

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 001-38560

AADI BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

17383 Sunset Boulevard Suite A250
Pacific Palisades, California
(Address of principal executive offices)

61-1547850
(I.R.S. Employer
Identification No.)

90272
(Zip Code)

(424) 473-8055

(Registrant's telephone number, including area code)

Aerpio Pharmaceuticals, Inc.
c/o 10663 Loveland-Madeira Road #168
Loveland, OH 45140

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value per share	AADI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 5, 2021, the registrant had 20,894,029 shares of common stock, \$0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

AADI BIOSCIENCE, INC.

Condensed Consolidated Balance Sheets

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

	September 30, 2021 <i>(unaudited)</i>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 161,375	\$ 4,455
Accounts receivable	—	14,149
Prepaid expenses and other current assets	643	81
Total current assets	162,018	18,685
Property and equipment, net	14	21
Operating lease right-of-use assets	597	119
Intangible asset, net	3,880	—
Other assets	2,263	—
Total assets	\$ 168,772	\$ 18,825
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 5,205	\$ 2,392
Accrued liabilities	6,250	4,099
Payable to related party	22	14,314
Convertible related party promissory notes payable at fair value	—	9,029
Operating lease liabilities, current portion	90	125
Other current liabilities	—	99
Total current liabilities	11,567	30,058
Convertible promissory notes payable at fair value	—	1,102
Payable to related party	5,757	—
Operating lease liabilities, net of current portion	523	—
Other liabilities	—	97
Total liabilities	17,847	31,257
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Series Seed preferred stock, \$0.0001 par value, zero and 734,218 shares authorized, issued and outstanding as of September 30, 2021 and December 31, 2020, respectively; aggregate liquidation preference of \$0 and \$1,101 as of September 30, 2021 and December 31, 2020, respectively	—	—
Series A preferred stock, \$0.0001 par value, zero and 7,211,948 shares authorized, issued and outstanding as of September 30, 2021 and December 31, 2020, respectively; aggregate liquidation preference of \$0 and \$28,433 as of September 30, 2021 and December 31, 2020, respectively	—	1
Common stock, \$0.0001 par value; 300,000,000 and 20,000,000 shares authorized; 20,883,454 and 2,542,358 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	277,618	20,161
Accumulated deficit	(126,695)	(32,595)
Total stockholders' equity (deficit)	150,925	(12,432)
Total liabilities and stockholders' equity (deficit)	\$ 168,772	\$ 18,825

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands, except shares and earnings per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	<i>(unaudited)</i>		<i>(unaudited)</i>	
Revenue				
Grant Revenue	\$ —	\$ 231	\$ 120	\$ 431
Total revenue	<u>—</u>	<u>231</u>	<u>120</u>	<u>431</u>
Operating expenses				
Research and development	5,754	2,395	12,443	9,684
General and administrative	7,401	499	8,793	1,700
Impairment of acquired contract intangible asset	74,156	—	74,156	—
Total operating expenses	<u>87,311</u>	<u>2,894</u>	<u>95,392</u>	<u>11,384</u>
Loss from operations	<u>(87,311)</u>	<u>(2,663)</u>	<u>(95,272)</u>	<u>(10,953)</u>
Other income (expense)				
Change in fair value of convertible promissory notes	380	—	1,585	—
Gain upon extinguishment of debt	—	—	196	—
Interest income	—	1	1	41
Interest expense (includes related party amounts of \$142, \$204, \$542 and \$531, respectively)	(157)	(229)	(608)	(585)
Total other income (expense), net	<u>223</u>	<u>(228)</u>	<u>1,174</u>	<u>(544)</u>
Loss before income tax expense	(87,088)	(2,891)	(94,098)	(11,497)
Income tax expense	—	(1)	(2)	(1)
Net and comprehensive loss	<u>(87,088)</u>	<u>(2,892)</u>	<u>(94,100)</u>	<u>(11,498)</u>
Cumulative dividends on convertible preferred stock	(154)	(247)	(647)	(740)
Net and comprehensive loss attributable to common stockholders	<u>\$ (87,242)</u>	<u>\$ (3,139)</u>	<u>\$ (94,747)</u>	<u>\$ (12,238)</u>
Net and comprehensive loss per share attributable to common stockholders, basic and diluted	<u>\$ (9.17)</u>	<u>\$ (1.23)</u>	<u>\$ (19.37)</u>	<u>\$ (4.81)</u>
Weighted average number of common shares outstanding used in computing net and comprehensive loss per share attributable to common stockholders, basic and diluted	<u>9,510,379</u>	<u>2,542,358</u>	<u>4,890,556</u>	<u>2,542,358</u>

