million initial milestone payment as a current liability within contingent consideration as of March 31, 2024 and paid this milestone on April 1, 2024. In addition, as of March 31, 2024, the Company concluded the second milestone payment was probable and therefore recognized the \$5.0 million milestone as a current liability within contingent consideration as of March 31, 2024. The Company will continue to monitor the third milestone each reporting period.

# Aevi Merger Possible Future Milestone Payments

In the first quarter of 2020, the Company consummated its merger with Aevi 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 March 31, 2024 and no future contingent consideration will be recognized.

The second milestone is the receipt of an NDA approval for either AVTX-006 or AVTX-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of \$4.5 million. The contingent consideration related to the second development milestone will be recognized if and when such milestone is probable and can be reasonably estimated. No contingent consideration related to the second development milestone had been recognized as of March 31, 2024. The Company will continue to monitor the second milestone each reporting period.

# AVTX-006 Royalty Agreement with Certain Related Parties

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

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

# Karbinal Royalty Make-Whole Provision

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

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

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

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

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

#### Overview

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

Management's primary evaluation of the success of the Company is the ability to progress its pipeline assets forward towards commercialization or opportunistically outlicensing rights to indications or geographies. We believe the ability to achieve the anticipated milestones as presented in the following chart represents our most immediate evaluation points as to the progress of our goal to move the pipeline forward.

Compound	Indication	PreClin	P1	P2	Р3	Anticipated Milestones
AVTX-009	Hidradenitis suppurativa (HS)					P2 Topline Results 2026
Anti-IL-1β mAb	Autoimmune Indication TBD					TBD
Next Generation IL-1β (extended half-life)						TBD
Quisovalimab AVTX-002, Anti-LIGHT mAb				$\rightarrow$		Under strategic review
AVTX-008 BTLA agonist fusion protein						Under strategic review

# **Recent Developments**

On March 27, 2024, the Company acquired AVTX-009, a Phase 2-ready anti-IL-1β mAb, through a merger with AlmataBio Inc. ("AlmataBio") with and into its wholly owned subsidiary (the "Almata Transaction"). Additionally, on March 28, 2024, the Company closed a private placement investment for up to \$185 million in gross proceeds, including an initial upfront gross investment of \$115.6 million. The upfront net proceeds were approximately \$108.1 million after deducting transaction costs. The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of warrants issued in the financing.

#### Liquidity

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

For the three months ended March 31, 2024, Avalo generated a net loss of \$121.3 million and negative cash flows from operations of \$6.2 million. As of March 31, 2024, Avalo had \$110.2 million in cash and cash equivalents. In March 2024, the Company closed a private placement investment for up to \$185 million in gross proceeds, including an initial upfront gross investment of \$115.6 million. Net proceeds were \$108.1 million after deducting transaction costs. The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of warrants issued in the financing.

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

# **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 March 31, 2024 and 2023

Product Revenue, Net

There was no net product revenue for the three months ended March 31, 2024, compared to \$0.5 million for the three months ended March 31, 2023. The decrease was driven by the planned expiration of our license and supply agreement for our only commercially marketed product, Millipred® on September 30, 2023.

We do not expect gross product revenue for Millipred®, which the Company considered a non-core asset. However, the Company will continue to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or benefit) for differences between actuals or updated estimates to the reserves previously recognized.

# Cost of Product Sales

Cost of product sales were minimal for the three months ended March 31, 2024, compared to \$0.6 million for the same period in 2023. The decrease in cost of product sales during the period was primarily related to the expiration of Avalo's license and supply agreement for Millipred® on September 30, 2023.

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

# Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,			ch 31,
	2024		2023	
Nonclinical expenses	\$	152	\$	364
Clinical expenses		62		2,776
CMC expenses		254		1,292
Internal expenses:				
Salaries, benefits and related costs		1,324		1,193
Stock-based compensation expense		269		326
Other		55		57
	\$	2,116	\$	6,008

Research and development expenses decreased \$3.9 million for the three months ended March 31, 2024. This decrease was mainly driven by a \$2.7 million decrease in clinical expenses and a \$1.0 million decrease in chemistry, manufacturing, and controls ("CMC") expenses. Clinical and CMC expenses decreased due to decreased activities as a result of the AVTX-002 PEAK trial concluding in June of 2023 and the corresponding timing of raw material orders.

We expect future research and development expenses to increase in 2024 as a result of acquiring AVTX-009 in late March 2024 and our associated development plans.

# Acquired in-process research and development

In the first quarter of 2024, we acquired AVTX-009, a Phase 2 ready anti-IL-1β mAb, through a merger with AlmataBio, Inc. ("AlmataBio") and its wholly owned subsidiary (the "Almata Transaction"), resulting in us acquiring \$27.5 million of in-process research and development ("IPR&D"). The fair value of the IPR&D, substantially all of which is related to AVTX-009, was immediately recognized as acquired IPR&D expense as there is no alternative future use. There was no acquired IPR&D for the three months ended March 31, 2023.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2024 and 2023 (in thousands):

		Three Months Ended March 31,			
	2024		2023		
Salaries, benefits and related costs	\$	909	\$	754	
Legal, consulting and other professional expenses		1,576		1,182	
Stock-based compensation expense		360		529	
Advertising and marketing expense		7		13	
Other		341		230	
	\$	3,193	\$	2,708	

General and administrative expenses increased \$0.5 million for the three months ended March 31, 2024 compared to the prior period. The increase was driven by \$0.4 million increase in legal, consulting and other professional expenses for consulting activities incurred prior the close of the Almata Transaction.

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

Other Expense, Net

The following table summarizes our other expense, net for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months	Ended March 31,
	2024	2023
Excess of warrant fair value over private placement proceeds	(79,276)	_
Private placement transaction costs	(9,220)	_
Change in fair value of derivative liability	(120)	(180)
Interest income (expense), net	100	(949)
Other expense, net	_	(26)
	\$ (88,516)	\$ (1,155)

Other expense, net increased for the three months ended March 31, 2024 compared to the prior period primarily due to the excess of warrant fair value over private placement proceeds. On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received shares of Series C Preferred Stock and warrants to purchase shares of Avalo's common stock (or number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into).

The warrants did not meet the equity contract scope exception and therefore were classified as a liability upon issuance. The initial measurement of the warrant liability of \$194.9 million exceeded the proceeds received from the private placement investment of \$115.6 million, which resulted in a \$79.3 million loss recognized in other expense, net. The fair value of the warrant liability was estimated using a Black-Scholes option-pricing model and the key input driving the fair value was the closing stock price of \$21.75 on March 28, 2024, which was the initial valuation date, as well as the last trading day of the first quarter of 2024.

As the warrants are carried at fair value, future changes in fair value will be recognized in other (expense) income, net at each reporting period until the warrants are either exercised or expired. Notably, future increases or decreases to the stock price at each reporting period will drive increases or decreases, respectively, to the fair value of the warrant liability. The warrants are set to expire on the earlier of five years from the date of issuance or 30 days after the public announcement of the first patient dosed in a Phase 2 trial of AVTX-009 in hidradenitis suppurativa (the "Dosing Date"). However, if the Requisite Stockholder Approval, the date the Company shareholders approve the issuance of common stock for conversion of Series C Preferred Stock and for exercise of warrants, has not been received by the Dosing Date, then the warrants will expire on the earlier of the five years from the date of issuance or 30 days following receipt of the Requisite Stockholder Approval. Refer to Note 6 - Fair Value Measurements of the unaudited consolidated financial statements for more information.

Additionally, other expense, net increased as a result of the recognition of \$9.2 million of private placement transaction costs, largely consisting of the placement agent fee of \$7.0 million due on the transaction close date, and \$1.7 million fee payable upon exercise of the warrants issued in the private placement investment. The Company recognized this \$1.7 million fee within other expense, net given the warrants are in the money as of the quarterly period ended March 31, 2024.

Finally, the Company fully paid off its loan in the third quarter of 2023, driving the change in interest income (expense) from the prior period.

Income Tax Expense

The Company recognized minimal income tax expense for both the three months ended March 31, 2024 and 2023.

# Liquidity and Capital Resources

# Uses of Liquidity

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

# Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,			
	·	2024		2023
Net cash (used in) provided by:	-			
Operating activities	\$	(6,202)	\$	(10,052)
Investing activities		356		(133)
Financing activities		108,612		13,748
Net increase in cash and cash equivalents	\$	102,766	\$	3,563

Three Months Ended March 21

Net cash used in operating activities

Net cash used in operating activities was \$6.2 million for the three months ended March 31, 2024 and consisted primarily of a net loss of \$121.3 million and adjustments to reconcile net loss to net cash used in operating activities including the excess of warrant fair value over private placement investment proceeds of \$79.3 million, acquired IPR&D of \$27.5 million, transaction costs payable upon exercise of the warrants issued pursuant to the private placement investment of \$1.7 million, and stock-based compensation of \$0.6 million. Accrued expenses and other liabilities increased primarily due to the \$1.7 million transaction costs payable upon exercise of the warrants issued pursuant to the private placement investment.

Net cash used in operating activities was \$10.1 million for the three months ended March 31, 2023, and consisted primarily of a net loss of \$10.0 million and non-cash adjustments to reconcile cash used in operating activities including stock-based compensation expense of \$0.9 million. Changes in net liabilities were primarily driven by a \$4.9 million decrease in accrued expenses and other liabilities partially offset by a \$2.7 million increase in accounts payable and \$1.1 million decrease in other receivables.

We expect future cash used in operating activities to increase in 2024 as a result of acquiring AVTX-009 in March 2024 and our associated development plans.

Net cash provided by (used in) investing activities

Net cash provided by investing activities for the three months ended March 31, 2024 consisted of the cash acquired as part of the Almata Transaction. Net cash used in investing activities was minimal for the three months ended March 31, 2023.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2024 consisted of gross proceeds of \$115.6 million from the private placement investment that closed on March 28, 2024 partially offset by transaction costs paid related to the private placement investment of \$7.0 million.

Net cash provided by financing activities for the three months ended March 31, 2023 consisted of net proceeds of \$13.7 million from an underwritten public offering closed in February 2023.

The Company could receive up to an additional \$69.4 million of gross proceeds upon the exercise of the warrants that were issued pursuant to the private placement investment that closed on March 28, 2024. The warrants are exercisable for approximately \$5.80 per underlying share of common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into) until the earlier of five years from the date of issuance or 30 days after the Dosing Date. However, if the Requisite Stockholder Approval, the date the Company shareholders approve the issuance of common stock for conversion of Series C Preferred Stock and for exercise of warrants, has not been received by the Dosing Date, then the warrants will expire on the earlier of the five years from the date of issuance of 30 days following receipt of the Requisite Stockholder Approval.

Critical Accounting Policies, Estimates, and Assumptions

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared in accordance with GAAP. In preparing the financial statements in conformity with GAAP, the Company makes estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements, the valuation of derivative liabilities, cash flows used in management's going concern assessment, income taxes, goodwill, and clinical trial accruals. The Company believes, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise. Our most critical accounting estimates and assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 29, 2024, except for the warrant liability and asset acquisition, both of which were recognized as a result of transactions that closed in the first quarter of 2024. There have been no significant changes to our critical accounting policies during the three months ended March 31, 2024, except for the asset acquisition and warrant liability accounting policies as described in Note 2 - Basis of Presentation and Significant Accounting Policies to our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q.

#### Warrant Liability

On March 28, 2024, the Company closed a private placement investment with institutional investors in which the investors received (i) 19,946 shares of non-voting convertible preferred stock (the "Series C Preferred Stock") and (ii) warrants to purchase up to an aggregate of 11,967,526 shares of Avalo's common stock (or a number of shares of Series C Preferred Stock convertible into the number of shares of common stock the warrant is then exercisable into). Refer to Note 11 - Capital Structure and sub-header "Q1 2024 Financing" for more information regarding the warrants.

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

The Company's warrant liability is measured at fair value each reporting period utilizing the Black-Scholes option pricing model, which requires assumptions including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, are subjective and require judgment to develop. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our warrant liability could be materially different.

The closing stock price of Avalo's common stock on March 28, 2024, which was the date the transaction closed, as well as the last trading day of the first quarter of 2024, was the main driver of the fair value of the warrant liability. Future increases or decreases to the stock price at each reporting period will drive increases or decreases, respectively, to the fair value of the warrant liability. The expected term was estimated based on when the Company expects the Dosing Date, as defined in Note 11, to occur. If the Dosing Date occurs earlier or later than expected, then the expected term will decrease or increase, respectively, which may decrease or increase, respectively, the value of the warrant liability. Expected volatility is based on a blend between the Company's historical volatility and the volatility of comparable peer companies. The risk-free interest rate was based on the implied yield available on U.S. treasury securities with a maturity equivalent to the expected term. The warrant liability was classified as a Level 3 instrument as its value was based on unobservable market inputs.

	As of Marc	h 31, 2024
Common stock price	\$	21.75
Expected term (in years)		0.5
Expected volatility		109 %
Risk-free rate		5.35 %
Exercise price	\$	5.796933
Dividend yield rate		— %

The initial measurement of the warrant liability of \$194.9 million exceeded the proceeds received from the private placement investment of \$115.6 million, which resulted in a \$79.3 million loss recognized in other expense, net. Subsequently, the warrants are carried at fair value with changes in fair value recognized in the Company's unaudited consolidated statements of operations and comprehensive loss until either exercised or expired.

### Asset Acquisition

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

In the first quarter of 2024, we acquired AVTX-009, a Phase 2 ready anti-IL-1 $\beta$  mAb, through a merger with AlmataBio, Inc. and its wholly owned subsidiary, resulting in us acquiring \$27.5 million of IPR&D. The fair value of the IPR&D, substantially all of which is related to AVTX-009, was immediately recognized as acquired IPR&D expense as there is no alternative future use.

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

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

## Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

#### Item 4. Controls and Procedures.

### **Evaluation of Disclosure Controls and Procedures**

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

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

## **Changes in Internal Control Over Financial Reporting**

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

## PART II - OTHER INFORMATION

## Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 29, 2024 (the "2023 10-K"), 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 may also materially adversely affect our business, financial condition, or future results of operations and the trading price of our common stock.

# Item 6. Exhibits.

Exhibit Number	Description of Exhibit
2.1*	Agreement and Plan of Merger and Reorganization, dated March 27, 2024, by and among Avalo Therapeutics, Inc., Project Athens Merger Sub, Inc., Second Project Athens Merger Sub, LLC, and AlmataBio, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed on March 28, 2024).
3.1	Certificate of Designation for Avalo Therapeutics, Inc.'s Series C Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on March 28, 2024).
3.2	Certificate of Designation for Avalo Therapeutics, Inc.'s Series D Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.2 to the Form 8-K filed on March 28, 2024).
3.3	Certificate of Designation for Avalo Therapeutics, Inc.'s Series E Preferred Stock filed with the Secretary of State of Delaware on March 27, 2024 (incorporated by reference to Exhibit 3.3 to the Form 8-K filed on March 28, 2024).
3.4	Fifth Amended and Restated Bylaws of Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Form 10-K filed on March 29, 2024).
4.1*	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on March 28, 2024).
10.1#+	Asset Purchase Agreement, dated December 6, 2023, by and among AlmataBio, Inc., Leap Therapeutics, Inc., and Flame Biosciences LLC.
10.2#+	License Agreement by, dated November 25, 2019, by and between Flame Biosciences LLC and Eli Lilly and Company.
10.3#+	First Amendment to License Agreement, dated February 2, 2021, by and between Flame Biosciences LLC and Eli Lilly and Company.
10.4*	Securities Purchase Agreement, dated March 27, 2024, by and among Avalo Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on March 28, 2024).
10.5	Registration Rights Agreement, dated March 27, 2024, by and among Avalo Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 102 to the Form 8-K filed on March 28, 2024).
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets as of March 31, 2024 (Unaudited) and December 31, 2023; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three Months Ended March 31, 2024 and 2023; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three Months Ended March 31, 2024 and 2023; (iv) Condensed Consolidated Statements of Preferred Stock and Changes in Stockholders' (Deficit) Equity (Unaudited) for the Three Months Ended March 31, 2024 and 2023; and (v) Notes to Unaudited Financial Statements.

104 Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

- \*Certain exhibits and schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted exhibits or schedules upon request by the U.S. Securities and Exchange Commission.
- # Certain confidential portions to this exhibit have been omitted from this filing pursuant to Item 601(b)(2) 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.

Date: May 13, 2024

/s/ Christopher Sullivan
Christopher Sullivan

Chief Financial Officer

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

# 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.

# ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this "Agreement") is entered into as of December 6, 2023 (the "Effective Date"), by and among AlmataBio, Inc., a Delaware corporation (the "Buyer"), Leap Therapeutics, Inc., a Delaware corporation ("Parent"), and Flame Biosciences LLC, a Delaware limited liability company ("Flame" and, together with Parent, the "Sellers").

### Introduction

WHEREAS, the Sellers desire to sell, transfer and assign to the Buyer, and the Buyer desires to purchase from the Sellers, the Transferred Assets (as defined below), subject to the assumption by the Buyer of the Assumed Liabilities (as defined below), upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Buyer and the Sellers agree as follows:

### ARTICLE I

### PURCHASE AND SALE OF THE TRANSFERRED ASSETS

- 1.1. <u>Purchase and Sale of Assets</u>. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Sellers agree to sell, convey, transfer, assign and deliver to the Buyer, and the Buyer agrees to purchase from the Sellers, all of the right, title and interest of Sellers in and to the Transferred Assets. For purposes of this Agreement, "<u>Transferred Assets</u>" means:
- (a) the Patent Rights set forth on Schedule 1.1(a) (including any continuation, divisional, continuation-in-part, substitution, reissue, renewal, reexamination, supplemental protection certificate, extension, or foreign counterpart, of any of the Patent Rights set forth on Schedule 1.1(a) if any such continuation, divisional, continuation-in-part, substitution, reissue, renewal, reexamination, supplemental protection certificate, extension, or foreign counterpart, is owned by Sellers or their controlled Affiliates as of immediately prior to the Closing and was filed by Sellers or their controlled Affiliates at any time after the consummation of the Merger on January 17, 2023) (the "Transferred Patents");
- (b) any and all regulatory filings, marketing authorizations, permits, licenses, registrations, regulatory clearances, approvals, concessions, designations, qualifications, registrations, certifications and similar items in each case granted by Governmental Entities and set forth on Schedule 1.1(b), in each case, in or related to any jurisdiction anywhere in the world (the "Transferred Permits");

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- (c) any and all Know-How owned by Sellers or their controlled Affiliates as of immediately prior to the Closing that (i) pertains or relates solely to any Product or, as of immediately prior to the Closing, is being used or held for use by Sellers solely in connection with any Product, and (ii) immediately prior to the consummation of the Merger on January 17, 2023, was owned by Flame Bioscience, Inc. ("Sellers' Predecessor") and was then being used or held for use by Sellers' Predecessor solely in connection with any Product (the "Transferred Know-How");
- (d) any inventories of Product (including, if any, all bulk and vialed inventory, existing finished quantities, work in process, raw materials, constituent substances, materials, stores and supplies, as well as any trade and sample inventories and any precursors, including cell lines) that are set forth on Schedule 1.1(d) (the "Transferred Inventory"), except to the extent any such inventories of Product are depleted, spoiled, damaged, lost or otherwise no longer available to Sellers at any time during the period commencing on the Effective Date and ending on the Closing Date;
- (e) the Sellers' (and their controlled Affiliates') right, title and interest in and to all Contracts set forth on Schedule 1.1(e) (the "Transferred Contracts");
- (f) all of Sellers' claims, causes of action, defenses, counterclaims or other rights, if any, (whether known or unknown, matured or unmatured, accrued or contingent), in each case only to the extent that such claims, causes of action, defenses, counterclaims or other rights, if any, arise out of or relate to any of the Transferred Assets or any Assumed Liabilities; and
- (g) the Sellers' (and their controlled Affiliates') right, title and interest in and to all books, documentation, ledgers, files, reports, lab notebooks, clinical data, plans and operating records that are, or come to be, in the possession or control of the Seller or its controlled Affiliates, in each case only to the extent that such books, documentation, ledgers, files, reports, lab notebooks, clinical data, plans and operating records pertain or relate to any Transferred Assets or any Assumed Liabilities (the "Transferred Books and Records").
- 1.2. Excluded Assets. Notwithstanding anything to the contrary in this Agreement, the Buyer is only purchasing the Transferred Assets, and the Transferred Assets shall not include any of the Excluded Assets. For purposes of this Agreement, "Excluded Assets" means all assets, rights and properties of the Sellers or any of their controlled Affiliates other than the Transferred Assets. Without limitation of the foregoing, the Excluded Assets shall include the following:
- (a) all accounts receivable, cash and cash equivalents or similar investments, other current assets, bank accounts, commercial paper, certificates of deposit, Treasury bills and other marketable securities, including security deposits, reserves, prepaid rents and prepaid expenses;
- (b) all assets, properties or rights set forth on, and all rights, title, interest, assets or properties arising under, any Contract that is not a Transferred Contract;
- (c) all insurance policies, surety bonds or self-insurance of the Sellers or any of its controlled Affiliates and all claims, credits, causes of action or rights thereunder (including rights to assert claims thereunder);
- (d) all minute books of the Sellers or any of their controlled Affiliates and other corporate records of the Sellers or any of their controlled Affiliates;

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- (e) all rights of the Sellers or any of their controlled Affiliates arising under this Agreement or the Ancillary Agreements;
- (f) all interests in the share capital and other equity interests of the Sellers or any of their controlled Affiliates;
- (g) all Tax refunds and Tax deposits and all Tax books and records; and
- (h) all claims, causes of action, defenses, counterclaims or other rights, if any, (whether known or unknown, matured or unmatured, accrued or contingent) other than those rights included in the Transferred Assets pursuant to Section 1.1(f).
- 1.3. <u>Assumption of Liabilities</u>. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Buyer shall assume and agree to perform, pay, satisfy or discharge when due the Assumed Liabilities. For purposes of this Agreement, "<u>Assumed Liabilities</u>" means the following Liabilities:
- (a) all Liabilities that at any time (whether prior to, on or after the Closing) arise out of, or relate to, the prosecution, ownership, operation, maintenance, sale, lease or use of any Transferred Asset or any Product;
  - (b) all Liabilities that at any time (whether prior to, on or after the Closing) arise under any of the Transferred Contracts; and
- (c) all Liabilities for which the Buyer agrees to be liable hereunder or that are otherwise apportioned to the Buyer hereunder, including, without limitation, pursuant to <u>Section 1.7(a)</u> and <u>Section 4.4(b)</u>
- 1.4. <u>Retained Liabilities</u>. Notwithstanding anything to the contrary in this Agreement, the Assumed Liabilities shall not include any of the Retained Liabilities, and the Buyer does not hereby and shall not assume or in any way undertake to perform, pay, satisfy or discharge any Retained Liabilities. For purposes of this Agreement, "<u>Retained Liabilities</u>" means all Liabilities of the Sellers and their Subsidiaries other than the Assumed Liabilities. Without limitation of the foregoing, the Retained Liabilities shall include the following:
  - (a) all Liabilities of the Sellers and Subsidiaries to the extent relating to any Excluded Assets; and
- (b) all Liabilities for any and all income Taxes of the Sellers (including any income Taxes of the Sellers arising as a result of the transfer by the Sellers to the Buyer of the Transferred Assets).
- 1.5. <u>Consideration</u>. At the Closing, upon the terms and subject to the conditions set forth herein, the Buyer shall purchase from the Sellers the Transferred Assets in exchange for the Aggregate Consideration as set forth in this Agreement and the assumption of the Assumed Liabilities.
  - 1.6. Closing; Delivery and Payment.