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Amounts in thousands, including share amounts)

	For the Three and Nine Months Ended September 30, 2021 (unaudited)								
	Series Seed Preferred Stock		Series A Preferred Stock		Stockholders' Equity (Deficit)				Total
	Shares	Amount	Shares	Amount	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	
Balance at January 1, 2021	734	\$ —	7,212	\$ 1	2,542	\$ 1	\$ 20,161	\$ (32,595)	\$ (12,432)
Share-based compensation expense	—	—	—	—	—	—	36	—	36
Net and comprehensive loss	—	—	—	—	—	—	—	(5,476)	(5,476)
Balance at March 31, 2021	734	—	7,212	1	2,542	1	20,197	(38,071)	(17,872)
Share-based compensation expense	—	—	—	—	—	—	39	—	39
Net and comprehensive loss	—	—	—	—	—	—	—	(1,536)	(1,536)
Balance at June 30, 2021	734	—	7,212	1	2,542	1	20,236	(39,607)	(19,369)
Exercise of stock options to purchase common stock	—	—	—	—	61	—	745	—	745
Issuance of common stock to PIPE Investors, net of issuance costs	—	—	—	—	11,853	1	145,383	—	145,384
Issuance of common stock to former stockholders of Aerpio upon Merger	—	—	—	—	3,209	—	105,888	—	105,888
Conversion of convertible promissory note into common stock upon Merger	—	—	—	—	698	—	9,130	—	9,130
Conversion of convertible preferred stock into common stock upon Merger	(734)	—	(7,212)	(1)	2,520	—	—	—	(1)
Share-based compensation expense	—	—	—	—	—	—	648	—	648
Cumulative dividends paid on Series A preferred stock	—	—	—	—	—	—	(4,412)	—	(4,412)
Net and comprehensive loss	—	—	—	—	—	—	—	(87,088)	(87,088)
Balance at September 30, 2021	—	\$ —	—	\$ —	20,883	\$ 2	\$ 277,618	\$ (126,695)	\$ 150,925

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit) (continued)
(Amounts in thousands, including share amounts)

For the Three and Nine Months Ended September 30, 2020 (unaudited)

	Series Seed Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In Capital		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Par Value				
	Balance at January 1, 2020	734	\$ —	7,212	\$ 1	2,542	\$ 1	\$ 20,022	\$ (29,117)	\$ (9,093)
Share-based compensation expense	—	—	—	—	—	—	29	—	29	
Net and comprehensive loss	—	—	—	—	—	—	—	(3,324)	(3,324)	
Balance at March 31, 2020	734	—	7,212	1	2,542	1	20,051	(32,441)	(12,388)	
Share-based compensation expense	—	—	—	—	—	—	37	—	37	
Net and comprehensive loss	—	—	—	—	—	—	—	(5,282)	(5,282)	
Balance at June 30, 2020	734	—	7,212	1	2,542	1	20,088	(37,723)	(17,633)	
Share-based compensation expense	—	—	—	—	—	—	34	—	34	
Net and comprehensive loss	—	—	—	—	—	—	—	(2,892)	(2,892)	
Balance at September 30, 2020	734	\$ —	7,212	\$ 1	2,542	\$ 1	\$ 20,122	\$ (40,615)	\$ (20,491)	

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

AADI BIOSCIENCE, INC.