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(a) The Closing shall take place simultaneously with the execution and delivery of this Agreement remotely, via electronic exchange of documents.

# (b) At the Closing:

- (i) the Buyer shall deliver the Closing Date Consideration by wire transfer of immediately available funds to an account designated in writing by the Sellers;
  - (ii) the Sellers shall execute and deliver to the Buyer a Bill of Sale in the form attached hereto as Exhibit A (the "Bill of Sale");
- (iii) the Buyer shall execute and deliver to the Sellers an Assumption of Assumed Liabilities Agreement in the form attached hereto as Exhibit B (the "Assumption Agreement")
- (iv) the Buyer shall execute and deliver to the Sellers an Assignment and Assumption Agreement in the form attached hereto as Exhibit D (the "Assignment and Assumption Agreement," and, together with the Bill of Sale, the Assumption Agreement, and the Additional Transfer Documents (defined below), the "Ancillary Agreements");
- (v) the Sellers shall make available to the Buyer, to enable the Buyer to take possession and control of, each to the extent existing in physical form and in the possession of the Sellers, the Transferred Books and Records and the Transferred Know-How;
- (vi) the Sellers shall make available to the Buyer, to enable the Buyer to take possession and control of, all of the other Transferred Assets of a tangible nature;
- (vii) the Sellers shall deliver to the Buyer a certificate, executed by each Seller's corporate secretary on behalf of such Seller, certifying as to the resolutions of the members or directors of such Seller, as applicable, authorizing and approving the sale of the Transferred Assets to the Buyer pursuant to this Agreement and the other Contemplated Transactions;
- (viii) the Buyer shall deliver to the Sellers a certificate, executed by the Buyer's corporate secretary on behalf of the Buyer, certifying as to the resolutions of the board of directors of the Buyer authorizing and approving the purchase of the Transferred Assets by the Buyer pursuant to this Agreement and the other Contemplated Transactions;
- (ix) Flame shall deliver to the Buyer evidence, in form and substance reasonably satisfactory to the Buyer, that Flame has obtained all of the consents and provided all notices set forth on Schedule 1.6(b)(ix); and
- (x) the Sellers shall deliver to the Buyer a certification that Flame is not a foreign person in accordance with the Treasury Regulations under Section 1445 of the Code.

## 1.7. Taxes and Fees.

(a) <u>Transfer Taxes</u>. All transfer, sales, and use taxes, deed excise stamps and similar charges ("<u>Transfer Taxes</u>"), if applicable, related to the Contemplated Transactions shall be borne by the Buyer. The required party shall file all necessary Tax Returns and other documentation

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with respect to such Transfer Taxes required by a Governmental Entity to be filed and, if required by applicable Law, the other party will, and will cause its controlled Affiliates to, join in the execution of any such Tax Returns and other documentation. The Sellers and the Buyer shall cooperate in the preparation and filing of all forms and documentation necessary to provide exemption from Transfer Tax, to the extent permitted by applicable Law.

- (b) Withholding Taxes. The Buyer will be entitled to deduct and withhold from the amounts otherwise payable by it pursuant to this Agreement such amounts that it is required to deduct and withhold with respect to the making of such payment under the Code, or any provision of state, local or foreign Tax Law, and to collect any necessary Tax forms, including Forms W-8 or W-9, as applicable, or any similar information, from the Sellers and any other recipient of payments hereunder; provided, however, that the Buyer will (i) promptly (and in any event no later than five (5) Business Days prior to the date on which such payment is made or, in the case of a change in applicable Law after the date of this Agreement that would require withholding from such amounts, as soon as practicable) notify the Sellers of any intention to so deduct and withhold and provide the Sellers the opportunity to provide any statement, form, or other documentation that would reduce or eliminate any such requirement to deduct and withhold; (ii) remit and report any such amount required to be deducted and withheld to the applicable Governmental Entity in accordance with applicable Law; (iii) promptly provide to the Sellers a certificate, receipt or other documentation of proof of such remittance reasonably acceptable to the Sellers; and (iv) cooperate with the Sellers as reasonably requested with respect to the filing of any Tax Return or conduct of any claim relating to any available refund of such amount remitted. In the event that any amount is so deducted and withheld, and properly remitted, such amount will be treated for all purposes of this Agreement as having been paid to the person to whom the payment from which such amount was withheld was made.
- 1.8. Wrong Pocket Assets. If at any time or from time to time after the Closing until the date that is twelve (12) months after the Closing Date, Sellers or any of their controlled Affiliates, on the one hand, or the Buyer or its Affiliates, on the other hand, shall receive or otherwise possess any asset or right that, effective as of the Closing, is a Transferred Asset belonging to the Buyer, on the one hand, or is an Excluded Asset belonging to the Sellers or any of their Affiliates, on the other, pursuant to this Agreement, the Sellers or the Buyer (as the case may be) shall promptly deliver and/or transfer, or cause to be delivered and/or transferred, such asset or right to the Person to whom, effective as of the Closing, such asset or right belongs pursuant to this Agreement. With respect to any Transferred Asset or any Excluded Asset that is subject to the foregoing provisions of this Section 1.8, the Person that is required to deliver or transfer such Transferred Asset or such Excluded Asset, as the case may be, pursuant to the foregoing provisions of this Section 1.8 shall hold such Transferred Asset or such Excluded Asset, as the case may be, in trust for the benefit of such other Person until such Transferred Asset or such Excluded Asset, as the case may be, is delivered or transferred in accordance with the provisions of this Section 1.8; provided, however, that the foregoing provisions of this sentence shall only be applicable with respect to any Know-How that is Transferred Know-How if, to Sellers' Knowledge, such Know-How is Transferred Know-How. Without limitation of the foregoing, in the event that, at any time or from time to time after the Closing, Sellers or any of their controlled Affiliates receives any payment in respect of any Transferred Asset or Buyer receives any payment in respect of an Excluded Asset, the Sellers or the Buyer (as applicable) shall promptly deliver such payment to an account designated in writing by the Buyer or the Sellers (as applicable) by wire transfer of immediat

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## 1.9. Milestone Payments.

- (a) <u>Milestone Events and Milestone Payments</u>. Subject to the terms and conditions of this Agreement, Buyer shall make each applicable payment (each a "<u>Milestone Payment</u>") set forth below to the Sellers promptly (and in any event no later than forty-five (45) days) after the achievement by any member of the Buyer Rights Group of the relevant event listed below (each, a "<u>Milestone Event</u>"):
  - (i) a one-time payment of (\*\*\*) upon First Commercial Sale of any Product for any indication in the United States;
- (ii) a one-time payment of (\*\*\*) upon the First Commercial Sale of any Product for any indication in any one of France, Germany, Italy, Spain or the United Kingdom;
- (iii) a one-time payment of (\*\*\*) upon the First Commercial Sale of any Product for any indication in any one of Japan or China;
  - (iv) a one-time payment of (\*\*\*) upon the cumulative worldwide Net Sales of the Products exceeding (\*\*\*);
  - (v) a one-time payment of (\*\*\*) upon the cumulative worldwide Net Sales of the Products exceeding (\*\*\*); and
  - (vi) a one-time payment of (\*\*\*) upon the cumulative worldwide Net Sales of the Products exceeding (\*\*\*).
- (b) For the avoidance of doubt, (i) no Milestone Payment shall be paid more than once, and (ii) the maximum cumulative amount of Milestone Payments shall not exceed (\*\*\*).

# (c) Diligence.

- (i) The Buyer shall, itself or through the members of the Buyer Rights Group, use Commercially Reasonable Efforts to develop at least one Product, to seek and obtain Regulatory Approval therefor, and to market, sell and otherwise commercialize any such Product for which Regulatory Approval has been obtained to achieve the Net Sales amounts set forth in the Milestone Events.
- (ii) Other than the diligence obligations specifically set forth in Section 1.9(c)(i) hereof, neither the Buyer nor any other member of the Buyer Rights Group shall have other diligence obligations with respect to achievement of any Milestone Event, or to develop, market or sell any Product. For clarification, a good faith determination by the Buyer or any other member of the Buyer Rights Group to discontinue or deprioritize the development or commercialization of any or all Products, or the development or commercialization by the Buyer or any other member of the Buyer Rights Group of a product similar to or competitive with a Product shall not constitute a breach of, or be restricted in any way by, this Agreement if, and for so long, as such discontinuation or de-prioritization is consistent with the requirements of Section 1.9(c)(i) hereof.

# (d) Reporting.

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(i) The Buyer shall provide (or may cause any applicable member of the Buyer Rights Group to provide) written notice to the
Sellers of (A) the achievement of each Milestone Event no later than thirty (30) days after the occurrence thereof and (B) any determination by the
Buyer or any applicable member of the Buyer Rights Group to terminate or discontinue further development or commercialization of any Product prior to
the payment of all Milestone Payments (which written notice under this clause (B) shall be given to the Sellers no later than thirty (30) days after any
such determination).

- (ii) The Buyer shall, and shall cause the other members of the Buyer Rights Group to, keep books and records sufficient to calculate Milestone Payments and reasonable documentation regarding the Products.
- (iii) Within 120 days following the end of each calendar year ending after the Closing Date and continuing until the earlier to occur of (A) all Milestone Events having been achieved or (B) the date that the Buyer and the other members of the Buyer Rights Group have permanently discontinued all development and commercialization activities with respect to the Products (but only if and for so long as such activities remain permanently discontinued) and Buyer has certified in writing to the Seller that such permanent discontinuation has occurred, Buyer shall provide to Sellers a reasonably detailed written report summarizing the efforts of the Buyer and the other members of the Buyer Rights Group to satisfy the diligence obligations set forth in Section 1.9(c)(i) and their progress with respect thereto (each, an "Annual Report"). Each Annual Report will contain any material updates to the applicable development plans or the applicable commercialization plans, as the case may be, occurring following the date on which the previous Annual Report was issued; provided, however, that the parties acknowledge and agree that the Buyer shall not be required to include the following information in any Annual Report (x) the status of enrollment of patient in any preclinical studies or clinical trials of any Product conducted by or on behalf of any member of the Buyer Rights Group, including information relating to any such patient's response to any Product, (y) information regarding the Buyer's cash or financial position, or (z) the content of any informal or oral discussions with or feedback from any Regulatory Authorities. Following receipt by the Sellers of each Annual Report, the Sellers may request a meeting with knowledgeable representatives of Buyer and its Affiliates who are directly involved and engaged in the development and/or commercialization activities (or in Buyer's oversight of such activities) that are subject to the diligence obligations set forth in Section 1.9(c)(i), which meeting shall take place promptly, and in any event not later than 90 calendar days following such request, in person or by telephone conference or video conference as mutually agreed. At such meeting, such representatives of Buyer and its Affiliates shall respond, during such meeting (or, if not then practicable, as promptly as practicable thereafter), to Sellers' reasonable inquiries to the extent appropriate for the purpose of providing Sellers with a reasonably detailed understanding of the efforts of Buyer and the other members of the Buyer Rights Group to satisfy the diligence obligations set forth in Section 1.9(c)(i) and their progress with respect thereto. For clarity, Sellers' reasonable inquiries at any such meeting may include or cover any of the topics or information that Buyer is permitted to exclude from the Annual Report pursuant to any of clauses (x) through (z) set forth above in this Section 1.9(d)(iii).
- (e) <u>Audits</u>. Upon the written request of the Sellers, the Buyer shall, and shall cause the other members of the Buyer Rights Group to, permit an independent public accountant selected by the Sellers and reasonably satisfactory to the Buyer and the relevant member of the Buyer Rights Group (the "<u>Accountant</u>") to have reasonable access upon reasonable prior notice and during normal business hours, but no more than once during any calendar year, to review the books and

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records of the Buyer and the other members of the Buyer Rights Group solely for the purpose of determining compliance with Section 1.9(a), Section 1.9(c)(i) and Section 1.9(d)(i) (an "Audit"), at the Sellers' expense. Before conducting the Audit, the Accountant must execute a reasonable confidentiality agreement with the Buyer and, if applicable, the relevant Buyer Rights Group member. In acting hereunder, the Accountant shall act as an expert and not as arbitrator, and Accountant's authority is limited to resolving disputed issues of fact (and not law). The procedures set forth in this Section 1.7(e) concerning the determinations set forth herein by the Accountant shall be governed by the law of expert determination and appraisal rather than the law of arbitration. If the Accountant concludes that any Milestone Payment was not paid when due, the Sellers shall be entitled to deliver a written notice of such non-payment (a "Dispute Notice"), in which case the Sellers and the Buyer shall, for a period of not less than thirty (30) calendar days after delivery of the Dispute Notice, attempt in good faith to resolve the items in dispute. If no agreement is reached by the Sellers and the Buyer as to the calculation of the disputed amount within thirty (30) calendar days after delivery of a Dispute Notice, then either party shall have the right to pursue applicable legal remedies in accordance with the provisions of Section 6.11. If the Sellers and the Buyer agree, or any dispute resolution mechanism determines that, any Milestone Payment was not paid as a result of an underreporting of Net Sales by more than (\*\*\*), the Buyer shall reimburse the Sellers for the reasonable out-of-pocket costs of the Audit and the reasonable costs and expenses of Sellers in investigating the same, including but not limited to attorneys fees. A quarterly period can only be subject to an Audit on one occasion and the Sellers shall not be permitted to Audit a calendar quarter more than six (6) years after the end of such calendar quarter.

- (f) Methods of Payments; Foreign Currency. All Milestone Payments shall be paid in Dollars by wire transfer to an account designated in writing by the Sellers. For all Net Sales and deductions or exclusions therefrom denominated in any currency other than Dollars, the amount of such sales in foreign currencies shall be converted into Dollars using the exchange rate for the relevant month (the "Monthly Rate"), such Monthly Rate being determined as the last price rate of exchange for such currencies on the last business day of the immediately preceding calendar month as published on Bloomberg page FXC (or such other publication as may be agreed upon in writing between the parties from time to time).
- (g) Contractual Rights Only. The rights and obligations of the Sellers under this Section 1.9, including the right to receive payments, (i) are purely contractual rights and not a security for purposes of any federal or state securities Laws, (ii) will not be represented by any form of certificate or instrument, (iii) do not give the Sellers any dividend rights, voting rights, liquidation rights, preemptive rights or other rights common to holders of the Buyer's equity securities and (iv) subject to Section 6.4, are not transferrable, assignable or redeemable (other than indirect transfers or assignments, transfers by operation of law or transfers or assignments to any Affiliate of the Sellers).

### ARTICLE II

## REPRESENTATIONS AND WARRANTIES OF THE SELLERS

Each of the Sellers represents and warrants to the Buyer, jointly and severally, as of the Effective Date, except as set forth herein or, subject to Section 6.12, in the Disclosure Schedule.

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2.1.	Organization,	Standing and Power.	Each Seller is duly	organized,	validly existing	and in good	standing under th	e Laws of I	Delaware, and
has all requis	ite corporate or	r limited liability com	pany, as applicable	, power and	authority to ow	n the Transfe	erred Assets owne	d by such S	eller.

# 2.2. <u>Authority; No Conflict; Required Filings and Consents.</u>

- (a) Each Seller has all requisite corporate or limited liability company, as applicable, power and authority to enter into this Agreement and each of the Ancillary Agreements to which it is a party and to consummate the Contemplated Transactions. The execution, delivery and performance by each Seller of this Agreement and each of the Ancillary Agreements to which it is or will be a party and the consummation by each Seller of the Contemplated Transactions have been duly authorized by all necessary corporate or limited liability company, as applicable, action on the part of such Seller. Each Seller has duly executed and delivered this Agreement and has duly executed and delivered (or at the Closing will duly execute and deliver) each Ancillary Agreement to which such Seller is a party. This Agreement is the legal, valid and binding obligation of each Seller, enforceable against such Seller in accordance with its terms, and each Ancillary Agreement to which a Seller is a party (or will be a party at the Closing) is or will be at the Closing, as applicable, the legal, valid and binding obligation of such Seller, enforceable against such Seller in accordance with its terms, except, in the case of this Agreement or any such Ancillary Agreement, as enforceability may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar Laws relating to or affecting the rights of creditors generally and by equitable principles, including those limiting the availability of specific performance, injunctive relief and other equitable remedies and those providing for equitable defenses (the "Bankruptcy Exception").
- (b) The execution, delivery and performance by each Seller of this Agreement and each of the Ancillary Agreements to which it is a party, and the consummation by each Seller of the Contemplated Transactions, do not and will not (i) conflict with, or result in any violation or breach of, any provision of the Certificate of Incorporation or Bylaws or limited liability company agreement, as the case may be, of such Seller, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under any Contract to which such Seller is a party, require the payment of a penalty under any Contract to which such Seller is a party, or result in the imposition of any Liens, other than Permitted Liens, on or with respect to any of the Transferred Assets, or (iii) subject to compliance with the requirements specified in Section 2.2(c), conflict with or violate any Permit, concession, franchise, license or Law applicable to such Seller or any of its properties or assets.
- (c) No consent, approval, license, Permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to each Seller in connection with the execution, delivery and performance by such Seller of this Agreement and each of the Ancillary Agreements to which it is a party or the consummation of the Contemplated Transactions.

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- (a) Each Seller has timely paid all income Taxes which will have been required to be paid on or prior to the date hereof by such Seller, the non-payment of which would result in a Lien on any Transferred Asset or would result in the Buyer becoming liable or responsible therefor.
- (b) The Sellers will timely pay all income Taxes that arise from or with respect to the Transferred Assets, that are incurred in or attributable to the Pre-Closing Tax Period and that Sellers are required to pay, the non-payment of which would result in a Lien on any Transferred Asset.
- (c) Since January 17, 2023, neither Seller has received any written notice that any of the Transferred Assets are subject to or encumbered by any Lien with respect to Taxes, other than a Permitted Lien.

# 2.4. <u>Intellectual Property</u>.

- (a) To Sellers' Knowledge, the Sellers' are the sole and exclusive owner of, or possess valid license rights to use, the FL-101/FL-103 Intellectual Property. For clarity, the scope of the foregoing sentence shall not be construed or interpreted, and shall not include, any representation or warranty that the practice or use of the FL-101/FL-103 Intellectual Property shall not infringe, misappropriate or violate the intellectual property rights of any person.
- (b) Since January 17, 2023, neither Seller nor any of its controlled Affiliates has assigned to any third party all or any portion of any ownership and title that such Seller or such controlled Affiliate, as applicable, may have or may have had with respect to the FL-101/FL-103 Intellectual Property. Since January 17, 2023, neither Seller nor any of its controlled Affiliates has granted to any third party any sublicense under any license rights that either Seller or any of its controlled Affiliates has to use FL-101/FL-103 Intellectual Property.
- (c) Since January 17, 2023, (i) the Sellers have not sent any written notice of infringement or misappropriation to, or asserted or threatened any action or claim of infringement or misappropriation against, any Person involving or relating to any FL-101/FL-103 Intellectual Property, (ii) to Sellers' Knowledge, Sellers have not been served with or provided written notice that there is any pending or threatened claim, interference, opposition or demand of any third party, including any controlled Affiliate of the Sellers, challenging the ownership, validity or scope of any FL-101/FL-103 Intellectual Property, and (iii) to the Sellers' Knowledge, neither the Sellers nor any of their controlled Affiliates have been served with or provided written notice that any FL-101/FL-103 Intellectual Property is the subject of any Order barring or limiting the Sellers' use of any such FL-101/FL-103 Intellectual Property.
- (d) Except as disclosed in Section 2.4(d) of the Disclosure Schedule, since January 17, 2023, (i) the Sellers have not granted any licenses to the FL-101/FL-103 Intellectual Property, (ii) the Sellers have not entered into any Contract (other than this Agreement and the Ancillary Agreements) that materially limits or restricts the Sellers' use of the FL-101/FL-103 Intellectual Property, and (iii) Sellers have not entered into any Contract that provides for the payment of royalties by the Sellers on or with respect to any of the FL-101/FL-103 Intellectual Property.

# 2.5. Contracts.

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- (a) To Sellers' Knowledge, Section 2.5(a) of the Disclosure Schedule sets forth a complete and accurate list of each Contract (i) to which either Seller is a party as of the Effective Date, (ii) that is being used or held for use by either Seller as of the Effective Date primarily in connection with any Product, (iii) to which, immediately prior to the consummation of the Merger on January 17, 2023, Sellers' Predecessor was a party and that was used or held for use by Sellers' Predecessor primarily in connection with any Product, and (iv) that Sellers' Predecessor made a representation and warranty in the Merger Agreement to the effect that, as of the date of the Merger Agreement, such Contract was a material contract of Sellers' Predecessor (collectively, the "Material Contracts").
- (b) Except as disclosed in Section 2.5(b) of the Disclosure Schedule, (i) the Sellers have furnished or made available to the Buyer a copy of each Material Contract in the form that such Material Contract is in Sellers' possession, (ii) since January 17, 2023, neither Seller has terminated, or entered into any Contract agreeing to terminate, any Material Contract, (iii) since January 17, 2023, neither Seller (or its applicable Affiliate) has received written notice from any third party that either Seller or any of its Affiliates is in violation in any material respect of or in default in any material respect under any Material Contract, and (iv) since January 17, 2023, neither Seller (or its applicable Affiliate) has delivered written notice to any third party to any Material Contract to the effect that such third party is in violation in any material respect of or in default in any material respect under such Material Contract.
- 2.6. <u>Litigation</u>. Since January 17, 2023, neither Seller has received any written notice that there is any action, suit, proceeding, claim, arbitration or investigation, pending or threatened against the Sellers or any of their controlled Affiliates with respect to, or primarily affecting, any Product. Since January 17, 2023, neither Seller has received any written notice that are unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards rendered by a court, an administrative agency or by an arbitrator against any of the Transferred Assets or against the Sellers or any of their controlled Affiliates with respect to, or primarily affecting, any Product. Since January 17, 2023, neither Seller has received any written notice that (i) there is any action, suit, proceeding, claim, arbitration or investigation pending or threatened against the Sellers, or (ii) the Sellers are subject to any outstanding order, writ, judgement, injunction or decree of any Governmental Entity that, in the case of either the foregoing clause (i) or the foregoing clause (ii), would, individually or in the aggregate (a) prevent or materially delay the consummation by the Sellers of the Contemplated Transactions, or (b) otherwise prevent or materially delay performance by the Sellers of their obligations under this Agreement.
- 2.7. <u>Compliance with Laws</u>. Since January 17, 2023, neither Seller has received any written notice alleging any material violation of any applicable Law with respect to any Product or the ownership or operation of the Transferred Assets.
- 2.8. Permits. Since January 17, 2023, neither Seller nor any of their controlled Affiliates has received any written notices that (i) it is in violation of any of the terms or conditions of any Transferred Permits, (ii) there is any action or claim pending or threatened to revoke, suspend, adversely modify or terminate any Transferred Permit or declare any Transferred Permit invalid in any material respect, or (iii) the Sellers or their controlled Affiliates do not have any Permit necessary for the Sellers to own, lease or otherwise operate the Transferred Assets and conduct their business as it relates to the Product.

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# 2.9. Regulatory Matters.

- (a) With respect to any Product, since January 17, 2023, neither Seller has received any written notice of FDA regulatory actions against the Sellers or any of their controlled Affiliates, including written notice of adverse findings, regulatory, untitled or warning letters or mandatory recalls, or any other written notice from any Governmental Entity alleging or asserting material noncompliance with any Law.
- (b) Since January 17, 2023, neither Seller nor any of its controlled Affiliates has received written notice of any pending or threatened claim, suit, proceeding, hearing, enforcement, audit or investigation from the FDA or any other Governmental Entity alleging that any operation or activity of the Sellers or any of their controlled Affiliates in connection with any Product is in material violation of the FDA Act or the respective counterparts thereof promulgated by applicable state Governmental Entities or Governmental Entities outside the United States, including, as applicable, the medicinal products and medical device Laws of the European Union. Since January 17, 2023, neither Seller has received written notice of any civil, criminal or administrative action, suit, demand, claim, complaint, hearing, proceeding or investigation that is pending or threatened against the Sellers or any of their controlled Affiliates in connection with any Product. Since January 17, 2023, neither Seller has received written notice that there has not been any material violation of any laws by the Sellers or any of their controlled Affiliates or any of its agents or contractors in Sellers' product development efforts, submissions or reports to any Governmental Entity in connection with any Product that would reasonably be expected to require investigation, corrective action or enforcement action.
- 2.10. <u>Brokers</u>. No agent, broker, investment banker, financial advisor or other firm or Person is or shall be entitled, as a result of any action, agreement or commitment of the Sellers or any of their controlled Affiliates, to any broker's, financial advisor's or other similar fee or commission (or reimbursement of expenses) in connection with any of the Contemplated Transactions.
- 2.11. <u>Title to Transferred Assets</u>. To Sellers' Knowledge, the Sellers' are the sole and exclusive owner of, and have good and valid title to, each of those Transferred Assets in which the Sellers have, or purport to have, an ownership interest, except for any minor imperfections of title that do not materially adversely affect Buyer's right to own, use or exploit any of such Transferred Assets; <u>provided</u>, <u>however</u>, that, notwithstanding the foregoing, no representation or warranty is made pursuant to this sentence with respect to any of the FL-101/FL-103 Intellectual Property. Since January 17, 2023, neither Seller nor any of its controlled Affiliates has assigned to any third party all or any portion of any ownership and title that such Seller or such controlled Affiliate, as applicable, may have or may have had with respect to any of the Transferred Assets. Since January 17, 2023, neither Seller has created, recorded or imposed any Lien (other than a Permitted Lien) on any of the Transferred Assets for the benefit of any Person. Since January 17, 2023, neither Seller has received any written notice that any of the Transferred Assets are subject to or encumbered by any Liens, other than Permitted Liens.
- 2.12. <u>Exclusive Representations and Warranties</u>. Other than the representations and warranties set forth in this <u>Article II</u>, neither Seller is making any other representations or warranties, express or implied, with respect to any Product, the Transferred Assets, or the Assumed Liabilities.

Page 12 ASSET PURCHASE AGREEMENT The Sellers hereby disclaim any other express or implied representations or warranties, including regarding any financial projections or other forward-looking statements provided by or on behalf of the Sellers or any Affiliates.

### ARTICLE III

## REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer represents and warrants to the Sellers as of the Effective Date except as set forth herein.

- 3.1. <u>Organization, Standing and Power</u>. The Buyer is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware, has all requisite corporate power and authority to carry on its business as now being conducted.
  - 3.2. Authority; No Conflict; Required Filings and Consents.
- (a) The Buyer has all requisite corporate power and authority to enter into this Agreement and each of the Ancillary Agreements to which it is or will be a party and to consummate the Contemplated Transactions. The execution, delivery and performance by the Buyer of this Agreement and each of the Ancillary Agreements to which it is or will be a party and the consummation by the Buyer of the Contemplated Transactions have been duly authorized by all necessary corporate action on the part of the Buyer. This Agreement has been, and each such Ancillary Agreement has been or at the Closing will be, duly executed and delivered by the Buyer. This Agreement is, and each such Ancillary Agreement is or, when duly executed and delivered by Buyer at the Closing, will be, the legal, valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, subject to the Bankruptcy Exception.
- (b) The execution, delivery and performance by the Buyer of this Agreement and each of the Ancillary Agreements to which it is a party, and the consummation by the Buyer of the Contemplated Transactions, do not and will not (i) conflict with, or result in any violation or breach of, any provision of the Certificate of Incorporation or Bylaws of the Buyer, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, require a consent or waiver under, require the payment of a penalty under or result in the imposition of any Lien, other than Permitted Liens, on or with respect to the Buyer's assets under, any of the terms, conditions or provisions of any lease, license, contract or other agreement, instrument or obligation to which the Buyer is a party or by which the Buyer or any of its properties or assets may be bound, or (iii) subject to compliance with the requirements specified in Section 3.2(c), conflict with or violate any permit, concession, franchise, license or Law applicable to the Buyer or any of its properties or assets.
- (c) No consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to the Buyer in connection with the execution, delivery and performance by the Buyer of this Agreement and each of the Ancillary Agreements to which it is a party or the consummation by the Buyer of the Contemplated Transactions.

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- 3.3. <u>Litigation</u>. There is no action, suit, proceeding, claim, arbitration or, to the Buyer's Knowledge, investigation pending or threatened, against the Buyer, and the Buyer is not subject to any outstanding order, writ, judgment, injunction or decree of any Governmental Entity that, in either case, would, individually or in the aggregate, (a) prevent or materially delay the consummation by the Buyer of the Contemplated Transactions or (b) otherwise prevent or materially delay performance by the Buyer of any of its obligations under this Agreement.
- 3.4. <u>Brokers</u>. No agent, broker, investment banker, financial advisor or other firm or Person is or shall be entitled, as a result of any action, agreement or commitment of the Buyer, to any broker's, finder's, financial advisor's or other similar fee or commission (or reimbursement of expenses) in connection with any of the Contemplated Transactions.
- 3.5. Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Article III, the Buyer is not making any other representations or warranties, express or implied, with respect to the Contemplated Transactions. The Buyer hereby disclaims any other express or implied representations or warranties, including regarding any financial projections or other forward-looking statements provided by or on behalf of the Buyer or any Affiliates.
- 3.6. <u>Independent Investigation</u>. Buyer has conducted its own independent investigation, review and analysis of the Transferred Assets and acknowledges that it has been provided adequate access to the personnel, properties, assets, premises, books and records, and other documents and data of the Sellers for such purpose. Buyer acknowledges and agrees that: (a) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, Buyer has relied solely upon its own investigation and the express representations and warranties of Seller set forth in <u>Article II</u> of this Agreement (including related portions of the Disclosure Schedules); and (b) neither the Sellers nor any other Person has made any representation or warranty as to the Sellers, the Transferred Assets, the Assumed Obligations or this Agreement, except as expressly set forth in <u>Article II</u> of this Agreement (including the related portions of the Disclosure Schedules).

### ARTICLE IV

## ADDITIONAL AGREEMENTS

4.1. <u>Confidentiality.</u> After the Closing Date, the Sellers will, and will cause their controlled Affiliates and their respective Representatives to, treat and hold as confidential, and not disclose to any Person (including any Affiliates) any of the Confidential Information, except (i) to the extent necessary to perform its obligations or enforce its rights under this Agreement or the Ancillary Agreements, (ii) to its Affiliates and its or their respective Representatives on a need-to-know basis (<u>provided</u> that the Sellers shall be responsible for any breach of this <u>Section 4.1</u> by any of its Affiliates or Representatives to which such information is disclosed in accordance with this clause (ii)) or (iii) notwithstanding anything in this <u>Section 4.1</u> to the contrary, a Seller may make any public disclosure it believes in good faith is required by any applicable Law or stock market or stock exchange rule. In the event that, at any time after the Closing, the Sellers or any of their Affiliates or its or their respective Representatives are requested or required (by oral question or request for information or documents in any legal proceeding, interrogatory, subpoena, civil investigative demand or similar process or as otherwise required by Law or pursuant to any listing agreement with any securities exchange) to disclose any Confidential Information, to the extent practicable and

Page 14 ASSET PURCHASE AGREEMENT permitted by applicable Law, the Sellers will notify the Buyer promptly of the request or requirement so that the Buyer may seek, at its expense, an appropriate protective order or waive compliance with the provisions of this Section 4.1, and, in the absence of a protective order or upon the receipt of a waiver hereunder, the Sellers or any of their Affiliates may disclose any such Confidential Information; provided, however, that, at the request and at the expense of the Buyer, and to the extent practicable and permitted by applicable Law, the Sellers shall use commercially reasonable efforts to obtain any reasonably available assurance that confidential treatment will be accorded to such portion of the Confidential Information to be disclosed as the Buyer shall designate. For the avoidance of doubt, nothing in this Agreement shall in any way (a) limit or restrict the Sellers' or any of its Affiliates' right or ability to engage in any activity or business, whether or not competitive with the business of the Buyer or any of its Affiliates or (b) limit or restrict the Buyer's or any member of the Buyer Rights Group's right or ability to engage in any activity or business, whether or not competitive with the business of the Sellers or any of their Affiliates.

- 4.2. Public Disclosure. The press release, if any, announcing the execution of this Agreement shall be issued in such form and on such timing as shall be mutually agreed upon by the Sellers and the Buyer on or prior to the Effective Date. Subject to Section 4.1, unless otherwise required by applicable Law or by any listing agreement with any securities exchange, the Sellers and the Buyer shall not, and cause their respective Affiliates not to, make any public announcement with respect to this Agreement or the Contemplated Transactions, or otherwise communicate with any news media regarding this Agreement or the Contemplated Transactions, without the prior written consent of the Buyer or the Sellers, as applicable; provided that after the Contemplated Transactions have been announced, the Sellers and their Affiliates and the Buyer and its Affiliates shall be entitled to respond publicly to questions in the ordinary course or issue any press release or make any other public statement that, in each case, does not disclose additional material Confidential Information of the other party and is not inconsistent with any public statement previously issued or made by it in accordance with the provisions of this Section 4.2.
- 4.3. <u>Further Assurances</u>. Each of the parties will execute and deliver any further instruments and documents as may be required or that any other party reasonably may request in order to carry out the purposes of this Agreement.

### 4.4. Tax Matters.

- (a) The Buyer and the Sellers agree to furnish or cause to be furnished to each other, upon request, as promptly as practicable, such information and assistance relating to the Transferred Assets (including access to books and records) as is reasonably necessary for the filing of all Tax Returns, the making of any election relating to Taxes, the preparation for any audit by any Governmental Entity, and the prosecution or defense of any claim, suit or proceeding relating to any Tax. The Buyer and the Sellers (and their respective Subsidiaries) shall retain all books and records with respect to Taxes pertaining to the Transferred Assets for a period of at least six years following the Closing Date. The Sellers and the Buyer shall cooperate with each other in the conduct of any audit or other proceeding relating to Taxes involving the Transferred Assets.
- (b) Any real property, personal property or similar Taxes applicable to the Transferred Assets for any taxable period (regardless of whether any such taxable period ends at any time prior to, on, or at any time after, the Closing Date) (collectively, the "Section 4.4(b) Tax

Page 15 ASSET PURCHASE AGREEMENT Obligations") shall be paid or reimbursed, as applicable, by the Buyer. The Buyer shall reimburse or pay the Sellers an amount equal to any such real property, personal property or similar Taxes paid or payable by the Sellers. Such reimbursements or payments by the Buyer shall be made on the Closing Date or, if later, on the date such Taxes are due (or thereafter, promptly after request by the Sellers if such Taxes are not paid or reimbursed by the Buyer on or prior to the Closing Date). Without limiting any of the foregoing provisions of this Section 4.4(b), Section 4.4(b) Tax Obligations shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law.

- (c) Two alternative proposed schedules allocating the Aggregate Consideration (including any Retained Liabilities treated as consideration for the Transferred Assets for Tax purposes) in accordance with Section 1060 of the Code are attached as Exhibit C-1 and Exhibit C-2 (each a "Proposed Allocation Schedule" and collectively, the "Proposed Allocation Schedules"). The Sellers and Buyer agree to file their respective IRS Forms 8594 and all federal, state and local Tax Returns in accordance with whichever of the Proposed Allocation Schedules Parent determines in its sole discretion, provided that Parent hereby agrees to make such determination and provide written notice thereof to Buyer and Flame no later than February 28, 2024 (the Proposed Allocation Schedule so determined by Parent is referred to herein as the "Allocation Schedule").
- 4.5. <u>Bulk Sales Laws</u>. The parties hereby waive compliance with the provisions of any bulk sales, bulk transfer or similar Laws of any jurisdiction that may otherwise be applicable with respect to the sale of any or all of the Transferred Assets to Buyer.
- 4.6. Shared Contracts. With respect to any Shared Contract, Buyer and Flame shall use commercially reasonable efforts following the Closing to negotiate between themselves and with the applicable third party that is a party to such Shared Contract (the "Applicable Third Party") the terms of a written agreement or a series of written agreements (collectively, the "Applicable Replacement Contract") that will supersede and replace such Shared Contract, which Applicable Replacement Contract shall provide that (i) all of the rights and obligations of Flame and its Affiliates (including Parent) that otherwise would have accrued under such Shared Contract from and after the Closing, but only to the extent that such rights and obligations relate or pertain to any Product, any Transferred Asset or the research, development, manufacture, sale or other commercialization of any Product or any Transferred Asset, shall solely be applicable to, and shall solely benefit and burden, as applicable, the Buyer, and shall not be applicable to, and shall not benefit or burden, Flame or any of its Affiliates (including Parent), (ii) Buyer shall assume and be responsible for any obligations or liabilities of Flame and its Affiliates (including Parent) under such Shared Contract that are accrued as of the Closing Date or arose, accrued or otherwise relate to any period prior to the Closing Date, but only to the extent that such obligations or liabilities relate or pertain to any Product, any Transferred Asset or the research, development, manufacture, sale or other commercialization of any Product or any Transferred Asset, and Flame and its Affiliates (including Parent) shall be released from any and all of such assumed obligations or liabilities, (iii) all of the rights and obligations of Flame and its Affiliates (including Parent) that otherwise would have accrued under such Shared Contract from and after the Closing, but only to the extent that such rights and obligations do not relate or pertain to any Product, any Transferred Asset or the research, development, manufacture, sale or other commercialization of any Product or any Transferred Asset, shall solely be applicable to, and shall solely benefit and burden, as applicable, Flame, and shall not be applicable to, and shall not benefit or burden, Buyer or any of its Affiliates, and (iv) Flame shall retain and be responsible for

Page 16 ASSET PURCHASE AGREEMENT any and all obligations or liabilities of Flame under such Shared Contract that are accrued as of the Closing Date or arose, accrued or otherwise relate to any period prior to the Closing Date, but only to the extent that such obligations or liabilities do not relate or pertain to any Product, any Transferred Asset or the research, development, manufacture, sale or other commercialization of any Product or any Transferred Asset. Promptly following the Closing (and in no event more than 60 days following the Closing), Buyer and Flame shall execute and deliver each such Applicable Replacement Contract that has been negotiated by, and is in form and substance reasonably satisfactory (consistent with the foregoing provisions of this Section 4.6) to, Buyer, Flame and the Applicable Third Party, and Buyer and Flame shall have used and shall use commercially reasonable efforts (consistent with the foregoing provisions of this Section 4.6) to cause the Applicable Third Party to execute and deliver the Applicable Replacement Contract promptly following the Closing (and in no event more than 60 days following the Closing).

- 4.7. Shared Know-How. In the event that, as of immediately prior to the Closing, there is any Shared Know-How, (i) Sellers shall grant, or cause to be granted, and hereby do grant, to the Buyer a worldwide, non-exclusive, perpetual (unless terminated by Sellers on account of any material breach by Buyer of its obligations under this Section 4.7), fully paid-up and royalty free license (with the right to grant sublicenses through multiple tiers of sublicenses) under all of the right, title and interest of Sellers and their Affiliates in and to any such Shared Know-How solely to practice and use any such Shared Know-How to research, develop, manufacture, use, sell or otherwise commercialize any Product or Products, and (ii) the Buyer shall reimburse Seller for its actual out-of-pocket costs and expenses that (1) solely arise out of the Buyer's practice, use or exploitation of the Shared Know-How to research, develop, manufacture, use, sell or otherwise commercialize any Product or Products or (2) arise under any Contract to the extent that the Shared Know-How is practiced, used or exploited by Buyer pursuant to such Contract to research, develop, manufacture, use, sell or otherwise commercialize any Product or Products. Sellers shall execute and deliver any further instruments and documents as may be reasonably required or as reasonably required or as reasonably required by Buyer to effect the foregoing terms of this Section 4.7.
- 4.8. Promptly following the Closing (and in no event more than 15 days following the Closing), the Sellers shall execute and deliver to the Buyer an IND transfer letter to FDA for each of the Transferred Permits, in form and substance reasonably satisfactory to Buyer, and such other instruments of transfer, conveyance and assignment as the Buyer may reasonably request in order to effect the sale, transfer, conveyance and assignment to the Buyer of all right, title and interest in and to the Transferred Assets in accordance with the terms and conditions of this Agreement (the "Additional Transfer Documents").

### ARTICLE V

## INDEMNIFICATION

5.1. <u>Indemnification by the Sellers</u> Subject to the terms and conditions of this <u>Article V</u>, from and after the Closing, the Sellers shall, jointly and severally, defend and indemnify the Buyer and its Affiliates in respect of, and hold it harmless against, any and all Damages suffered or incurred by the Buyer and its Affiliates to the extent resulting from or constituting:

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- (a) any inaccuracy in or breach of any of the representations or warranties of any Seller in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of any Seller pursuant to this Agreement;
- (b) any breach or failure to perform by any Seller of any covenant or agreement contained in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of any Seller pursuant to this Agreement; or
- (c) any claim by a Third Party against Buyer and its Affiliates to the extent based upon, resulting from or arising out of any Retained Liabilities or Excluded Assets.
- 5.2. <u>Indemnification by the Buyer</u>. Subject to the terms and conditions of this <u>Article V</u>, from and after the Closing, the Buyer shall defend and indemnify each of the Sellers and their Affiliates in respect of, and hold it harmless against any and all Damages suffered or incurred by the Sellers and their Affiliates to the extent resulting from or constituting:
- (a) any inaccuracy in or breach of any of the representations or warranties of the Buyer in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of the Buyer pursuant to this Agreement;
- (b) any breach or failure to perform by the Buyer of any covenant or agreement contained in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of the Buyer pursuant to this Agreement;
  - (c) any Assumed Liabilities; or
- (d) any claim by a Third Party against either Seller or any Affiliate of a Seller to the extent based upon, resulting from or arising out of the ownership, use, conduct or operation of the Transferred Assets, or the payment and/or performance of (or the failure to pay or perform) any of the Assumed Liabilities, by the Buyer or any of its Affiliates, licensees, sublicensees or contractors at any time after the Closing.