Condensed Consolidated Statements of Cash Flows
(Amounts in thousands)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:	<i>(unaudited)</i>	
Net and comprehensive loss	\$ (94,100)	\$ (11,498)
Adjustments to reconcile net and comprehensive loss to net cash used in operating activities:		
Impairment of acquired contract intangible asset	74,156	—
Change in fair value of convertible promissory notes (includes related party amounts of \$135 and \$0, respectively)	(1,585)	—
Non-cash interest expense (includes related party amounts of \$542 and \$531, respectively)	584	585
Gain on forgiveness of Payroll Protection Plan loan	(196)	—
Share-based compensation expense	723	100
Non-cash lease expense	133	124
Depreciation and amortization expense	33	7
Changes in operating assets and liabilities:		
Accounts receivables	14,149	54
Prepaid expenses and other current assets	(526)	(37)
Other non-current assets	430	—
Operating lease liability	(121)	(146)
Accounts payable and accrued expenses	4,860	1,611
Payable to related party	(8,535)	(226)
Net cash used in operating activities	(9,995)	(9,426)
Cash flows from investing activities:		
Cash acquired in connection with the Merger	29,700	—
Transaction expenses related to Merger	(4,501)	—
Net cash provided by investing activities	25,199	—
Cash flows from financing activities:		
Issuance of common stock upon exercise of stock options	745	—
Issuance of common stock to PIPE Investors	155,000	—
Costs incurred in connection with issuance of common stock	(9,617)	—
Dividends paid	(4,412)	—
Proceeds from issuance of convertible promissory notes	—	1,000
Proceeds from Payroll Protection Loan Program	—	194
Net cash provided by financing activities	141,716	1,194
Net increase (decrease) in cash and cash equivalents	156,920	(8,232)
Cash and cash equivalents at beginning of year	4,455	15,962
Cash and cash equivalents, end of period	\$ 161,375	\$ 7,730
Supplemental disclosure of cash flow information:		
Issuance of common stock upon Merger	\$ 105,888	\$ —
Operating lease liability arising from obtaining right-of-use asset	\$ 610	\$ —
Conversion of convertible promissory note into common stock upon merger	\$ 9,130	\$ —

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)**

1. Nature of Organization and Operations

Aadi Bioscience, Inc. (together with its subsidiaries, the “Company” or “Aadi”) is a clinical stage biopharmaceutical company focused on development and commercialization of precision medicines targeted to rare mutation-driven diseases. Aadi’s initial focus is on the development of nab-sirolimus (sirolimus albumin-bound nanoparticles for injectable suspension, or “ABI-009”) for diseases driven by the mTOR pathway activation through mutations or deletions of specific genes such as Tuberous Sclerosis Complex 1 and 2 (“TSC1” and “TSC2”) or PTEN. ABI-009 is licensed to Aadi by Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, now Bristol Myers Squibb Company (“Celgene”), for all therapeutic areas including oncology, cardiovascular, and metabolic related diseases.

The Company’s historical operations have consisted principally of performing research and development activities and raising capital. The Company’s activities are subject to significant risks and uncertainties, including failing to secure additional funding before sustainable revenues and profit from operations are achieved.

Merger with Aerpio Pharmaceuticals, Inc. and Name Change

On May 16, 2021, the Company, then operating as Aerpio, entered into the Agreement and Plan of Merger (“Merger Agreement”) with Aspen Merger Subsidiary, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Aerpio (“Merger Sub”) and Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc. (“Private Aadi”)).

Pursuant to the terms set forth in the Merger Agreement and effective August 26, 2021 (the “Effective Time”): (i) Merger Sub merged with and into Private Aadi, with Private Aadi surviving as a wholly-owned subsidiary of Aerpio (the “Merger”), (ii) Aerpio changed its name to Aadi Bioscience, Inc. in connection with and immediately prior to the Effective Time of the Merger, and (iii) Aerpio effected a 15:1 reverse stock split of the Aerpio common stock (“Reverse Stock Split”) immediately prior to the Effective Time of the Merger. At the Effective Time, each share of Private Aadi common stock outstanding immediately prior to the Effective Time, including the shares of Private Aadi common stock issuable upon the conversion of all shares of preferred stock and convertible promissory notes immediately prior to the closing of the Merger, were converted into the right to receive shares of the Company’s common stock based on an exchange ratio of 0.3172 (the “Exchange Ratio”), after taking into account the Reverse Stock Split.

Pursuant to the Merger Agreement, Aerpio assumed all of the outstanding and unexercised options to purchase shares of Private Aadi capital stock under the Private Aadi Amended and Restated 2014 Equity Incentive Plan (the “Private Aadi Plan”), and, in connection with the Merger, such options were converted into options to purchase shares of the Company’s common stock based on the Exchange Ratio. At the closing of the Merger at the Effective Time, the Company issued an aggregate of 5,776,660 shares of common stock to holders of Private Aadi common stock, including for shares of Private Aadi common stock issuable upon the conversion of all shares of preferred stock and convertible promissory notes outstanding immediately prior to the Effective Time. In connection with the Merger, the Company entered into a Contingent Value Rights Agreement (the “CVR Agreement”) with a legacy director of Aerpio, as Holder Representative (as defined in the CVR Agreement), and American Stock Transfer & Trust Company, LLC, as Rights Agent (as defined in the CVR Agreement), in accordance with the terms of the Merger Agreement. The CVR Agreement entitles each holder of Aerpio common stock as of immediately prior to the closing of the Merger (each, a “CVR Holder”) to receive one contingent value right (“CVR”) for each outstanding share of Aerpio common stock held by such CVR Holder as of immediately prior to the closing of the Merger, each representing the right to receive certain net proceeds, if any, derived from the CVR completed during a CVR Payment Period, which means successive six-month periods, prior to the expiration of the CVR Term (as defined in the CVR Agreement), with any potential payment obligations continuing until the earlier of (a) the 20-year anniversary of the Effective Time and (b) the time at which the license agreement with Gossamer Bio, Inc., the underlying basis for the CVR, has expired or been terminated. Under the terms of the Merger Agreement, as related to the CVR, the Company is entitled to 10% of any proceeds paid from the underlying license agreement plus reimbursement of expenses. There can be no assurances that any proceeds will result therefrom.