# 5.3. Claims for Indemnification.

(a) Third-Party Claims. All claims for indemnification made under this Agreement resulting from, related to or arising out of a third-party claim against an Indemnified Party (a "Third-Party Claim") shall be made in accordance with the following procedures. A Person entitled to indemnification under this Article V (an "Indemnified Party") shall give prompt written notification to the Indemnifying Party (a "Third-Party Claim Notice") of the commencement of any action, suit or proceeding relating to a Third-Party Claim for which indemnification may be sought. For purposes of this Agreement, "Indemnifying Party" means (i) in the case of a claim for indemnification by the Buyer or any of its Affiliates, the Sellers and (ii) in the case of a claim for indemnification by the Sellers or any of their respective Affiliates, the Buyer. Such Third-Party Claim Notice shall include a description in reasonable detail (to the extent then known by the Indemnified Party) of (A) the facts constituting the basis for such Third-Party Claim and (B) the amount of the Damages claimed (the "Third-Party Claim Amount"). No delay or failure on the part of the Indemnified Party in so notifying the Indemnifying Party shall relieve the Indemnifying Party of any liability or obligation hereunder except to the extent the Indemnifying Party is actually

Page 18 ASSET PURCHASE AGREEMENT prejudiced thereby. Within thirty (30) Business Days after delivery of such Third-Party Claim Notice, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense with counsel reasonably satisfactory to the Indemnified Party of any such Third- Party Claim seeking (i) solely monetary damages or (ii) injunctive relief that would reasonably be expected to be immaterial to the operations or business of the Indemnified Party and monetary damages. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The party not controlling such defense may participate therein at its own expense; provided that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith shall be considered "Damages" for purposes of this Agreement; provided, however, that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one (1) counsel for the Indemnified Party. The party controlling such defense shall keep the other party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim that (x) does not include a complete release of the Indemnified Party from all liability with respect thereto, (y) includes any admission by, or finding adverse to, the Indemnified Party or (z) imposes any liability or obligation on the Indemnified Party, in each case, without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(b) Procedure for Claims Not Involving Third Parties. An Indemnified Party wishing to assert a claim for indemnification under this Article V that does not involve a third-party claim shall deliver to the Indemnifying Party a written notice (a "Claim Notice") which contains (i) a description and the amount (the "Claim Amount") of any Damages, (ii) a statement that the Indemnified Party is entitled to indemnification under this Article V and a reasonable explanation of the basis therefor and (iii) a demand for payment in the amount of such Damages. Within thirty (30) Business Days after delivery of such Claim Notice, the Indemnifying Party shall deliver to the Indemnified Party a written response in which the Indemnifying Party shall either (A) agree that the Indemnified Party is entitled to receive all of the Claim Amount (in which case such response shall be accompanied by a payment to the Indemnified Party of the Claim Amount by the Indemnifying Party by wire transfer of immediately available funds (or, if the Indemnified Party is entitled to receive part, but not all, of the Claim Amount (the "Agreed Amount") (in which case such response shall be accompanied by a payment to the Indemnified Party of the Agreed Amount by the Indemnifying Party by wire transfer of immediately available funds (or, if the Indemnifying Party is a Seller, an acknowledgement of the Buyer's right to set off such amount in accordance with Section 5.7)) or (C) contest that the Indemnifying Party is entitled to receive any of the Claim Amount. If such dispute is not resolved within thirty (30) days following the delivery by the Indemnifying Party of such response, the Indemnifying Party and the Indemnified Party shall each have the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 6.11.

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# 5.4. Survival.

- (a) The representations and warranties of the Sellers and the Buyer set forth in this Agreement shall survive the Closing and the consummation of the Contemplated Transactions and remain in full force and effect until the date that is twelve (12) months after the Closing Date, at which time they shall expire; provided, however, that the Fundamental Reps shall survive until the earlier of (i) the satisfaction or termination of all obligations of the Buyer under Section 1.9, and (ii) 60 days after the expiration of the applicable statute of limitations. The covenants and agreements of the Sellers and the Buyer set forth in this Agreement shall survive the Closing and the consummation of the Contemplated Transactions in accordance with their terms or, if no time limit is stated therein, indefinitely.
- (b) If an indemnification claim is asserted in writing pursuant to Section 5.3 prior to the expiration as provided in Section 5.4(a) of the representation or warranty that is the basis for such claim, then such representation or warranty shall survive until, but only for the purpose of, the resolution of such claim.

# 5.5. <u>Limitations</u>.

- (a) Notwithstanding anything to the contrary contained in this Agreement, (i) except with respect to the Fundamental Reps and with respect to any breach or inaccuracy of any representation or warranty (other than a Fundamental Rep) made by any Seller in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of any Seller pursuant to this Agreement, which breach or inaccuracy constitutes, or arises or results from, actual and intentional common law fraud (as defined under Delaware common law), the amount of Damages that may be recovered by an Indemnified Party under Section 5.1(a) or Section 5.2(a) shall not exceed the lesser of (1) (\*\*\*) or (2) the aggregate amount of Milestone Payments that at any time (whether prior to, at the time, or after, the Indemnified Party has made any such claim for indemnification pursuant to Section 5.1(a) or Section 5.2(a), as applicable) has actually been paid or is actually paid to Sellers pursuant to Section 1.9 of this Agreement and/or was required to be paid or is required to be paid to Sellers pursuant to Section 1.9 of this Agreement but has not been paid, and (ii) the amount of Damages that may be recovered by an Indemnified Party under Section 5.1(a) or Section 5.2(a) with respect to breach of any Fundamental Rep, or with respect to breach of any representation or warranty (other than a Fundamental Rep) made by any Seller in this Agreement, any Ancillary Agreement or any certificate or instrument delivered by or on behalf of any Seller pursuant to this Agreement, which breach or inaccuracy constitutes, or arises or results from, actual and intentional common law fraud, shall not exceed the aggregate amount of Milestone Payments that at any time (whether prior to, at the time, or after, the Indemnified Party has made any such claim for indemnification pursuant to Section 5.1(a) or Section 5.2(a), as applicable) has actually been paid or is actually paid to Sellers pursuant to Section 1.9 of this Agreement, and/or was required to be paid or is required to be paid to Sellers pursuant to Section 1.9 of this Agreement but has not been paid. For clarity, it is understood and agreed that none of the foregoing provisions of this <u>Section 5.5(a)</u> shall limit any of the provisions set forth in <u>Section 5.5(d)</u> or <u>Section 5.7</u> below.
- (b) In no event shall any Indemnifying Party be responsible or liable for any Damages or other amounts under this Article V that are (i) consequential damages or Damages for lost profits or diminution in value, or (ii) punitive, special, trebled or exemplary damages, in each

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- (c) Except with respect to claims for specific performance as provided in Section 6.10, from and after the Closing, the rights of the Indemnified Parties under this Article V shall be the sole and exclusive remedies of the Indemnified Parties with respect to claims under, or otherwise relating to the transactions that are the subject of, this Agreement any Ancillary Agreement and/or any certificate or instrument delivered by or on behalf of the Indemnifying Party pursuant to this Agreement (including, without limitation, any claims for actual and intentional common law fraud (as defined under Delaware common law)). Without limitation of the foregoing, in no event shall any party, its successors or permitted assigns be entitled to claim or seek rescission of the Contemplated Transactions.
- (d) Notwithstanding anything express or implied in this Agreement to the contrary, (i) the sole recourse of Buyer to satisfy any indemnification amount or payment to which Buyer is entitled to pursuant to this Article V shall be to exercise Buyer's right of set-off pursuant to, and in accordance with, the provisions of Section 5.7 below, and (ii) except with respect to claims for specific performance as provided in Section 6.10, from and after the Closing, Buyer's right of set-off pursuant to, and in accordance with, the provisions of Section 5.7 below shall be the sole and exclusive remedy of Buyer with respect to claims under, or otherwise relating to the transactions that are the subject of, this Agreement, any Ancillary Agreement and/or any certificate or instrument delivered by or on behalf of any Seller pursuant to this Agreement (including, without limitation, any claims for actual and intentional common law fraud (as defined under Delaware common law)). In the event that the exercise by Buyer of its right of set-off pursuant to, and in accordance with, the provisions of Section 5.7 below, are not sufficient to satisfy any indemnification amount, payment or claim to which Buyer is entitled pursuant to this Article V, such unsatisfied amount, payment or claim other than to set off such amounts pursuant to Section 5.7.
- (e) Payments by an Indemnifying Party pursuant to Section 5.1 or Section 5.2 in respect of any Damages shall be limited to the amount of any liability or damage that remains after deducting therefrom any insurance proceeds and any indemnity, contribution or other similar payment received by the Indemnified Party in respect of any such claim. The Indemnified Party shall use its commercially reasonable efforts to recover under insurance policies or indemnity, contribution or other similar agreements for any Damages, provided that satisfaction of the foregoing provisions of this sentence shall not be a condition precedent to the exercise by an Indemnified Party of any right to make or satisfy any claim for indemnification pursuant to this Article V. In the event that an Indemnified Party recovers under any insurance policies or indemnity, contribution or other similar agreement for any Damages for which such Indemnified Party has already been indemnified pursuant to this Article V, then such Indemnified Party shall pay to the Indemnifying Party the amount of any such recovery under any such insurance policies or indemnity, contribution or other similar agreements.
- (f) Each Indemnified Party shall take, and cause its Affiliates to take, all commercially reasonable steps to mitigate any Damages upon becoming aware of any event or circumstance that would be expected to, or does, give rise thereto.

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- (g) The Indemnifying Party shall not be liable under this <u>Article V</u> for any Damages based upon or arising out of any inaccuracy in or breach of any of the representations or warranties of the Indemnified Party contained in this Agreement if the Indemnified Party had knowledge of such inaccuracy or breach prior to the Closing.
- (h) Without limiting the generality of any of the foregoing provisions of this Section 5.5 or the provisions of Section 5.7 hereof, a party to this Agreement shall have the right to satisfy any indemnification amount or payment that such party would otherwise by required to pay or make pursuant to this Article V in such party's capacity as an Indemnifying Party to any other party to this Agreement in such other party's capacity as an Indemnified Party by setting off against any such indemnification amount or payment that such party would otherwise be required to pay or make pursuant to this Article V as an Indemnifying Party any indemnification amount or payment that such party would otherwise be entitled to receive from any other party pursuant to this Article V in such party's capacity as an Indemnified Party. In the event that a party exercises its right of set-off under this Section 5.5(h), such party shall provide written notice of exercise to the other party, which notice shall specify the particulars of the set-off, and both parties shall be deemed to have satisfied and discharged their respective obligation pursuant to this Article V to make payment of their respective indemnification amounts or payments are subject to set-off pursuant to this Section 5.5(h).
- 5.6. <u>Indemnification Payments</u>. All indemnification payments made hereunder shall be treated by all parties as adjustments to the Aggregate Consideration for Tax purposes unless otherwise required by Law.
- 5.7. Setoff. Except for, and without limiting, any set-off rights that Buyer may have under Section 5.5(h), the sole and exclusive recourse of Buyer to recover and satisfy any indemnification amount or payment to which Buyer is or becomes entitled pursuant to this Article V shall be to set off any such indemnification amount or payment to which Buyer is or becomes entitled against Buyer's obligation to make payment of any Milestone Payment that is owed or thereafter becomes payable to the Sellers pursuant to this Agreement and has not yet been paid to the Sellers. In the event Buyer exercises its set off rights pursuant to this Section 5.7 and withholds from any Milestone Payment the amount of any Damages to which Buyer is or becomes entitled pursuant to this Article V, upon the final resolution of the claim for indemnification with respect to which such offset has been made, Buyer shall pay Sellers the amount, if any, by which the amount offset exceeds the amount of Damages to which the Buyer has been finally determined to be entitled in connection with such resolution, together with interest thereon at the prime rate as published by the Wall Street Journal Online as of the date the applicable payment was due, plus (\*\*\*).
- 5.8. <u>Tax Treatment of Indemnification Claims</u>. All indemnification payments made under this Agreement shall be treated by the parties as an adjustment to the Purchase Price for Tax purposes, unless otherwise required by Law.

# ARTICLE VI

## MISCELLANEOUS

6.1. <u>Notices</u>. All notices and other communications hereunder shall be in writing and shall be deemed duly delivered (i) three (3) Business Days after being sent by registered or certified mail,

Page 22 ASSET PURCHASE AGREEMENT return receipt requested, postage prepaid, (ii) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable nationwide overnight courier service or (iii) on the date of confirmation of receipt (or, the first Business Day following such receipt if the date of such receipt is not a Business Day) of transmission by facsimile, in each case to the intended recipient as set forth below:

# (a) if to the Buyer, to

AlmataBio, Inc. 650 Ponce De Leon Ave Ste. 300 #1489 Atlanta, Georgia 30308 Attention: Patrick J. Crutcher

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

Hutchison PLLC 701 Corporate Center Drive, Suite 250 Raleigh, NC 27607 Attention: John Rudd

## (b) if to the Sellers, to:

Leap Therapeutics, Inc.
47 Thorndike Street, Suite B1-1
Cambridge, MA 02141
Attention: Douglas Onsi, President & CEO

Flame Biosciences LLC c/o Leap Therapeutics, Inc. 47 Thorndike Street, Suite B1-1 Cambridge, MA 02141 Attention: Douglas Onsi, President & CEO

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

Morgan, Lewis & Bockius LLP One Federal Street Boston, MA 02110 Attention: Julio E. Vega

Any party may give any notice or other communication hereunder using any other means (including personal delivery, messenger service, ordinary mail or electronic mail), but no such notice or other communication shall be deemed to have been duly given unless and until it actually is received by the party for whom it is intended. Any party may change the address to which notices and other communications hereunder are to be delivered by giving the other party notice in the manner herein set forth.

- 6.2. Entire Agreement. This Agreement (including the Disclosure Schedule and the Schedules and Exhibits hereto and the documents and instruments referred to herein that are to be delivered at the Closing, including the Ancillary Agreements) constitutes the entire agreement between the parties hereto and supersedes any prior understandings, agreements or representations by or between the parties, written or oral, with respect to the subject matter hereof, including Confidentiality Agreement dated July 6, 2023 by and between the Buyer and the Parent.
- 6.3. No Third-Party Beneficiaries. This Agreement is not intended, and shall not be deemed, to confer any rights or remedies upon any Person other than the parties and their respective successors and permitted assigns, to create any agreement of employment with any Person or to otherwise create any Third-Party beneficiary hereto.
- 6.4. Assignment. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of Law or otherwise by the Sellers or the Buyer, as the case may be, without the prior written consent of the Buyer or the Sellers, respectively, and any such assignment without such prior written consent shall be null and void, except that, following the Closing, (i) a party may assign any of its rights, interests and obligations under this Agreement, in whole or from time to time in part, to one (1) or more of its Affiliates and (ii) a party may assign this Agreement in its entirety to its successor in interest in connection with a merger, reorganization, sale of all or substantially all of such party's assets or equity; provided that in each case no such assignment shall limit, relieve or offset the assigning party's obligation hereunder. This Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the parties and their successors and permitted assigns.
- 6.5. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.
- 6.6. Counterparts and Signature. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original but both of which together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each of the parties and delivered to the other party, it being understood that both parties need not sign the same counterpart. This Agreement may be executed and delivered by facsimile or .pdf transmission.
- 6.7. <u>Interpretation</u>. When reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or Section of this Agreement, unless otherwise indicated. The table of contents and headings contained in this Agreement are for convenience of reference only and

Page 24 ASSET PURCHASE AGREEMENT shall not affect in any way the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the parties to express their mutual intent, and no rule of strict construction shall be applied against any party. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa. Any reference to any federal, state or local Law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation." Any reference to a "party" or "parties" shall mean a party or parties to this Agreement (and their respective successors and permitted assigns). For the purposes of this Agreement, "furnished to the Buyer" shall mean "furnished or made available to the Buyer or its Representatives, including in the Sellers' electronic data room prior to the Closing Date."

- 6.8. Governing Law. This Agreement and any claims arising therefrom shall be governed by and 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 Laws of any jurisdiction other than those of the State of Delaware.
- 6.9. Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT OR THE OTHER DOCUMENTS ENTERED INTO OR DELIVERED IN CONNECTION WITH THE CONTEMPLATED TRANSACTIONS IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE CONTEMPLATED TRANSACTIONS. EACH PARTY TO THIS AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 6.9.
- 6.10. Remedies. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one (1) remedy will not preclude the exercise of any other remedy. The parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which they are entitled at law or in equity without the necessity of demonstrating the inadequacy of monetary damages and without the posting of a bond.
- 6.11. <u>Submission to Jurisdiction</u>. Each of the parties (a) consents to submit itself to the exclusive personal jurisdiction of any state or federal court sitting in the State of Delaware, County of New Castle, in any action or proceeding arising out of or relating to this Agreement or any of the

Page 25 ASSET PURCHASE AGREEMENT Contemplated Transactions, (b) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court, (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement or any of the Contemplated Transactions in any other court. Each of the parties waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other party with respect thereto. Any party may make service on another party by sending or delivering a copy of the process to the party to be served at the address and in the manner provided for the giving of notices in Section 6.1. Nothing in this Section 6.11, however, shall affect the right of any party to serve legal process in any other manner permitted by law.

- 6.12. <u>Disclosure Schedule</u>. The Disclosure Schedule shall be arranged in sections corresponding to the numbered sections contained in <u>Article II</u> and the disclosure with respect to a representation and warranty contained in <u>Article II</u> shall also qualify any other representations and warranties in <u>Article II</u> to the extent that it is readily apparent on the face of such disclosure that such disclosure also qualifies or applies to such other representations and warranties. The mere inclusion of an item in the Disclosure Schedule as an exception to a representation or warranty (or covenant, as applicable) shall not be deemed an admission that such item represents a material exception or material fact, event or circumstance. Nothing in the Disclosure Schedule is intended to broaden the scope of any representation or warranty contained in this Agreement or to create any covenant on the part of the Sellers. No disclosure in the Disclosure Schedules shall be deemed to create any rights in any third party.
- 6.13. <u>Fees and Expenses</u>. Except as otherwise expressly provided herein, all fees and expenses incurred in connection with this Agreement and the Contemplated Transactions shall be paid by the party incurring such fees and expenses.
  - 6.14. Amendment. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the parties.
- 6.15. Extension; Waiver. The parties may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other parties, (b) waive any inaccuracies in the representations and warranties contained herein or in any document delivered pursuant hereto and (c) waive compliance with any of the agreements or conditions contained herein. Any agreement on the part of a party to any such extension or waiver shall be valid only if set forth in a written instrument signed on behalf of such party. Such extension or waiver shall not be deemed to apply to any time for performance, inaccuracy in any representation or warranty, or noncompliance with any agreement or condition, as the case may be, other than that which is specified in the extension or waiver. The failure of any party to assert any of its rights under this Agreement or otherwise shall not constitute a waiver of such rights.

## ARTICLE VII

## **DEFINITIONS**

For purposes of this Agreement, each of the following terms has the meaning set forth below or as defined herein.

Page 26 ASSET PURCHASE AGREEMENT "Affiliate" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such Person, and, with respect to the foregoing, the term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, by contract or otherwise.

"Aggregate Consideration" means (a) the Closing Date Consideration, and (b) any Milestone Payments that become due and payable pursuant to this Agreement.

"Business Day" means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in Boston, Massachusetts are permitted or required by Law, executive order or governmental decree to remain closed.

"Buyer Rights Group" means (a) the Buyer; (b) with respect to any Product, any Person to which any right to sell such Product is licensed, sublicensed, assigned, transferred or otherwise granted by the Buyer or any Affiliate of the Buyer, or any Person to whom an option to acquire such right is granted by the Buyer or any Affiliate of the Buyer; (c) with respect to any Product, any Person to which the right to sell such Product is licensed, sublicensed, assigned, transferred or otherwise granted by any Person described in clause (b) above or in this clause (c), or any Person to whom an option to acquire such right is granted by any Person described in clause (b) above or in this clause (c); (d) with respect to any Product, any successor or assign of any Person described in clauses (a), (b) or (c) above or this clause (d) with respect to such Person's interest in such Product; and (e) with respect to any Product, any Affiliate of any Person described in clauses (a), (b), (c), or (d) involved (or that upon exercise of any option would be involved) in the development or commercialization of such Product with or on behalf of such Person. For the avoidance of doubt, Buyer Rights Group shall include a reseller or distributor of a Product that (i) purchases such Product for resale, and (ii) either (1) needs a license or sublicense from a Buyer Rights Group member to FL-101/FL-103 Intellectual Property in order to distribute or resell such Product or (2) agrees to make any upfront payment, option payment, milestone payment, royalty payments or other payments or to pay or provide any other consideration to any Person in the Buyer Rights Group in connection with the grant to such reseller or distributor of the right (or an option to acquire such right) to distribute or resell such Product or the appointment of such reseller or distributor (it being understood and agreed, for clarity, that payment by such reseller or distributor of the purchase price for the quantities or units of Product purchased by such reseller or dis

"China" means the People's Republic of China and all of its territories or possessions, including, Hong Kong and Macau.

"Closing" means the closing of the transactions contemplated by this Agreement.

"Closing Date" means the date of the Closing.

"Closing Date Consideration" means a non-refundable payment of (\*\*\*).

"Code" means the United States Internal Revenue Code of 1986, as amended.

Page 27 ASSET PURCHASE AGREEMENT "Commercially Reasonable Efforts" means, for purposes of Section 1.9(c) of this Agreement, the use of such efforts and resources as are used by a biopharmaceutical company of similar size and market capitalization as Buyer (or that of the applicable member of the Buyer Rights Group if it is of a larger size and market capitalization than Buyer) in the exercise of its commercially reasonable business practices relating to the development and commercialization of pharmaceutical or biological products with similar commercial potential as the relevant Product at a similar stage in product lifecycle, taking into consideration the safety and efficacy of the product, the risks inherent in the development and commercialization of the product, its competitiveness compared to alternative products, the proprietary position of the product (including scope and duration of relevant Patent Rights), the scope of marketing approval, the regulatory status of the product, whether the product is subject to a clinical hold, recall or market withdrawal and the anticipated profitability of the product. The Sellers acknowledge that discontinuation of research, development or commercialization activities with respect to Products may constitute "Commercially Reasonable Efforts."

"Confidential Information" means (a) any information relating to any Product or the Transferred Assets that, immediately prior to the Closing, is not publicly available and is owned by, exclusively licensed to, or held subject to obligations of confidentiality or non-disclosure by, either Seller or any of their respective controlled Affiliates, except to the extent that such information (i) becomes publicly available after the Closing other than through improper disclosure by the Sellers, any of their controlled Affiliates or any of their respective Representatives or (ii) shall have become known to the Sellers or any of their Affiliates at any time (either prior to or after the Closing) from a source (other than the Buyer and its Affiliates) not known by either Seller to be bound by a confidentiality obligation to any Person (including, without limitation, either Seller, Buyer, their respective Affiliates and their respective Representatives) with respect to such information, and (b) any Transferred Know-How that, immediately prior to the Closing, is not publicly available, except to the extent that such Transferred Know-How (1) becomes publicly available after the Closing other than through improper disclosure by the Sellers, any of their controlled Affiliates or any of their respective Representatives or (2) shall have become known to the Sellers or any of their Affiliates at any time (either prior to or after the Closing) from a source (other than the Buyer and its Affiliates) not known by either Seller to be bound by a confidentiality obligation to any Person (including, without limitation, either Seller, Buyer, their respective Affiliates and their respective Representatives) with respect to such Transferred Know-How.

"Contemplated Transactions" means the transactions contemplated by this Agreement and the Ancillary Agreements.

"Contracts" means all contracts, leases (other than real property leases), deeds, mortgages, licenses, instruments, notes, commitments, undertakings, indentures, engagement letters and all other agreements, commitments and legally binding arrangements, whether written or oral.

"<u>Damages</u>" means losses, damages, fines, fees, penalties, interest, awards and judgments of any kind, including reasonable attorneys' and consultants' fees and expenses and other reasonable legal costs and expenses incurred in prosecution, investigation, remediation, defense or settlement.

"Disclosure Schedule" means the disclosure schedule delivered by the Sellers to the Buyer and dated as of the date of this Agreement.

"Dollar" or "\$" means the lawful currency of the United States.

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- "Domain Names" means all domain names, including all applications and registrations thereof, as may exist anywhere in the world.
- "EMA" means the European Medicines Agency and any successor agency thereto or any equivalent agency in the United Kingdom or any other member state of the E.U.
- "European Union" or "E.U." means (i) all countries that are member states of the European Union as of the date hereof or at any time thereafter and (ii) the United Kingdom.
  - "FDA" means the U.S. Food and Drug Administration and any successor agency thereto.
- "FDA Act" means the Federal Food, Drug and Cosmetic Act and applicable implementing regulations issued by the FDA, including, as applicable, those requirements relating to the FDA's current good manufacturing and quality system practices, good laboratory practices and good clinical practices and investigational use.
- "First Commercial Sale" means, with respect to a Product and jurisdiction, the first sale on a commercial basis to a Third Party of such Product in such jurisdiction after Regulatory Approval has been obtained in such jurisdiction for such Product.
  - "FL-101/FL-103 Intellectual Property" means the FL-101/FL-103 Patents and the FL-101/FL-103 Know-How.
- "FL-101/FL-103 Know-How" means any and all Know-How owned by Sellers or their controlled Affiliates as of immediately prior to the Closing that (i) pertains or relates primarily to any Product or, as of immediately prior to the Closing, are being used or held for use by Sellers primarily in connection with any Product, and (ii) immediately prior to the consummation of the Merger on January 17, 2023, was owned by Sellers' Predecessor and was then being used or held for use by Sellers' Predecessor primarily in connection with any Product.
- "FL-101/FL-103 Patents" means the Patent Rights owned by or licensed to Sellers or their controlled Affiliates as of immediately prior to the Closing that (i) immediately prior to the consummation of the Merger on January 17, 2023, were owned by or licensed to Sellers' Predecessor, and (ii) claim or cover the Product.
  - "France" means the Republic of France and all of its territories or possessions.
- "Fundamental Reps" means the representations and warranties set forth in (i) Section 2.1 (Organization, Standing and Power), (ii) Section 2.2(a) (Authority), (iii) Section 2.10 (Brokers), (iv) Section 2.11 (Title to Transferred Assets), (v) Section 3.1 (Organization, Standing and Power), (vi) Section 3.2(a) (Authority) and (vii) Section 3.4 (Brokers).
  - "GAAP" means United States generally accepted accounting principles consistently applied.
  - "Germany" means the Federal Republic of Germany and all of its territories or possessions.
- "Governmental Entity" means any national, multinational, state, provincial, local, foreign or other court, arbitrational tribunal, administrative agency or commission or other governmental or regulatory authority, agency or instrumentality.

"Health Authorities" means the Governmental Entities which administer Health Laws, including the FDA.

"Health Law" means any Law the purpose of which is to ensure the safety, efficacy and quality of medicines by regulating the research, development, manufacturing and distribution of such products, including any Law relating to good laboratory practices, good clinical practices, investigational use, product marketing authorization, manufacturing compliance and approval, good manufacturing practices, labeling, advertising, promotional practices, safety surveillance, record keeping and filing of required reports such as the FDA Act, the Public Health Service Act, as amended, their associated rules and regulations promulgated thereunder.

"IND" means Investigational New Drug application.

"Intellectual Property" means any and all intellectual property rights and other similar proprietary rights in any jurisdiction, whether registered or unregistered, whether owned or held for use under license, including all rights and interests pertaining to or deriving from (a) Domain Names, copyrights and designs, (b) Patent Rights, (c) Trademarks, (d) Know-How and computer software programs and applications, including data files, source code, object code and software-related specifications and documentation, and (e) other tangible or intangible proprietary or confidential information and materials, including proprietary databases and data compilations, in each case, including any registrations of, applications to register, and renewals and extensions of, any of the foregoing with or by any Governmental Entity in any jurisdiction.

"Italy" means the Republic of Italy and all of its territories or possessions.

"Japan" means Japan and all of its territories or possessions.

"Know-How" means any and all information, know-how, trade secrets, ideas, inventions, invention disclosures, discoveries and improvements, data, files, plans, operating records, instructions, proprietary or other processes, formulas, formulation information, manufacturing or other technology, validations, package specifications, chemical specifications, chemical and finished goods analytical test or other methods, stability data, clinical data, nonclinical data, safety data, adverse event report data, databases, manufacturing know-how, product specifications, information with respect to expert opinions, drawings, schematics, reports and information (whether or not patented or patentable), technology and techniques. For the avoidance of doubt, Know-How excludes Patent Rights (and any inventions claimed or disclosures made under any Patent Rights), Trademarks and Domain Names.

"Knowledge" means (a) with respect to the Sellers, the actual knowledge (without any investigation, review, inspection or searches of (1) any files, documents, books or records, (2) any databases, dockets, registries or governmental, administrative or court filings, or (3) any assets, properties or liabilities of Sellers) of the following employees of the Seller(s): Douglas Onsi and Augustine Lawlor, and (b) with respect to the Buyer, the actual knowledge (without any investigation, review, inspection or searches of (1) any files, documents, books or records, (2) any databases, dockets, registries or governmental, administrative or court filings, or (3) any assets, properties or liabilities of Buyer) of the following employees or directors of the Buyer or its Affiliates: Patrick Crutcher, Justin DeMartino and Tatyana Touzova.

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"Law" means any law, statute or ordinance, common law or any rule, regulation, standard, judgment, order, writ, injunction, decree or agency requirement of any Governmental Entity.

"<u>Liability</u>" means any debt, liability or obligation (whether direct or indirect, absolute or contingent, accrued or unaccrued, liquidated or unliquidated, known or unknown, determined or determinable or due or to become due), including all costs and expenses relating thereto.

"Lien" means any mortgage, security interest, pledge, conditional sale or other title retention agreement, lien, charge or encumbrance.

"Merger" means the mergers pursuant to, and in accordance with, the Merger Agreement that resulted in the acquisition by Flame of Sellers' Predecessor and its business, assets and liabilities.

"Merger Agreement" means that certain Agreement and Plan of Merger, dated as of January 17, 2023, by and among Parent, Flame, Fire Merger Sub, Inc., Sellers' Predecessor, and Shareholder Representative Services LLC, in its capacity as representative of the stockholders of Sellers' Predecessor.

"NDA" means a New Drug Application as described in 21 C.F.R. § 314.50 and submitted to the FDA or a comparable application submitted to an applicable Governmental Entity outside the United States.

"Net Sales" means the gross amount invoiced by members of the Buyer Rights Group for sales of Products for end use or consumption to Third Parties, less the total of the following deductions, determined in accordance with GAAP, to the extent they are included in the gross invoiced sale price of the Products (and, in such case, such deductions must be set forth and itemized in the applicable invoice or invoices or in a separate written document so as to show their inclusion in the gross invoiced sale price of the Products) or otherwise directly paid or incurred by members of the Buyer Rights Group with respect to the sale of the Product to such Third Party as follows:

- (a) normal and customary trade discounts, credits or allowances (including volume) actually given;
- (b) reasonable and customary freight, postage, shipping, and insurance, expenses;
- (c) sales, value added and other taxes and duties (but not including taxes assessed against the income derived from such sale);
- (d) tariffs, customs or excise duties, surcharges and other compulsory governmental charges;
- (e) government mandated rebates and discounts;
- (f) bona fide retroactive price reductions and reasonable allowances for bad debt; and
- (g) any rebates, fees, credits, allowances and chargebacks actually given to any managed care organization, wholesaler, distributor, buying group, health care insurance carrier, chain pharmaceutical, mass merchandizer, staff model HMO, pharmacy benefit manager and hospital

Page 31 ASSET PURCHASE AGREEMENT buying group/group purchasing organization and credits or allowances for returns, rejections, defects or recalls.

For the avoidance of doubt, Product provided by a member of the Buyer Rights Group for clinical trial or other developmental purposes will not be included in Net Sales.

Net Sales shall also include the gross amount of any upfront license fee or sublicense fee, any other kind of upfront payment, any option grant fee or payment, any option exercise fee or payment, any milestone payment, and/or any license or sublicense or other kind of maintenance fee actually received by Buyer or any of its Affiliates for and in consideration, in whole or in part, for the grant by the Buyer, any Affiliate of the Buyer or any of their respective successors or assigns of any right (or any option to acquire such right) to develop, make, have made, use, sell or otherwise commercialize any Product pursuant to any license, sublicense, assignment, transfer or otherwise (including, without limitation, (i) any grant or appointment pursuant to any contract of any type or kind and (ii) any grant or exercise of any such option).

"Order" means any order, award, decree or injunction, ruling or writ issued, made or rendered by a Governmental Entity.

"Ordinary Course of Business" means the ordinary course of business consistent in all material respects with past custom and practice.

"<u>Patent Rights</u>" means all issued patents and pending patent applications, including any provisional, continuation, divisional, continuation-inpart application, substitution, reissue, renewal, reexamination, supplemental protection certificate, extension, counterpart, registration or confirmation of or related to any such patent or patent application, as each of the foregoing may exist anywhere in the world.

"Permitted Liens" means (i) Liens disclosed on Section 6.1(a) of the Disclosure Schedule, (ii) any restrictions, limitations or conditions set forth in or imposed pursuant to the Transferred Contracts or the Transferred Permits, or (iii) any non-exclusive license of any Intellectual Property granted in the Ordinary Course of Business.

"Person" means any individual, corporation, partnership, limited liability company, firm, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Entity or other entity.

"Pre-Closing Tax Period" means (i) any Tax period ending on or before the Closing Date and (ii) with respect to a Tax period that commences on or before but ends after the Closing Date, the portion of such period up to and including the Closing Date.

"Product" means Seller's proprietary IL-1ß antibodies designated as FL-101 and FL-103, as further described on <u>Schedule A</u>, and including, without limitation, (i) any of such proprietary IL-1ß antibodies in any form or formulation, and (ii) any pharmaceutical composition or product that includes as a component thereof any of such proprietary IL-1ß antibodies in any form or formulation.

Page 32 ASSET PURCHASE AGREEMENT "Regulatory Approval" means the approval of the applicable Regulatory Authority necessary for the marketing and sale of a product in a jurisdiction, and including the expansion or modification of the label for additional indications or uses.

"Regulatory Authority" means the FDA, EMA or any other Governmental Entity in another country or jurisdiction that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval for a product, or otherwise regulating the research, development or commercialization of a product, in such jurisdiction, including the EMA, and any successor(s) thereto.

"Representatives" means, with respect to any Person, such Person's officers, directors, employees, consultants, independent contractors, accountants, legal and other representatives and agents.

"Shared Contracts" means those Contracts, if any, set forth on Section 6.1(b) of the Disclosure Schedule.

"Shared Know-How" means any and all Know-How owned by Sellers or their controlled Affiliates as of immediately prior to the Closing that (i) pertains or relates primarily to any Product or, as of immediately prior to the Closing, is being used or held for use by Sellers primarily in connection with any Product, and (ii) immediately prior to the consummation of the Merger on January 17, 2023, was owned by Sellers' Predecessor and was then being used or held for use by Sellers' Predecessor primarily in connection with any Product.

"Spain" means the Kingdom of Spain and all of its territories or possessions.

"Subsidiary" means, with respect to any Person, any entity of which (i) securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by such Person or (ii) 50% or more of such entity's equity interests are at the time directly or indirectly owned by such Person.

"Taxes" means (a) all taxes, charges, fees, levies or other similar assessments or Liabilities in the nature of a tax, including income, gross receipts, ad valorem, premium, value-added, excise, real property, personal property, sales, use, service, transfer, withholding, employment, payroll and franchise taxes imposed by any Governmental Entity and (b) any interest, fines, penalties, assessments or additions to tax resulting from, attributable to or incurred in connection with any tax described in clause (a) or any contest or dispute thereof.

"<u>Tax Returns</u>" means all reports, returns, declarations, statements or other information required to be supplied to any Governmental Entity in connection with Taxes (including any attachments thereto or amendments thereof).

"Third-Party" means any Person other than the Sellers or Buyer or an Affiliate of the Sellers or Buyer.

Page 33 ASSET PURCHASE AGREEMENT "Trademarks" means all trademarks, service marks, trade names, logos, brands and other source identifiers, including all applications and registrations of the foregoing, as each of the foregoing may exist anywhere in the world.

"United Kingdom" or "U.K." means the United Kingdom of Great Britain and Northern Ireland and all of their territories or possessions.

"United States" or "U.S." means the United States of America and all of its territories and possessions.

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IN WITNESS WHEREOF, the Buyer and the Sellers have caused this Agreement to be signed by their respective officers thereunto duly authorized as of the date first written above.

#### **BUYER:**

ALMATABIO, INC.

By /s/ Patrick J. Crutcher Name: Patrick J. Crutcher Title: Chief Executive Officer

## **SELLERS:**

LEAP THERAPEUTICS, INC.

By: <u>/s/ Douglas E. Onsi</u> Name: Douglas Onsi Title: President

FLAME BIOSCIENCES LLC

By: <u>/s/ Douglas E. Onsi</u> Name: Douglas Onsi Title: President

## EXHIBIT A

## BILL OF SALE

# EXHIBIT B

ASSUMPTION OF ASSUMED LIABILITIES AGREEMEN	١T
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# EXHIBIT C-1 PURCHASE PRICE ALLOCATION SCHEDULE

# EXHIBIT C-2 PURCHASE PRICE ALLOCATION SCHEDULE

## EXHIBIT D

## ASSIGNMENT AND ASSUMPTION AGREEMENT

# LICENSE AGREEMENT

by and between

# FLAME BIOSCIENCES, INC. and

# **ELI LILLY and COMPANY**

# 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 (the "Agreement"), is entered into as of November 25th, 2019 (the "Signing Date"), is entered into by and between FLAME BIOSCIENCES, INC., a Delaware corporation with a place of business at 555 Madison Ave, Suite 1201, New York, NY 10022 ("Flame"), and ELI LILLY AND COMPANY, an Indiana corporation with a place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285 ("Lilly"). Flame and Lilly may be referred to herein individually as a "Party" or collectively as the "Parties".

#### Recitals

- A. Lilly has developed and controls certain technology, patent rights and proprietary materials related to a certain compound that is an anti IL-lb monospecific antibody known by Lilly as LY2189102.
- B. Lilly wishes to grant to Flame, and Flame wishes to receive, an exclusive license in the Field for the Territory to such technology, patent rights and proprietary materials under the terms and conditions set forth in this Agreement.

## **Agreement:**

## 1. **DEFINITIONS**

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

- B.1 "Affiliate" means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.1, "control" shall mean (a) in the case of a corporate entity, direct or indirect ownership of (\*\*\*) or more of the stock or shares having the right to vote for the election of directors of such corporate entity and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.
- B.2 "Applicable Laws" shall mean all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the activities references in the sentence where the term is used as contemplated by this Agreement.
- B.3 **"Biologics License Application"** or **"BLA"** means an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce, or any similar application or submission for marketing authorization of a Licensed

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LICENSE AGREEMENT

Product filed with a Regulatory Authority to obtain Regulatory Approval for such product in a country or group of countries.

- B.4 "Business Day" means any day other than a Saturday or a Sunday on which the banks in New York, New York are open for business.
- B.5 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- B.6 "Calendar Year" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.
- B.7 "Combination(s)" means a Licensed Product containing the Licensed Compound and one or more additional active compounds or pharmaceutical ingredients not licensed hereunder (each such additional ingredient, an "Other Product"), whether co-formulated or copackaged.
- B.8 "Commercialization" or "Commercialize" means activities taken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, pricing determination, manufacturing, importation, offering for sale, sale and distribution for commercial sale, of a pharmaceutical product and post-launch medical activities, including without limitation: (a) manufacturing, importation and distribution for commercial sale; (b) strategic marketing, sales force detailing, advertising, and market and product support; (c) medical education and liaison and any phase IV clinical trials; (d) all customer support and product distribution, invoicing and sales activities; (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals; (f) expanded target product profile activities after receipt of initial Regulatory Approval for the relevant product; and (g) pricing, formulary and reimbursement related activities, including pricing and reimbursement approvals.
- B.9 "Commercially Reasonable Efforts" shall have the meaning provided in Section 2.4(b) of this Agreement.
- B.10 "Confidential Information" means all confidential or proprietary information disclosed or made available by a Party (the "Disclosing Party") or its Representatives to the other Party (the "Receiving Party") or its Representatives pursuant to, or in connection with the purpose of, this Agreement or pursuant to the Confidentiality Agreement, in each case, whether in written, oral, graphic, electronic or other form. Notwithstanding the foregoing or any other provision of this Agreement to the contrary: (a) except as expressly set forth in clause (b) of this sentence, the Confidential Information identified on Exhibit C shall be deemed the Confidential Information of both Parties, and each Party shall be deemed the Receiving Party with respect thereto; and (b) solely in the event of termination of this Agreement by Flame pursuant to Section 9.3, or by Lilly pursuant to Section 9.4, the Confidential Information identified on Exhibit C shall be deemed the Confidential Information of Lilly, and Lilly shall be deemed the Disclosing Party and Flame the Receiving Party with respect thereto.

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- 1.11 "Confidentiality Agreement" shall mean the Mutual Confidentiality Agreement between the Parties dated August 20, 2018.
- 1.12 "Control", "Controls" or "Controlled by" means (except as used in Section 1.1, above), with respect to any item of or right under Patents or Know-How, the ability of the specified Party or any of its Affiliates, whether through ownership, license or other right (other than pursuant to this Agreement), to grant access to, license or sublicense such item or right without violating the terms of any agreement or other arrangement with any Third Party.
- 1.13 "Data Exclusivity Period" means the period during which any Regulatory Authority within the Territory prohibits reference for purposes of obtaining Regulatory Approval of a pharmaceutical product, without the consent of the owner of the regulatory submission materials, to the clinical and other data that is contained in such materials, and that is not published or publicly available outside of such submission.
- 1.14 "Develop" or "Development" or "Developing" means research, discovery, process development, manufacturing and importation for preclinical and clinical uses, and preclinical and clinical drug or biological development activities, including, without limitation, test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, in each case, of a Licensed Compound or Licensed Product for use in the Field, and to the extent normally undertaken during the development (as opposed to Commercialization) phase of such Licensed Compound or Licensed Product's life cycle. Development shall exclude all Phase IV clinical trials.
- 1.15 **"Effective Date"** shall mean that certain date that Flame has satisfied both of the following requirements: (i) made the cash payment to Lilly required under Section 4.l(a) within the time period provided therein and (ii) signed the Equity Agreements and issued to Lilly the initial common stock in accordance under Section 4.1(b) within the time period provided therein.
- 1.16 **"EMA"** means the European Medicines Agency or any successor agency thereto in the European Union having substantially the same function.
- 1.17 **"Equity Agreements"** shall mean the Common Stock Purchase Agreement in the form of Schedule 1 and the Investor Rights Agreement in the form of Schedule 2.
- 1.18 **"Equity Securities"** means any and all shares of common stock or preferred stock of Flame, and any and all securities of Flame convertible into or exchangeable or exercisable for (whether or not subject to contingencies or the passage of time, or both), such shares, including, without limitation, options, warrants and other rights to acquire such shares.
- 1.19 "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- 1.20 **"Field"** means any and all uses in human and animal diseases.

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- 1.21 **"First Commercial Sale"** means, with respect to any Licensed Product, the first sale to a Third Party for end use or consumption of such Licensed Product in a country after Regulatory Approval has been granted by the Regulatory Authority of such country, if such Regulatory Approval is required, or, if Regulatory Approval is not required, upon the first such sale.
- 1.22 "GAAP" means US Generally Accepted Accounting Principles as the same may be in effect from time to time.
- 1.23 "Good Clinical Practices" or "GCP" means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") E6 and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50, 54, 56,312 and 314, as may be amended from time to time, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.
- 1.24 "Generic Version" shall mean with respect to a particular Licensed Product sold by Flame or any of its Affiliates or Sublicensees in the Territory, a pharmaceutical product sold by a Third Party (other than a Sublicensee or any other Third Party in a chain of distribution originating from Flame or any of its Affiliates or Sublicensees) in the Territory: (a) that contains Licensed Compound (and, if applicable, the same Other Product(s) as such Licensed Product) in the same dosage form as such Licensed Product; and (b) has received Regulatory Approval from the relevant Regulatory Authority in the Territory in reliance on the Regulatory Approval for such Licensed Product in the Territory.
- 1.25 "Good Laboratory Practices" or "GLP" means the then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58 and/or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development ("OECD"), and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.
- 1.26 "Good Manufacturing Practices" or "cGMP" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the WHO TRS 986 Annex 2, TRS 961 Annex 6 and TRS 957 Annex 2, (d) ICH Q7 guidelines, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

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- 1.27 "Governmental Authority" shall mean any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, state or local authority or any political subdivision thereof, or any association of countries.
- 1.28 "Government or Public Official" means: (i) any officer or employee of: (a) a government, or any department or agency thereof; (b) a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; or (c) a public international organization (such as the United Nations, the International Monetary Fund, the International Committee of the Red Cross, and the World Health Organization), or any department or agency thereof; (ii) any political party or party official or candidate for public or political party office; and (iii) any person acting in an official capacity on behalf of any of the foregoing.
- 1.29 "IND" means a submission for approval in the Territory to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.30 **"Know-How"** means any proprietary and confidential scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including any of the foregoing that are databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, manufacturing process and development information, results or data.
- 1.31 "Licensed Compound" means the certain compound that is an anti IL-1b monospecific antibody known by Lilly as LY2189102 with the structure set forth on Exhibit A. For clarity, notwithstanding anything to the contrary, the term "Licensed Compound" specifically excludes any other monospecific antibody (except for LY2189102) that may bind to the same or partially same epitope and; further, for clarity, since the Licensed Compound, by definition, is only an anti IL-lb monospecific antibody, the term "Licensed Compound" specifically excludes a bispecific antibody with any anti IL-lb activity.
- 1.32 "Licensed Know-How" means solely the Know-How (excluding any Know-How covered by a claim of any published Licensed Patent) that is set forth on Exhibit C.
- 1.33 "Licensed Patents" means Patents Controlled by Lilly or any of its Affiliates as of the Effective Date that contain one or more claims covering the Licensed Compound or Licensed Product or the Manufacture of the Licensed Compound or Licensed Product (specifically excluding any claim covering manufacturing for any Patents filed after the Effective Date but including Patents with a filing date prior to the Effective Date (the "Prior Manufacturing Patents") including any Patents filed after the Effective Date that claim priority to the Prior Manufacturing Patents), or the composition of matter, or any method of use of the Licensed Compound or Licensed Product, including without limitation the Program-Specific Patents.

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- 1.34 "Licensed Product" means any pharmaceutical composition or preparation containing or comprising a Licensed Compound (whether or not as the sole active ingredient), including all formulations and dosage forms thereof.
- 1.35 "Licensed Technology" shall mean Licensed Patents and Licensed Know-How.
- 1.36 "Listed Patents" shall mean the patents and patent applications listed in Exhibit B hereto.
- 1.37 "Major Country" means each or any of the United States. (\*\*\*).
- a.38 "Manufacture" and "Manufacturing" shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of Licensed Compound or Licensed Product, or any intermediate of either of the foregoing, including process development, process qualification and validation, scale-up, preclinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.
- a.39 "Net Sales" shall mean, with respect to a Licensed Product, the gross amount invoiced by Flame (including a Licensee Affiliate) or any sublicensee thereof to unrelated Third Parties, excluding any sublicensee, for the Licensed Product (in final form for end use, but exclusive of inter-company transfers) in the Territory, less the following items consistent with U.S. Generally Accepted Accounting Principles consistently applied:
  - (a) Trade, quantity and cash discounts allowed;
- (b) any tax imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes;
  - (c) allowance for distribution expenses not to exceed (\*\*\*) of gross sales;
- (d) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances, not to exceed(\*\*\*) of gross sales, which effectively reduce the net selling price, including those granted to managed health care organizations, wholesalers, buying groups, retailers or to federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers; and
  - (e) Licensed Product returns and allowances not to exceed (\*\*\*) of gross sales.

Such amounts shall be determined from the books and records of Flame, affiliates of Flame or any sublicensee maintained in accordance with GAAP, or in the case of sublicensees, such similar accounting principles, consistently applied. Flame further agrees in determining such amounts, it will use Flame's then current standard procedures and methodology, including Flame's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars or, in the case of sublicensees, such similar methodology, consistently applied.

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Sales between or among Flame and its Affiliates and its Sublicensees shall be excluded from the computation of Net Sales, but Net Sales shall include the first sales to Third Parties (other than Sublicensees) by Flame or any such Affiliates or Sublicensees. The supply (at no cost) of Licensed Product as samples, for use in non-clinical or clinical studies of Flame or any of its Affiliates or Sublicensees, or for use in any tests or studies of Flame or any of its Affiliates or Sublicensees reasonably necessary to comply with any Applicable Laws, regulation or request by a regulatory or governmental authority shall not be included within the computation of Net Sales.

In the event that the Licensed Product is sold as part of a Combination Product (where Combination is defined above in § 1.7), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product by the fraction, A / (A+B) where A is the weighted average sale price of the Licensed Product when sold separately in finished form, and B is the weighted average sale price of the other product(s) sold separately in finished form.

In the event that the weighted average sale price of the Licensed Product can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is the weighted average sale price of the Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Licensed Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (l) minus (B / C) where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of both the Licensed Product and the other product(s) in the Combination Product cannot be determined, the Net Sales of the Licensed Product shall be deemed to be equal to (\*\*\*) of the Net Sales of the Combination Product.

The weighted average sale price for a Licensed Product, other product(s), or Combination Product shall be calculated once each Calendar Year and such price shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of a Licensed Product, other product(s), or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into U.S. dollars) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial calendar year) of the preceding Calendar Year for the respective Licensed Product, other product(s), or Combination Product. In the initial Calendar Year, a forecasted weighted average sale price will be used for the Licensed Product, other product(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following Calendar Year.

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- a.40 "Other Licensed Patents" shall mean Licensed Patents that are not Program-Specific Patents.
- 1.41 "Patent(s)" means all patents and patent applications in any country or supranational jurisdiction, including any provisionals, substitutions, divisions, continuations, continuations-in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, any other pre or post-grant forms of any of the foregoing, any confirmation patents or registration patents or patents of addition, utility models, patent term extensions or restorations, and supplementary protection certificates or requests for continued examinations and the like, including any and all foreign counterparts of any of the foregoing.
- 1.42 "Patent Files" shall mean: (a) the complete file histories for the Program-Specific Patents in the possession of Lilly or any of its Affiliates; and (b) all files relating to the Program Specific Patents that are held or maintained on Lilly's or its Affiliate's behalf by Lilly's or its Affiliate's outside patent counsel, including all contents of such files.
- 1.43 "Patent Prosecution" or "Prosecution" means, with respect to a Patent, (a) preparing, filing and prosecuting applications (of all types) for such Patent, (b) paying filing, issuance and maintenance fees relating to such Patent, (c) managing and conducting any interference, opposition, invalidation, re-issue, reexamination, revocation, nullification, post-grant review, *inter partes* review, derivation proceeding, cancellation proceeding or other similar administrative proceeding or administrative appeal thereof with respect to such Patent, and (d) settling any interference, opposition, revocation, nullification or cancellation proceeding.
- 1.44 "Phase III Clinical Study" means a human clinical trial designed as a pivotal study to confirm, with statistical significance, the efficacy and safety of a Licensed Product with respect to a particular indication, which trial is performed for purposes of filing an BLA or similar application to obtain Regulatory Approval for such Licensed Product in any country or regulatory jurisdiction, as defined in 21 C.F.R. § 312.2l(c), as may be amended from time to time, or any analogous clinical trial described or defined in Applicable Laws and guidelines in the Territory.
- 1.45 **"Program"** shall mean all of Lilly's and its Affiliates' activities (including activities performed by any Third Party on behalf of Lilly or any of its Affiliates) directed to the Development, Manufacture, use, offer for sale, sale or import of Licensed Compounds and Licensed Products up to the Effective Date.
- 1.46 **"Program-Specific Patents"** shall mean the Listed Patents and any and all Patents corresponding to the Listed Patents throughout the world, whether now existing or hereafter filed or issued.
- 1.47 **"Regulatory Applications"** means any and all applications that are necessary and appropriate to obtain a Regulatory Approval with respect to a Licensed Product, including, without limitation, all required documents, data and information concerning a Licensed Product, filed or required to be filed with or, otherwise submitted to, a Regulatory Authority.

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- 1.48 **"Regulatory Approval"** means all approvals from the relevant Regulatory Authority to market and sell a Licensed Product (or for purposes of Sections 1.12 and 1.20, a pharmaceutical product) in the Territory (including all applicable pricing and reimbursement approvals).
- 1.49 "Regulatory Authority" means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, sale, reimbursement or pricing of a Licensed Product in the Territory.
- 1.50 **"Regulatory Materials"** shall mean all Regulatory Approvals, Regulatory Applications and other regulatory submissions in the Territory for any Licensed Compound or Licensed Product, and all correspondence with such Regulatory Authorities relating to any Licensed Compound or Licensed Product; that, in each case, are in the possession of or controlled by, or held by or for, Lilly or any of its Affiliates at the Effective Date, whether generated, filed or held by or for Lilly or its Affiliates.
- 1.51 "Related Party" means, with respect to Flame, its Affiliates and Sublicensees.
- 1.52 **"Representatives"** shall mean, with respect to a Party, such Party's Affiliates, and such Party's and its Affiliates' directors, officers, employees, consultants, contractors, licensees, sublicensees, agents and other representatives.
- 1.53 **"Sublicense Agreement"** means any agreement entered into by Flame with a Sublicensee.
- 1.54 **"Sublicensee"** means any Third Party to which Flame or a Sublicensee grants a sublicense of the rights granted to Flame under the Licensed Patents or Licensed Know-How.
- 1.55 "Territory" means worldwide.
- 1.56 "Third Party" means an entity other than (a) Lilly and its Affiliates, and (b) Flame and its Affiliates.
- 1.57 "Valid Claim" means, with respect to a country, a claim of an issued and unexpired Patent included within the Licensed Patents in such country which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise in such country.

#### 2. LICENSE

#### **B.1** License to Flame

As of the Effective Date, Lilly, on behalf of itself and its Affiliates, hereby grants to Flame an exclusive (even as to Lilly and its Affiliates, except for research purposes as described below), worldwide, royalty bearing license, with the right to grant sublicenses (subject to Section 2.2), under the Licensed Patents and Licensed Know-How to research, Develop, Commercialize,

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Manufacture, make, have made, use, sell, have sold, offer to sell, and import the Licensed Compound and Licensed Product in the Field. Lilly and its Affiliates retain a non-exclusive license, (\*\*\*). The Parties acknowledge that the license grant above is, by definition, limited to the Licensed Compound and Licensed Product in its monospecific form and, therefore, such license grant specifically excludes and Lilly and its Affiliates retain any and all rights to research and develop and commercialize antibodies (other than the monospecific form of LY2189102) that may bind to the same or partially same epitope, including a bispecific antibody with anti IL-lb activity and containing the same complementarity determining regions as LY2189102.

#### B.2 Sublicenses

The rights and licenses granted in Section 2.1 include the right to grant sublicenses, directly or through multiple tiers to Affiliates or Third Parties, provided that: (a) any sublicense granted by Flame under this Agreement (directly or indirectly through its Affiliate) to a Third Party shall be (i) in writing and (ii) subject in applicable respects to the provisions contained in this Agreement. Flame shall be responsible for the compliance of its Sublicensees with the applicable provisions contained in this Agreement.

## **B.3** Third Party Contractors

Flame shall have the right to retain a Third Party contractor to perform any activity in connection with Flame's exercise of any of its rights granted under Section 2.1, where such activity is to be performed at the direction and control and for the sole benefit of Flame or its Affiliates. Such retention of the Third Party contractor is not a sublicense within the meaning of Section 2.2 but is considered an activity of Flame under the license granted under Section 2.1.

## **B.4** Regulatory Interactions And Responsibility to Develop and Commercialize

- (a) <u>Regulatory Interactions</u>. Subject to the terms of this Agreement, Flame, its Affiliates or Sublicensees, or its or their designees will have the right to conduct, and shall be responsible for, all regulatory activities and interactions, at their cost, for the Licensed Products and will hold its own master file and be the liaison with regulatory agencies.
- (b) Responsibility to Develop and Commercialize. Flame, itself or through its Affiliates and Sublicensees, will use Commercially Reasonable Efforts to Develop and Commercialize one or more Licensed Products for therapeutic uses in the Field in the Territory. For clarity, development and commercialization of a Product as a diagnostic product is not sufficient to comply with the diligence obligations. Flame will be responsible for all its costs and expenses associated with development, regulatory and commercialization activities. The term "Commercially Reasonable Efforts" means, with respect to Flame, those efforts and resources commensurate with those efforts commonly used in the biotechnology or pharmaceutical industry by a company of comparable size in connection with the development or commercialization of pharmaceutical products that are of similar status, stage of development, life cycle and commercial potential, including issues of safety and efficacy, the patent or proprietary position of the product, the regulatory status and approval process, the probable

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profitability of the applicable product, and other relevant factors such as technical, legal, scientific or medical factors.

- (c) GCP and GLP Compliance. The Development of the Licensed Product shall be conducted by Flame using GCP and good laboratory practices ("GLP"). GLP means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time. GCP means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 3 I 2 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.
- (d) <u>Compliance with Animal Care and Use Requirements</u>. Flame shall comply with all Applicable Laws pertaining to the care and use of experimental animals and that all animals used in experiments with Licensed Compound shall be provided with humane care and treatment in accordance with the current applicable veterinary practices. Company shall also comply with Lilly animal care and use requirements referenced in the attached **Exhibit D**.
- B.5 Progress Reports. During the Term of the Agreement, Flame shall keep Lilly regularly informed of the progress of its efforts to Develop the Licensed Compound and/or the Licensed Product, including providing (\*\*\*) written updates to Lilly within thirty (30) days of (\*\*\*) of each year during the Term of this Agreement, including a summary of (\*\*\*). In addition, during the Term of the Agreement, upon the reasonable request of Lilly, but no more frequently than one time in each Calendar Year, Lilly and Flame shall meet by telephone, videoconference, or in-person at a mutually agreeable location to discuss the topics described in the progress reports. Notwithstanding anything to the contrary in this Section 2.5 or elsewhere in this Agreement, if at any point Lilly or its Affiliate, directly or indirectly, has (\*\*\*) one or more molecule(s) utilizing the same mechanism of action and targeting the same indications, as the Licensed Compound and/or Licensed Product, the reports, information and meetings required under this Section 2.5 and elsewhere in this Agreement shall no longer apply and Flame shall in lieu thereof provide to Lilly only a high level summary of development activities (\*\*\*) within thirty (30) days (\*\*\*) of each year.

Page 11 LICENSE AGREEMENT B.6 If at any time Flame or its Affiliates receive written term sheet (or similar written expression of interest) from a Third Party for any rights in the Licensed Compound/Product or acquisition of Flame, unless prohibited by Applicable Law, Flame will notify Lilly of the same promptly thereafter but in no event less than (\*\*\*) days after receipt of such written terms.

#### 3. TECHNOLOGY TRANSFER

- (a) <u>General</u>. Within (\*\*\*) of the Effective Date, the Parties will coordinate and agree to a technology transfer plan for Lilly to provide and transfer to Flame the Lilly Know-How but only to the extent as set forth on <u>Exhibit C</u> and was not previously provided to Flame (the "Technology Transfer Plan"), which may be updated or amended by the mutual agreement by the Parties from time to time as needed. For purposes of clarity, Lilly will transfer only the Lilly Know-How referenced in <u>Exhibit C</u> to Flame in accordance with the Technology Transfer Plan, and Flame will cooperate to facilitate the receipt of such transfer of Lilly Know How. Unless Lilly otherwise agrees, all Licensed Know-How will be transferred in its current form and will not be re-formatted or otherwise modified for Flame's benefit. If in the future the parties mutually agree (such agreement will not be unreasonably withheld) that Lilly possessed data as of the Effective Date (and Lilly still possesses at the time of such request) that is (\*\*\*) to develop the Licensed Compound or Licensed Product, Flame will have the right to request such data and Lilly (subject to the mutual agreement of the Parties as referred to above) will provide such data to Flame. Lilly will be compensated at the rate of (\*\*\*) per hour for such activities payable within (\*\*\*) days after receipt of such data.
- (b) Only Exhibit C Know How. Notwithstanding anything to the contrary in this Agreement, Lilly will have no obligation under this this Agreement to transfer any Lilly Know How or material other than the items specifically described in the attached Exhibit C to Flame in accordance with the Technology Transfer Plan, and Flame will cooperate to facilitate such transfer.
- (c) <u>Tech-Transfer Assistance</u>. Lilly will provide written or verbal responses to reasonable questions relating to the Licensed Compound or Licensed Product for a period of (\*\*\*) days following the Effective Date provided under no circumstance shall such assistance exceed (\*\*\*) hours. For clarity, except as specifically provided in this Article 3, Lilly shall have no other obligations to provide any assistance in connection with technology transfer under this Agreement.

#### 4. PAYMENTS

## 4. 1 Upfront Payments and Equity

- (a) <u>Upfront</u>. In consideration for the exclusive license rights granted by Lilly to Flame hereunder, Flame will pay Lilly a nonrefundable and non-creditable upfront payment of (\*\*\*) within (\*\*\*) calendar days of the Signing Date.
- (b) <u>Equity</u>. Also in consideration for the exclusive license rights granted by Lilly to Flame hereunder, within (\*\*\*) calendar days of the Signing Date Flame shall enter into and

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deliver the Common Stock Purchase Agreement in the form of Schedule I and will issue to Lilly the number of shares of common stock of Flame pursuant to the terms set forth in the Common Stock Purchase Agreement (such agreement, the "Stock Purchase Agreement" and such shares, the "License Shares"). The License Shares will represent (\*\*\*) of Flame's fully diluted capital stock as of the date of execution of the Stock Purchase Agreement. Contemporaneous with the execution of the Stock Purchase Agreement, Flame and Lilly will enter into an Investor Rights Agreement in the form of Schedule 2 (the "Investor Rights Agreement"). If as of the initial common stock issuance to Lilly under the Stock Purchase Agreement at the Closing, Flame has not yet issued and sold Equity Securities in a bona fide equity financing, in a single transaction or series of related transactions, resulting in gross proceeds to Flame of not less than (\*\*\*), then the Investor Rights Agreement will include Article IV which will provide Lilly with the right to receive additional shares of Flame common stock, for no additional consideration, in order to ensure that Lilly continues to own (\*\*\*) of Flame's fully diluted capital stock following each issuance of capital stock by Flame after the date of the Investor Rights Agreement until (and including) Flame's issuance of capital stock for proceeds of not less than (\*\*\*) in a bona fide equity financing, all on the terms and subject to the conditions set forth in the Investor Rights Agreement. The parties agree that a breach by Flame of such Article IV of the Investor Rights Agreement, and a failure of Flame to cure within thirty (30) days following receipt of written notice from Lilly made within thirty (30) days after Lilly first becomes aware of such breach, will entitle Lilly to terminate this Agreement and the Investor Rights Agreement and to seek all rights and remedies available hereunder and thereunder in connection with such breach.

(c) <u>Closing</u>. This Agreement shall come into effect as of the date that Flame has satisfied its obligations under Section 4.1(a) and 4.1(b) within the time period specified therein (the "Closing"). Upon Flame's delivery of the cash payment required under Section 4.1(a) within the time period required therein and Flame's delivery of the Equity Agreements executed by Flame and issuance of the shares of common stock to Lilly under the Stock Purchase Agreement within the time period required under Section 4.1(b), this License Agreement shall automatically come into effect without the need for further action on the part of either party. If on or before the (\*\*\*) calendar day following the Signing Date Flame has not (i) made the cash payment to Lilly required by Section 4.1(a); or has not (ii) delivered to Lilly the Equity Agreements executed by Flame and issued the shares of common stock to Lilly under the Stock Purchase Agreement, then this Agreement shall not come into effect and shall automatically be null and void and of no force and effect.

## 1.2 Regulatory and Commercial Milestone Payments

(a) <u>Initial Regulatory Milestone</u>. Flame will make a one-time non-refundable and noncreditable payment to Lilly in the amount of (\*\*\*) as follows: (i) If the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration trial occurs as evidenced by written documentation from the Regulatory Authority of a Major Country (\*\*\*) shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the payment upon the first submission by Flame, its Affiliate or Sublicensee of a BLA or equivalent in any Major Country for the Licensed Product; and (ii) If the first dosing of the first

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patient in a Phase III Clinical Trial or an equivalent registration trial occurs (\*\*\*) shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the payment upon the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration for the Licensed Product by Flame, its Affiliate or Sublicensee. Such payment will be made within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee.

(b) <u>Subsequent Regulatory Milestones</u>. Within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee, of each of the milestone events set forth in the table below (each, a "**Regulatory Milestone Event**") by the Licensed Product, Flame will make the corresponding one-time non-refundable and noncreditable payment to Lilly.

	the Licensed Product	Milestone Payment (U.S. dollars)
1.	First Regulatory Approval of an BLA or equivalent in the (***) for the Licensed Product	(***)
2.	First Regulatory Approval of an BLA or equivalent in (***) for the Licensed Product	(***)
3.	First Regulatory Approval of an BLA or equivalent for the Licensed Product in any (***).	(***)
	Total Regulatory Milestones	(***)

For each of Regulatory Milestone only one payment shall ever be due and payable with respect to the occurrence of each milestone by the Licensed Product containing the Licensed Compound.

(c) <u>Commercial Milestones</u>. Within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee, of each of the milestone events set forth in the table below (each, a "**Commercial Milestone Event**") for the Licensed Product, Flame will make the corresponding one-time non-refundable and noncreditable payment to Lilly.

	Commercial Milestones for the Licensed Product	Milestone Payment (U.S. dollars)
1.	At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (***)	(***)
2.	At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (***)	(***)
3.	At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (***)	(***)

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4. At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (\*\*\*)

**Total Commercial Milestones** 

(\*\*\*)

(\*\*\*)

For each of Commercial Milestone only one payment shall ever be due and payable with respect to the occurrence of each milestone.

## 1.3 Royalties

Subject to Section 4.5, Flame will pay Lilly a tiered royalty on the Calendar Year Net Sales of the Licensed Product as follows:

```
Portion of Calendar Year Net Sales of the Licensed Product (U.S. dollars) Royalty rate applicable to such portion

(***)
(***)
More than (***) to (***)
(***)
More than (***) (i.e., (***))
(***)
```

## 1.4 Royalty Payments

Royalty obligations under Sections 4.3 (subject to adjustment pursuant to Section 4.5) shall commence on the date of First Commercial Sale of the Licensed Product in the Territory, and expire on a country-by-country basis, on the latest of the following dates (the "Royalty Term"):

- (a) the (\*\*\*) anniversary of the date of First Commercial Sale of the Licensed Product in such country;
- (b) the expiration of the last-to-expire Licensed Patent having a Valid Claim covering the (\*\*\*) of the Licensed Product as Commercialized in the country at issue; and
  - (c) the expiration of any Data Exclusivity Period for the Licensed Product in the country at issue.

Following the expiration of the Royalty Term with respect to the Licensed Product in a country, the licenses and rights granted to Flame hereunder with respect to the Licensed Product in the Territory shall become fully paid-up, royalty-free non-exclusive license. Notwithstanding

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anything herein to the contrary, with respect to the Licensed Product only a single royalty payment shall be due and payable, regardless if such Licensed Product is covered by more than one Valid Claim or its distribution involves more than one country.

## 1.5 **Royalty Reductions**

- (a) <u>Step-Down for Generic Version Provided No Valid Claim and No Data Package Exclusivity.</u> On a country-by-country basis in the event that a Generic Version of the Licensed Product is commercially launched in a particular country and the Net Sales of such Licensed Product in such country subsequently decreases for (\*\*\*) by more than (\*\*\*) from the level of Net Sales in such country for such Licensed Product for the calendar quarter immediate( y prior to the entry of such Generic Version of such Licensed Product then the royalty owed to Lilly associated with such Net Sales for such Licensed Product in such country commencing on such date for the remainder of the Royalty Term shall be reduced by (\*\*\*).
- (b) <u>Third Party Licenses</u>. If Flame or any of its Related Parties (i) determines in good faith, and after consultation with Lilly, that it is reasonably necessary to obtain a license or other right from a Third Party under any Patent with one or more Valid Claims covering any Licensed Product or the Licensed Compound, or the composition of matter, method of use or manufacture thereof (including in connection with the settlement of a patent infringement claim), (in each case, "**Third Party IP Payments**"), then Flame may deduct (\*\*\*) of the Third Party IP Payments payable by Flame or any of its Related Parties to such Third Party from the (\*\*\*) otherwise payable by Flame to Lilly under Section 4.3.
- (c) <u>Royalty Reduction Cap.</u> Notwithstanding anything in this Section 4.5 to the contrary, in no case shall the royalties payable by Flame to Lilly under Section 4.3 with respect to Net Sales of such Licensed Product in such country be reduced by more than an aggregate of (\*\*\*) in any Calendar Quarter as a result of any and all reductions or offsets under this Section 4.5 of this Agreement. Any portion of the Third Party IP Payments payable to such Third Party with respect to such Licensed Product in such country that Flame would, but for the foregoing limitation on royalty reductions, be entitled to deduct under Section 4.5 shall be (\*\*\*).

#### 1.6 Reports; Payment of Royalty

During the Term, following the First Commercial Sale of the Licensed Product by Flame, Flame shall furnish to Lilly a (\*\*\*) written report for the Calendar Quarter showing the Net Sales of the Licensed Product subject to royalty payments sold by Flame and its Related Parties and broken down between Flame and any Sublicensees during the reporting period and the royalties payable under this Agreement. Flame shall also cooperate with Lilly to provide Lilly with such information that Lilly may reasonably request so as to enable Lilly to make quarterly accruals regarding royalties hereunder for financial reporting purposes. Reports shall be due thirty (30) days following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Flame will mail such reports to the attention of: Eli Lilly and Company, Lilly Royalty Administration in Finance, Drop Code 1064, Lilly Corporate Center, Indianapolis, Indiana, 46285.

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#### 1.7 Financial Audits

Flame will keep and maintain (and to the extent applicable, will cause its Affiliates and Sublicensees to keep and maintain) proper and complete records and books of account in such form and detail as is necessary for the determination and verification of the royalty amounts payable by Flame (on behalf of itself and its Affiliates and Sublicensees) to Lilly under this Agreement and for the purposes of this Agreement. Such records need only be kept and maintained for up to (\*\*\*) months after the end of any Calendar Year.

Within the term of this agreement and within (\*\*\*) years after its termination/expiration, Lilly shall not more than once each year have the right to have Lilly's independent certified public accountants inspect Flame's records for (\*\*\*) preceding years for the purpose of determining the accuracy of royalty payments. The independent certified public accountants shall keep confidential any information obtained during such inspection and shall report to Flame and Lilly only the amounts of net sales and royalties due and payable. If determined that additional royalties are owed, or that royalties were overpaid, during such period, Flame will pay Lilly the additional royalties, or Lilly will pay Flame the overpaid royalties within thirty (30) days of the date the independent certified public accountants written report is received by the paying party. The fees charged by such accounting firm will be paid by Lilly unless any additional royalties owed are at least (\*\*\*) and also exceed (\*\*\*) of the royalty obligation for the royalty period subject to the audit, in which case Flame will pay the reasonable fees of the accounting firm.

Flame shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Lilly's independent accountant to the same extent required of Flame under this Agreement.

Lilly shall treat all financial information subject to review as Flame's Confidential Information in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firms to enter into an acceptable confidentiality agreement with Flame, its Affiliate or Sublicensee, as applicable, obligating them to retain all such information in confidence pursuant to such confidentiality agreement.

#### 1.8 Payment Method

All payments to be made by Flame to Lilly under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to a bank account designated in writing by Lilly.

## 1.9 Late Payment

All late payments under the Agreement shall bear interest at the rate of (\*\*\*) for United States dollars as of the date such payment was due, taken from a widely accepted source of published interest rates, plus (\*\*\*) percentage points, or, if lower, the highest rate permitted by Applicable Law, until the date such payment is made.

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1.10 Tax Withholding If laws, rules or regulations require Flame or any Related Party to withhold income taxes or other taxes imposed upon payments due hereunder, Flame or such Related Party shall promptly notify Lilly of such requirement and shall make such withholding payments as required and subtract such withholding payments from the payments due. Flame shall, or shall require its Related Party to, submit any original receipts or other evidence of payment of any such withholding taxes to Lilly within (\*\*\*) days to allow Lilly to document such tax withholdings for purposes of claiming foreign tax credits and similar benefits and shall cooperate with reasonable requests of Lilly and at Lilly's expense (without acting to the detriment of Flame or any Related Party) to the extent necessary for Lilly obtaining such credits and benefits. Notwithstanding the foregoing, if Flame sublicenses or assigns its payment obligations to an Affiliate or to a Third Party, and such sublicense or assignment results in a greater amount of withholding tax which may be subtracted from payments to Lilly than if Flame had fulfilled its payment obligations to Lilly directly, such Affiliate or Third Party shall increase the payment to Lilly as necessary such that the amount received by Lilly after such required income tax withholding is equal to the amount Lilly would have received if Flame had fulfilled such payment obligations to Lilly directly. If Lilly subsequently becomes aware that it recoups through foreign lax credits and similar benefits the incremental increase in payment described in the preceding sentence, Lilly will bring this to the attention of Flame and will extend a credit applicable to subsequent payments due to Lilly hereunder in amounts and on terms acceptable to Lilly such that Lilly receives the equal amount that would have been received by Lilly pursuant to this Agreement had such sublicense or assignment not occurred.. For clarity, Flame (including its Affiliates, assignees and sublicensees) is solely responsible for any income tax due in connection with its income under this Agreement.

## 5. **CONFIDENTIALITY; PUBLICATION**

## **B.1** Nondisclosure Obligation

Except to the extent expressly authorized by this Agreement, during the Term and for (\*\*\*) years thereafter, the Receiving Party shall keep confidential, and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement, the Confidential Information of the Disclosing Party. The Receiving Party may use Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than (\*\*\*)) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party's Confidential Information by the Receiving Party or any of its Representatives.

## B.2 Exceptions

The Receiving Party's obligations under Section 5.1 shall not apply to any information that the Receiving Party can show by competent evidence: (i) is already known to it or its Affiliates at the time it is disclosed to any of them, as evidenced by the Receiving Party's written records, <u>provided</u> that Lilly shall not have the right to avail itself of the exception set forth in this

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clause (i) with respect to Licensed Know-How listed on **Exhibit C** for so long Lilly is deemed the Receiving Party with respect thereto; (ii) is or becomes generally known to the public through no act or omission of the Receiving Party or any of its Affiliates in violation of the terms of this Agreement; (iii) has been lawfully received by the Receiving Party or any of its Affiliates from a Third Party without restriction on its disclosure and without, to the knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party or any of its Affiliates; or (iv) has been independently developed by the Receiving Party or any of its Affiliates without use of or reference to the Confidential Information of the Disclosing Party or any of its Affiliates, provided that Lilly shall not have the right to avail itself of the exception set forth in this clause (iv) with respect to Licensed Know-How set forth on **Exhibit C** for so long Lilly is deemed the Receiving Party with respect thereto.

#### **B.3** Authorized Disclosure

Notwithstanding the provisions of Section 5.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting Patents as permitted by this Agreement;
- (b) enforcing the Receiving Party's rights under this Agreement and performing the Receiving Party's obligations under this Agreement;
  - (c) prosecuting or defending litigation as permitted by this Agreement;
- (d) complying with applicable court orders, applicable laws, rules or regulations, or the listing rules of any exchange on which the Receiving Party's or any of its Affiliates' securities are traded;
- (e) in the case of Flame as the Receiving Party during the Term or after expiration (but not earlier termination) of this Agreement, disclosure in submissions to or filings with any Regulatory Authority (including, without limitation, in INDs and BLAs) with respect to any Licensed Compound or Licensed Product, and in correspondence with any Regulatory Authority in the Territory regarding any Licensed Compound or Licensed Product or any of the foregoing submissions or filings in the Territory;
- (f) disclosure to the Receiving Party's Affiliates, to actual or potential Sublicensees (in the case of Flame as the Receiving Party during the Term or after expiration, but not earlier termination, of this Agreement), and to the Receiving Party's Representatives who, in each case, have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential Sublicensee, or Representative agrees to be bound by terms of confidentiality and non use at least as restrictive as those set forth in this Section 5; and
- (g) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in

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confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.

Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 5.3(c) or Section 5.3(d), each party (except in the case of Lilly, where Lilly may disclose a copy of the agreement in response to a valid request from a (\*\*\*) without complying with (i) or (ii) below) will (i) give reasonable advance notice to the Disclosing Party of such required disclosure, and (ii) at the Disclosing Party's request and expense, shall cooperate with the Disclosing Party's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law or regulation required, and/or to obtain other confidential treatment of such Confidential Information.

#### B.4 Publication

Lilly and its Affiliates shall not have the right to publish or present, and to authorize any Third Party to publish or present, the results of any study or clinical trial, or other development activities with respect to any Licensed Compound or Licensed Product, without the prior review or approval of Flame. Flame shall have the right in the future to issue a press release or other public statement describing Flame's progress or activities in developing the Licensed Product.

## **B.5** Publicity and Filing of this Agreement.

Flame shall have the right in the future to issue a press release or other public statement relating to this Agreement and the transactions contemplated hereunder, subject to Lilly's review and approval of such press release, approval not to be unreasonably withheld. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms proposed to be redacted: provided that each Party shall ultimately retain control over what information to disclose to any securities authority or stock exchange, as the case may be, and provided further that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor any of its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to any securities authority or stock exchange.

## **B.6** Prior Confidentiality Agreement

As of the Effective Date, the terms of this Article 5 shall supersede the Confidentiality Agreement, and any information disclosed by a Party pursuant to the Confidentiality Agreement shall be deemed Confidential Information of such Party for purposes of this Agreement, except as expressly provided in Section 1.10.

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#### 6. REPRESENTATIONS AND WARRANTIES

## **B.1** Mutual Representations and Warranties

Each party represents and warrants to the other that, as of the Effective Date:

- (a) it has the full right, power and authority to enter into this Agreement, and its execution of this Agreement, the fulfillment of its obligations and performance of its activities hereunder do not conflict with, violate, or breach, or constitute a default under, any material agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;
- (b) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;
- (c) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder. and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action;
  - (d) this Agreement is legally binding upon it, enforceable in accordance with its terms; and
- (e) all necessary consents, approvals and authorizations of all Governmental Authorities and other persons required to be obtained by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.

## **B.2** Representations and Warranties of Flame

Flame represents and warrants to Lilly that, as of the Effective Date:

- (a) neither Flame nor any of its Affiliates is debarred or disqualified under the Act or comparable Applicable Laws outside of the United States; and
- (b) no current employee of Flame or any of its Affiliates is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof.

## **B.3** Representations and Warranties of Lilly

Lilly represents and warrants to Flame that, as of the Effective Date:

(a) the Listed Patents constitute all Patents owned or Controlled by Lilly or any of its Affiliates as of the Effective Date in the Territory that contain one or more claims covering any Licensed Compound or Licensed Product, or the composition of matter or formulation, or any method of use or manufacture, of any Licensed Compound or Licensed Product;

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- (b) Lilly has provided or otherwise made available to Flame current, true and complete copies of all unpublished Listed Patents;
- (c) all documents required to be filed and all payments required to be made in order to prosecute and maintain each Patent in the Listed Patents prior to the Effective Date in the Territory have been filed or made, as the case may be, in a timely manner, and no action has been taken that would constitute waiver, abandonment or any similar relinquishment of such rights;
- (d) no Listed Patent in the Territory is or has been involved in any interference, opposition, reissue, reexamination, revocation, *inter* partes review, post-grant review, post-grant proceeding, or equivalent proceeding in which the scope, validity or enforceability of any such Listed Patent is being or has been contested or challenged, and to Lilly's knowledge, no such proceeding has been threatened with respect to any Listed Patent in the Territory;
- (e) no Listed Patent in the Territory has been adjudged invalid or unenforceable in whole or part, or, in the case of pending patent applications within the Listed Patents in the Territory, has been the subject of a final and non-appealable finding of unpatentability;
- (f) Lilly has the full right, power and authority to grant the rights and licenses it purports to grant hereunder, and neither Lilly nor any of its Affiliates has granted any Third Party any rights or licenses that would interfere or be inconsistent with Flame's rights and licenses hereunder;
- (g) to the knowledge of Lilly, there are no legal claims, judgments or settlements against or owed by Lilly or any of its Affiliates, threatened or pending legal claims or litigation, in each case relating to the Licensed Technology;
- (h) neither Lilly nor any of its Affiliates has received written notice from any Third Party claiming that the manufacture, use, sale, offer for sale or import of any Licensed Compound or Licensed Product infringes or misappropriates, or would infringe or misappropriate, the Patents or other intellectual property rights of any Third Party, and, to Lilly's knowledge, none of the manufacture, use, sale, offer for sale and import of Licensed Compounds and Licensed Products infringes the Patents or misappropriates any other intellectual property rights of any Third Party;

#### B.4 Covenants.

Each Party shall inform the other Party in writing immediately upon learning that it or any person or entity who has performed activities with respect to the Licensed Compound or a Licensed Product prior to the Effective Date is debarred or is the subject of a conviction described in Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or upon learning that any action is pending or threatened relating to the debarment or conviction of such Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the Development or Commercialization of the Licensed Compounds or Products.

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## **B.5** No Other Representations or Warranties

EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY AND ALL SUCH OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

#### **B.6** Limitation of Liability

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, OR LOST PROFITS, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 6.6 (\*\*\*).

#### 7. INDEMNIFICATION

## B.1 **By Lilly**

Lilly agrees to indemnify, defend and hold harmless Flame, its Affiliates, and their respective Representatives (individually and collectively, the "Flame Indemnitee(s)") from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (individually and collectively, "Losses"), to which any Flame Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "Claim"), to the extent such Losses arise out of (a) the gross negligence, illegal conduct or willful misconduct of Lilly or any Lilly Indemnitee or (b) Lilly's material breach of this Agreement; except, in each case, to the extent such Losses arise out of any Flame Indemnitee's gross negligence, illegal conduct or willful misconduct or Flame's breach of this Agreement.

## B.2 By Flame

Flame agrees to indemnify, defend and hold harmless Lilly, its Affiliates, and their respective Representatives (individually and collectively, the "Lilly Indemnitee(s)") from and against all Losses to which any Lilly Indemnitee may become subject as a result of any Claim, to the extent such Losses arise out of (a) the gross negligence, illegal conduct or willful misconduct of Flame or any Flame Indemnitee, (b) the use, Development, Manufacture, Commercialization, handling, storage or other disposition of the Licensed Compound or Licensed Product by or on behalf of Flame or any of its Related Parties, including without limitation any product liability claim, or (c) Flame's material breach of this Agreement; except, in each case, to the extent such Losses arise out of any Lilly Indemnitee's gross negligence, illegal conduct or willful misconduct or Lilly's breach of this Agreement.

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#### **B.3** Defined Indemnification Terms

Either the Lilly Indemnitee or the Flame Indemnitee shall be an "Indemnitee" for the purpose of this Article 7, and the Party that is obligated to indemnify the Indemnitee under Section 7.1 or Section 7.2 shall be the "Indemnifying Party".

#### B.4 Defense

The Indemnifying Party shall have the right to assume direction and control of the defense of the Claim at the Indemnifying Party's sole expense by counsel selected by Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such Claim subject to the terms of this Article 7, but shall consider in good faith all suggestions of the Indemnitee. Notwithstanding the foregoing, if the Indemnifying Party does not assume direction and control of the defense of the Claim within thirty (30) days after receiving notice of the Claim from the Indemnitee, the Indemnitee shall have the right to assume direction and control of such defense by counsel selected by the Indemnitee, and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnitee for all reasonable and documented costs, including reasonable attorney fees, incurred by the Indemnitee in defending itself within 30 days after receipt of any invoice therefor from the Indemnitee. If the Indemnitee assumes direction and control of the defense of such Claim in accordance with the preceding sentence, the Indemnifying Party may, at its own expense, participate in and monitor such defense with counsel of its own choosing.

#### B.5 Settlement

The Indemnifying Party may settle any such Claim or otherwise consent to an adverse judgment with respect to such Claim (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where (i) there is no admission of legal wrongdoing on the part of the Indemnitee, and (ii) the only liability or other obligation imposed on the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld.

#### B.6 Notice

The Indemnites shall notify the Indemnifying Party promptly of any Claim for which the Indemnites seeks indemnification under Section 7.1 or Section 7.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect to such Claim and the defense thereof.

## B.7 **Permission by Indemnifying Party**

The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any

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admission as to liability or fault without the express written permission of the Indemnifying Party.

#### **B.8** Flame's Insurance

Flame, at its own expense, shall maintain liability insurance in an amount adequate to cover its obligations under this Agreement during the Term. Flame shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to Lilly upon request.

## 8. INVENTIONS; PATENT PROVISIONS

## B.1 Ownership of Inventions

As between the Parties, Flame shall own the entire right, title and interest in and to any and all information and inventions, whether or not patentable, discovered, created, identified or made solely by Flame or any of its Representatives in the course of performing its obligations or exercising its rights under this Agreement, and all intellectual property rights in any of the foregoing. Inventorship shall be determined in accordance with U.S. patent laws.

#### B.2 Patent Filing, Prosecution and Maintenance

## (a) <u>Program-Specific Patents</u>.

- (i) Within thirty (30) days after the Effective Date, Lilly shall inform in writing any outside patent counsel and all local patent representatives used by Lilly or any of its Affiliates to Prosecute any Program-Specific Patent, that (A) the Program-Specific Patents have been exclusively licensed to Flame, (B) Flame has the first right to Prosecute the Program-Specific Patents, and (C) a copy of all future correspondence regarding the Program-Specific Patents should be sent to both Flame and Lilly, and Lilly shall forward copies of any correspondence it or any of its Affiliates receives from any such outside patent counsel or local patent representative or any patent office or other governmental body regarding the Program-Specific Patents to Flame. Upon Flame's written request, for a period of up to (\*\*\*) days following the Effective Date, Lilly will be responsible for Prosecuting the Program-Specific Patents on Flame's behalf at Flame's cost. For a period of (\*\*\*) after the Effective Date, at Flame's reasonable request, Lilly will, subject to reimbursement of its costs, cooperate with and reasonably assist and provide support to Flame in relation to the Prosecution of the Program-Specific Patents.
- (ii) Flame shall have the first right, but not the obligation, to Prosecute the Program-Specific Patents, at its sole cost and expense using outside counsel mutually acceptable to the Parties (such acceptance not to be unreasonably withheld). In the event that Flame desires to abandon or cease Prosecution of any such Program-Specific Patent, Flame shall provide written notice to Lilly thereof at least (\*\*\*) days prior to the next deadline for any action that must be taken with respect to such Program-Specific Patent in the relevant patent office. In such case, Lilly shall have the right, in its discretion, exercisable upon written notice to Flame

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delivered no later than (\*\*\*) days after receipt of notice from Flame, to assume responsibility for Prosecution of such Program-Specific Patent, at its sole cost and expense

- (iii) Flame shall keep Lilly reasonably informed regarding Flame's Prosecution activities with respect to Program Specific Patents, including periodic updates and advance notice of and reasonable opportunity to review material Patent filings prior to the time they are made. Flame shall consider in good faith any comments Lilly may make with respect to Flame's Prosecution activities with respect to Program Specific Patents.
- (b) Other Licensed Patents. Lilly shall have the sole right, but not the obligation, to Prosecute the Other Licensed Patents, at its sole cost and expense.

#### B.3 Cooperation

Each Party agrees to cooperate fully in the Prosecution of Licensed Patents under Section 8.2. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, that may be reasonably required so as to enable the other Party to Prosecute patent applications in any country as permitted by Section 8.2; and (b) promptly informing the other Party of any request for, or filing or declaration of, any interference, opposition, reissue, reexamination, revocation, *inter partes* review, post-grant review, post-grant proceeding or similar proceeding relating to any Licensed Patent received by the Party.

#### B.4 Enforcement and Defense of Patents

(a) Notice. Each Party shall notify the other Party in writing within ten (10) Business Days (except as expressly set forth below) of becoming aware of any alleged or threatened infringement by a Third Party of a Licensed Patent ("Infringement"), including (x) any such alleged or threatened Infringement on account of a Third Party's manufacture, use or sale of Licensed Compound or Licensed Product, (y) any certification filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions in connection with an ANDA (an Abbreviated New Drug Application in the United States or a comparable application for marketing approval under Applicable Law in any country other than the United States) or other BLA for a Licensed Product (a "Patent Certification"), and (z) any declaratory judgment action filed by a Third Party that is developing, manufacturing or commercializing Licensed Compound or Licensed Product alleging the invalidity, unenforceability or non infringement of any Licensed Patent ((x)-(z), collectively, "Competitive Infringement"); provided, however, that each Party shall notify the other Party of any Patent Certification regarding any Licensed Patent that it receives, and such Party shall provide the other Party with a copy of such Patent Certification, within five (5) days of receipt.

#### (b) Right to Enforce and Defend.

(i) Program-Specific Patents. Flame shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Competitive Infringement of a Program-Specific Patent, at Flame's expense and by counsel of its choice, and

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Lilly shall have the right to be represented in any such action or proceeding, at Lilly's expense and by counsel of its choice. If Flame fails to bring any such action or proceeding with respect to Competitive Infringement of any Program-Specific Patent within ninety (90) days following the notice of alleged Competitive Infringement, Lilly shall have the right to bring (or defend) and control any such action at its expense and by counsel of its choice, and Flame shall have the right, at its own expense, to be represented in any such action at its expense and by counsel of its choice.

- (ii) Other Licensed Patents. Lilly shall have the sole right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Infringement of an Other Licensed Patent, at Lilly's expense and by counsel of its choice; provided, however, that in the event of Competitive Infringement of an Other Licensed Patent, Lilly shall consider in good faith any request by Flame for consent to bring (or defend) and control any action or proceeding with respect to such Competitive Infringement.
- (c) <u>Cooperation</u>. In the event a Party brings (or defends) an infringement action in accordance with this Section 8.4, or in the event a Party is entitled to bring (or defend) an infringement action in accordance with this Section 8.4 but lacks standing to do so, the other Party shall cooperate fully, including, if required to bring (or defend) such action, the furnishing of a power of attorney or being named as a party. Neither Party shall enter into any settlement or compromise of any action under this Section 8.4 which would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.
- (d) Recovery. Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Section 8.4 with respect to Competitive Infringement, whether by way of settlement or otherwise, shall be applied first to reimburse the documented out-of-pocket legal expenses of the Party that brought (or defended) and controlled such action or proceeding incurred in connection with such action or proceeding, and second to reimburse the documented out-of-pocket legal expenses of the other Party incurred in connection with such action or proceeding, and any remaining amounts shall be (\*\*\*).

#### **B.5** Patent Term Extensions

Flame shall have the right to determine the Program-Specific Patents for which it will apply for patent extension in any country for any Licensed Product. Flame shall file for any such extension at Flame's cost and expense. Lilly shall provide (\*\*\*) assistance to Flame in connection with such filings, provided that Flame shall pay or reimburse any out-of-pocket costs incurred by Lilly in providing such assistance.

#### **B.6** Infringement of Third Party Rights

Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either Party pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Neither Party shall have the right to settle any

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patent infringement litigation under this Section 8.6 in a manner that diminishes the rights or interests of the other Party without the written consent of such other Party (which shall not be unreasonably withheld).

#### B.7 Trademarks

As between the Parties, Flame shall be responsible for selecting, in its sole discretion, and shall own all right, title and interest in and to any trademarks adopted by Flame for use with the Licensed Products anywhere in the world (including all goodwill accruing with respect to such use), and shall be responsible for the registration, filing, maintenance and enforcement thereof. Flame shall have no right to use any trademark, tradename, or corporate name of Lilly or any of its Affiliates with the Licensed Products.

#### 9. TERM AND TERMINATION

#### **B.1** Term and Expiration

This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Sections 9.2, 9.3 or 9.4, the term of this Agreement (the "**Term**") shall continue in effect until the expiration of the last-to-expire Royalty Term for any and all Licensed Products.

#### **B.2** Termination On Mutual Agreement

This Agreement may be terminated by the mutual written agreement of the Parties.

#### **B.3** Unilateral Termination by Flame

Flame shall have the right to terminate this Agreement, in its entirety, in its sole discretion by giving (\*\*\*) days' advance written notice to Lilly.

#### **B.4** Termination for Cause

- (a) <u>Material Breach</u>. This Agreement may be terminated by a Party at any time during the Term upon written notice to the other Party if such other Party is in material breach of its obligations under this Agreement and has not cured such breach within (i) (\*\*\*) days in the case of any failure to make when due any payment hereunder, (ii) in all other cases (\*\*\*) days. Any such termination shall become effective at the end of such (\*\*\*) or (\*\*\*) (as applicable) period unless the breaching Party has cured such breach prior to the end of such period or has commenced all actions reasonable to timely cure such breach and continues to work diligently to accomplish such cure within (\*\*\*) days. Any right to terminate under this Section 9.4 shall be stayed in the event that, during any cure period, the Party alleged to have been in material breach shall have in good faith initiated dispute resolution in accordance with Article 10 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Article 10.
- (b) <u>Insolvency</u>. Either Party will have the right to terminate this Agreement in the event of a general assignment for the benefit of creditors of the other Party, or if proceedings of a

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case are commenced in any court of competent jurisdiction by or against such other Party seeking (i) such other Party's reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (ii) the appointment of a receiver or trustee for or over such other Party's property, or (iii) similar relief in respect of such other Party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue undismissed, or an order with respect to the foregoing shall be entered and continue unabated, for a period of more than (\*\*\*) days.

- Right of Reversion. Without limiting Flames's obligations under this Agreement (including Section 2.4), or any other rights or remedies of Lilly under this Agreement, at any time prior to Flame's (or its Affiliate's or its or their Sublicensee's) receipt of Regulatory Approval for the Licensed Product, in the event that Flame (or its Affiliate or its or their sublicensee) has not conducted any material development activities with respect to the Licensed Compound or Licensed Product for a period of (\*\*\*) consecutive months; provided, that such (\*\*\*) month period shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is prohibited from undertaking development activities due to a clinical hold mandated by a Regulatory Authority, Flame will notify Lilly in writing of the same and the Parties will discuss in good faith the reasons for such lack of development and potential resolution(s) thereof; provided that in the event that Flame does not commence any material development activities within (\*\*\*) months of such written notice to Lilly, Lilly shall have the right to terminate this Agreement and have the rights to the Licensed Compound revert to Lilly, subject to Lilly's payment of the Alternate Royalty Rate for Net Sales in accordance with Section 9.5(c) upon delivery of at least (\*\*\*) days' prior written notice to Flame
- (d) <u>Damages</u>. If either Party has the right to terminate this Agreement under Section 9.4, it may at its sole option, elect either to (i) terminate this Agreement and pursue any legal or equitable remedy available to it or (ii) maintain the Agreement in effect and pursue any legal or equitable remedy available to it.

#### **B.5** Effect of Expiration or Termination

- (a) <u>Expiration</u>. Upon expiration (but not earlier termination) of this Agreement, the license and rights under Licensed Know-How granted by Lilly to Flame pursuant to this Agreement shall survive on a nonexclusive, royalty-free, fully-paid, irrevocable and perpetual basis.
- (b) <u>Any Termination</u>. Upon any termination of this Agreement prior to its expiration, all licenses and rights granted by Lilly to Flame pursuant to this Agreement shall automatically terminate and revert to Lilly, and all other rights and obligations of the Parties under this Agreement shall terminate, and any Sublicense shall automatically terminate; in each case, except as expressly provided elsewhere in this Article 9.
- (c) <u>Termination by Flame Pursuant to Section 9.3 or by Lilly Pursuant to Section 9.4.</u> In the event of termination of this Agreement by Flame pursuant to Section 9.3, or by Lilly pursuant to Section 9.4, the following provisions shall apply:

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(i) Subject to Lilly's payment of the Alternate Royalty Rate for Net Sales of Licensed Product made by Lilly or its Affiliates or licensees, effective as of such termination, Flame shall, and it hereby does, grant to Lilly:
(1) Flame, effective as of such termination, hereby grants to Lilly an exclusive, worldwide (except as expressly set forth below), with the right to sublicense, under Flame Program-Specific Patents and Flame Know-How (each as defined below), to Develop make, have made, use, sell, have sold, offer for sale and import Licensed Compounds and Licensed Products in the Field;

- (2) Flame, effective as of such termination, hereby grants to Lilly a non-exclusive, worldwide (except as expressly set forth below), with the right to sublicense, under Flame Blocking Patents (defined below), to Develop, make, have made, use, sell, have sold, offer for sale and import Licensed Compounds and Licensed Products in the Field; and
- (3) Flame, within ninety (90) days of the effective date of such termination (unless otherwise mutually agreed to by the Parties in writing), agrees to transfer and assign to Lilly of all Regulatory Applications and Regulatory Approvals for Licensed Products held in the name of Flame or any of its Affiliates (other than the Regulatory Materials, if any, previously transferred to Flame from Lilly, which will be transferred and assigned back to Lilly pursuant to Section 9.5(c)(ii)).

For purposes of this Section 9.5(c)(i):

- a. "Alternate Royalty Rate" shall mean (i) (\*\*\*) if the Licensed Product as of the date of termination of the Agreement has not completed phase I clinical trial; (ii) (\*\*\*) if the Licensed Product as of the date of termination of the Agreement has completed a phase I clinical trial but has not yet completed phase II clinical trial; (iii) (\*\*\*) of the royalty rates set forth in Section 4.3 if the Licensed Product as of the date of termination of the Agreement has completed a phase II clinical trial but has not yet achieved Regulatory Approval; and (iv) (\*\*\*) royalty rates set forth in Section 4.3 if the Licensed Product as of the date of termination of the Agreement had achieved Regulatory Approval.
- b. "Flame Program-Specific Patents" means all Patents Controlled (other than pursuant to the license granted to Flame by Lilly under this Agreement) by Flame that, in each case, (A) claim only the composition of matter or formulation of, or any method of making or using, any Licensed Compound or Licensed Product (excluding any Other Product), and (B) do not claim the composition of matter or formulation of, or any method of making or using, any compound that is not a Licensed Compound or any product that is not a Licensed Product:
- c. "Flame Know-How" means all Know-How (excluding any Know-How covered by a claim of any published Flame Program-Specific Patent) that is (a) Controlled as of the effective date of termination of this Agreement by Flame or any of its Affiliates and (b) reasonably necessary or useful for, or was actually used or generated by or on behalf of Flame or any of its Affiliates in, the Manufacture, Development, Commercialization or

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use of any Licensed Compound or Licensed Product; but excluding the Licensed Know-How; and

- d. "Flame Blocking Patents" means Patents Controlled (other than pursuant to the license granted to Flame by Lilly under this Agreement) by Flame, other than Flame Program-Specific Patents, that claim inventions actually practiced or generated by or on behalf of Flame in the development, manufacture, use, sale, offer for sale or import of any Licensed Compound or any Licensed Product (excluding any Other Product) prior to termination of this Agreement;
- (ii) As promptly as practicable (and in any event within ninety (90) days) after such termination, Flame shall, unless otherwise mutually agreed to by the Parties in writing: (A) transfer or assign, or cause to be transferred or assigned, back to Lilly or its designee all Regulatory Materials, if any, transferred by Lilly to Flame; and (B) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 9.5(c)(ii) to Lilly;
- (iii) Flame shall reasonably cooperate with Lilly and its designee(s) to facilitate a smooth, orderly and prompt transition of any ongoing Licensed Product development activities being conducted by or on behalf of Flame or its Affiliates to Lilly or its designee(s), with due regard for patient safety and in compliance with all Applicable Laws and GCP;
- (iv) Flame shall return to Lilly, unless otherwise mutually agreed to by the Parties in writing, all Confidential Information of Lilly then in Flame's possession except as necessary to exercise any licenses granted under Section 9.S(a) to Flame which are then irrevocable; and
- (v) any sublicense granted by Flame or its Affiliate to a Third Party under the license granted under Section 2.1 shall terminate as of the termination of this Agreement.

#### B.6 Accrued Obligations; Survival

Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. The following provisions shall survive the termination or expiration of this Agreement for any

Page 31 LICENSE AGREEMENT reason: Articles 1, 4 (to the extent payments have accrued prior to termination), 5.1, 5.2, 5.3, 5.6, 6.5, 6.6, 7, 9.5, 9.6, 10 and 11.4 through 11.17.

#### 10. DISPUTE RESOLUTION

#### B.1 Disputes

The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and/or obligations hereunder. Subject to Section 10.2, any claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (each, a "Dispute") will be referred to the Chief Executive Officer of Flame and the Vice President (\*\*\*) of Lilly or their respective designees for attempted resolution. In the event such executives are unable to resolve such Dispute within thirty (30) days of such Dispute being referred to them, then, the Parties may, by mutual agreement, submit such Dispute to non-binding mediation, which non-binding mediation may be terminated by either Party at will. With respect to any Dispute not resolved under the above provisions of this Section 10.1, either Party may initiate litigation in accordance with Section 11.8 of this Agreement to seek relief from a court of competent jurisdiction.

#### **B.2** Injunctive Relief and Patent Litigation

Nothing contained in this Agreement (including Section 10.1) shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing nonbinding mediation proceeding. In addition, either Party may immediately bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to Section I0.1 of this Agreement.

#### 11. MISCELLANEOUS

#### B.1 Compliance with Applicable Laws.

Each Party shall, and shall require its Affiliates, sublicensees, agents and subcontractors to comply in all material respects with all Applicable Laws in connection with the performance of their obligations and the exercise of their rights under this Agreement. Any internal compliance codes of a Party shall apply only to that Party, but the Parties agree to cooperate with each other to ensure that each Party is able to comply with the substance of its respective internal compliance codes and, to the extent practicable, to operate in a manner consistent with its usual compliance related processes.

#### **B.2** Compliance with Anti-Corruption and Privacy Laws.

(a) <u>Anti-Corruption and Privacy</u>. In connection with this Agreement, each Party and each of its Affiliates has complied and will comply with all applicable local, national, and

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international laws, regulations, and industry codes dealing with data protection and privacy of personal information ("Privacy Laws") and with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development ("OECD") Convention on Combating Bribery of Foreign Officials in International Business Transactions.

- (b) No Bribery. In connection with this Agreement, neither Party, nor any of its Affiliates, has made, offered, given, promised to give, or authorized, nor will make, offer, give, promise to give, or authorize, in a manner that violates Applicable Laws, any bribe, kickback, payment or transfer of anything of value, directly or indirectly, to any person or to any Government or Public Official for the purpose of: (i) improperly influencing any act or decision of the person or Government or Public Official; (ii) inducing the person or Government or Public Official to do or omit to do an act in violation of a lawful or otherwise required duty; (iii) securing any improper advantage; or (iv) inducing the person or Government or Public Official to improperly influence the act or decision of any organization, including any government or government instrumentality, in order to assist Flame or Lilly in obtaining or retaining business.
- (c) <u>Compliance in Development</u>. In connection with this Agreement, Flame specifically agrees that it will undertake all Development activities, in particular Development activities involving human subjects, in compliance with applicable GCPs, applicable Privacy Laws, and will utilize informed consent processes that permit the disclosure of such data in accordance with the terms of this Agreement.

#### B.3 Force Majeure

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

#### B.4 Rights Upon Bankruptcy

All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the US (collectively, the "*Bankruptcy Laws*"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement

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is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

#### B.5 Assignment

Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, such consent not to unreasonably withheld, provided that either Party may assign this Agreement and its rights and obligations hereunder, without the other Party's consent: (i) to any of its Affiliates, provided that the assigning Party shall remain liable and responsible to the non-assigning Party for the performance and observance of all such duties and obligations by such Affiliate; or (ii) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party ("Third Party Acquirer"), whether by merger, sale of stock, sale of assets or otherwise (each, a "Sale Transaction"), provided that in the event of a Sale Transaction (whether this Agreement is actually assigned or is assumed by the Third Party Acquirer or the surviving corporation resulting from such Sale Transaction by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the Third Party Acquirer that existed prior to the Sale Transaction shall not be included in the technology licensed hereunder or otherwise subject to this Agreement. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

#### B.6 Severability

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

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LICENSE AGREEMENT

#### B.7 Notices

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Flame, to: Flame Biosciences Inc.

555 Madison Avenue

Suite 1201

New York, New York 10022 Attn: Chief Executive Officer

with copy to: Torreya Partners LLC

555 Madison Avenue

Suite 1201

New York, New York 10022

if to Lilly, to: Eli Lilly and Company

Lilly Corporate Center Indianapolis, IN 46285

Attn: Office of Alliance Management

with copy to: Eli Lilly and Company

Lilly Corporate Center Indianapolis, IN 46285 Attn: General Patent Counsel

Facsimile:

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day (provided that if given by facsimile, the transmitting Party received confirmation of complete transmission); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

#### B.8 Applicable Law

This Agreement shall be governed by and construed in accordance with the laws of the United States federal law and Delaware state law, without reference to any rules of conflict of laws.

#### **B.9** Entire Agreement; Amendments

The Agreement contains the entire understanding of the Parties with respect to the rights and licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the rights and licenses granted hereunder are superseded by the terms of this Agreement, including the prior Confidentiality Agreement. The Agreement may be

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amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.

#### B.10 Headings

The captions to the several Articles and Sections hereof are for convenience of reference only, are not a part of the Agreement, 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.

#### **B.11** Independent Contractors

It is expressly agreed that Flame and Lilly shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Flame nor Lilly shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

#### B.12 Waiver

The failure by either Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement or any breach hereof by the other Party shall neither impair such provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or any other. No waiver by a Party of a particular provision or right shall be effective unless in writing, specific as to a particular matter and, if applicable, for a particular period of time, and signed by such Party.

#### **B.13** Cumulative Remedies

Except as expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available at law or in equity.

#### **B.14** Waiver of Rule of Construction

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

#### B.15 Construction

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 term "including" as used herein means including, without limiting the generality of any description that precedes such term, and shall 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 "Articles", "Articles",

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"Section", "Sections", "Exhibit" or "Exhibits" are references to the numbered Article(s) or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, 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 in effect as of the relevant time, and including the then-current amendments thereto; the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; 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 shall be interpreted in a correlative manner; and (t) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits).

#### **B.16** Use of Third Parties

Notwithstanding any delegation of obligations under this Agreement by a Party or its Affiliates or to a Third Party, such Party shall remain primarily liable and responsible for the performance of all of its obligations under this Agreement and for causing such Affiliates or Third Parties to act in a manner consistent herewith, to the extent applicable. No Party contracting with any Third Party shall agree to any term that would make it unable to comply with its obligations under this Agreement.

#### **B.17** Counterparts

The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties. Signatures provided by facsimile transmission or in AdobeTM Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

Signature Page Follows.

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LICENSE AGREEMENT

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives.

#### FLAME BIOSCIENCES, INC.

By: <u>/s/ Tim Opler</u>
Name: Tim Opler

Title: Chief Executive Officer Date: November 25, 2019

#### **ELI LILLY AND COMPANY**

By: /s/ Daniel M. Skovronsky, M.D., Ph.D.

Name: Daniel M. Skovronsky, M.D., Ph.D.

Title: President, Lilly Research Laboratories

Chief Scientific Officer Date: November 21, 2019

#### **EXHIBIT A:**

Licensed C	ompound	i Stru	icture
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**Listed Patents** 

#### **EXHIBIT** C:

Lilly Licensed Know How Materials and Related Documentation

#### **EXHIBIT D**

**Lilly Animal Care and Use Requirements** 

# 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.

#### FIRST AMENDMENT TO LICENSE AGREEMENT

between

Flame Biosciences, Inc. and Eli Lilly and Company

This First Amendment to the License Agreement (the "Amendment") is dated February 2, 2021, and amends that certain License Agreement dated November 25, 2019 between Flame Biosciences, Inc., a Delaware corporation with a place of business at 280 Union Square Drive, New Hope, Pennsylvania 18938 ("Flame"), and Eli Lilly and Company, having an address at Lilly Corporate Center, Indianapolis, Indiana, 46285, United States of America ("Lilly") (such agreement, the "Agreement"). Flame and Lilly may be referred to herein individually as a "Party" or collectively as the "Parties".

The Parties hereby agree to amend the Agreement as follows:

- 1. <u>Definitions</u>. Those capitalized terms not otherwise defined herein shall have the meaning established therefor under the Agreement.
- 2. Section 1.39(d) is hereby replaced with the following:
  - (d) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price, including those granted to managed health care organizations, wholesalers, buying groups, retailers or to federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers; and
- 3. Section 4.2(a) is hereby replaced with the following:
  - (a) Initial Regulatory Milestone. Flame will make a one-time non-refundable and noncreditable payment to Lilly in the amount of (\*\*\*) as follows: (i) If the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration trial occurs as evidenced by written documentation from the Regulatory Authority of a Major Country (\*\*\*) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the payment upon the first submission by Flame, its Affiliate or Sublicensee of a BLA or equivalent in any Major Country for the Licensed Product; and (ii) If the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration trial (\*\*\*) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the

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FIRST AMENDMENT TO LICENSE AGREEMENT

payment upon the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration for the Licensed Product by Flame, its Affiliate or Sublicensee. Such payment will be made within thirty (30) days after the first achievement, whether by Flame, its Affiliate or Sublicensee.

4. Section 4.3 is hereby replaced with the following:

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FIRST AMENDMENT TO LICENSE AGREEMENT

Subject to Section 4.5, Flame will pay Lilly a tiered royalty on the Calendar Year Net Sales of the Licensed Product as follows:

Portion of Calendar Year Net Sales of the Licensed Product (U.S. dollars)	Royalty rate applicable to such portion
(***) to (***)	(***)
More than (***) to (***)	(***)
More than (***) (i.e., (***))	(***)

4. <u>Miscellaneous</u>. This Amendment, when executed by the Parties, constitutes an amendment to the Agreement made in accordance therewith. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Amendment. Scanned, electronic, PDF exchange, and facsimile signatures will be as binding as original signatures.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the Amendment Effective Date and this Amendment is effective as of the Amendment Effective Date.

ELI LILLY AND COMPANY

FLAME BIOSCIENCES, INC.

Harlan F. Weisman W

By:

By:

Title:

Name:

Daniel Skovronsky MD PhD

Title:

President Lilly Research Labs

Date: 01/29/2021

Name: Harlan F. Weisman, M.D.

President & Chief Executive Officer

Date: 02/02/2021

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FIRST AMENDMENT TO LICENSE AGREEMENT

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

#### I, Garry Neil, certify that:

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

Date: May 13, 2024 /s/ Garry Neil, M.D.

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

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

#### I, Christopher Sullivan, certify that:

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

Date: May 13, 2024 /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 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garry Neil, Chief Executive Officer (principal executive officer) of the Registrant, and I, Christopher Sullivan, Chief Financial Officer (principal financial officer) of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: March 13, 2024 By: /s/ Garry Neil, M.D.

Name: Garry Neil, M.D.

Title: Chief Executive Officer

(Registrant's Principal Executive Officer)

Date: March 13, 2024 By: /s/ Christopher Sullivan

Name: Christopher Sullivan
Chief Financial Officer

Title: (Registrant's Principal Financial Officer)

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