The Merger has been accounted for using the reverse asset acquisition method under U.S. generally accepted accounting principles (“GAAP”). For accounting purposes, Private Aadi is considered to have acquired Aerpio and the Merger has been accounted for as a reverse asset acquisition. Private Aadi is considered the accounting acquirer even though Aerpio issued the common stock in the Merger based on the terms of the Merger Agreement and other factors including: (i) following the Merger, the stockholders of Private Aadi collectively owned a substantial portion of the voting rights of the Company; (ii) three (3) of seven (7) members of the board of directors of the Company post-Merger were composed of directors designated by Private Aadi under the terms of the Merger Agreement, and one (1) member of the board of directors of the Company post-Merger was a director mutually designated by Private

Aadi and Aerpio; (iii) existing members of Private Aadi's management became the management of the Company post-Merger; (iv) the PIPE Investors (as defined below) consist of individuals and funds, and for purpose of this analysis, while they owned approximately 55.6% on a fully-diluted basis, as of immediately following the Merger (and after giving effect to the PIPE Financing), no one individual or fund held more shares than the holders of Private Aadi collectively owned immediately following the Merger and they are not considered to be a single voting group; and (v) following the Merger, the Company is named "Aadi Bioscience, Inc." and headquartered in Pacific Palisades, California, and all ongoing operations of the Company are those of Private Aadi. To determine the accounting for this transaction under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. Upon closing of the Merger, substantially all of the fair value is concentrated in cash, working capital and a long-lived contract intangible asset. As such, the acquisition was treated as an asset acquisition. The net assets of Aerpio have been recorded at their relative fair value in the consolidated financial statements of the Company and the reported operating results prior to the Merger will be those of Private Aadi.

Pursuant to the closing of the Merger, Private Aadi's board of directors declared a 4% cumulative dividend on its preferred stock of \$4.4 million which was paid at the Effective Time.

PIPE Financing and Subscription Agreement

On May 16, 2021, the Company entered into a subscription agreement ("Subscription Agreement") with certain investors (the "PIPE Investors"), pursuant to which it would sell shares of its Common Stock concurrently with the closing of the Merger (the "PIPE Financing"). At the closing of the PIPE Financing, the Company entered into a Registration Rights Agreement, dated August 26, 2021 ("Registration Rights Agreement"), with the PIPE Investors. The PIPE Investors purchased an aggregate of 11,852,862 shares of common stock of the Company (the "PIPE Shares") for an aggregate purchase price of \$155.0 million pursuant to the Subscription Agreement ("PIPE Financing"). The aggregate net proceeds for the issuance and sale of the of the PIPE Shares was \$145.4 million, after deducting certain expenses incurred that were direct and incremental to the issuance of the PIPE Shares.

Immediately following the Effective Time, and after giving effect to the Reverse Stock Split and the PIPE Financing, there were approximately 20.8 million shares of common stock of the Company outstanding. Immediately following the Effective Time and after giving effect to the Reverse Stock Split and the PIPE Financing: (i) the Private Aadi stockholders owned approximately 29.2% of the outstanding shares of common stock; (ii) Aerpio's stockholders immediately prior to the Merger, whose shares of common stock, as adjusted for the Reverse Stock Split, remain outstanding after the Merger, owned approximately 15.2% of the outstanding shares of common stock; and (iii) the PIPE Investors owned approximately 55.6% of the outstanding shares of common stock, in each case as calculated on a fully-diluted basis.

Liquidity

Since inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations and has not realized revenues from its planned principal operations.

The Company has experienced net losses since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of \$126.7 million as of September 30, 2021 and net loss of \$87.1 million and \$94.1 million for the three and nine months ended September 30, 2021, respectively. To date, these operating losses have been funded primarily from outside sources of invested capital through the issuance of convertible promissory notes, grant funding, the sale of securities, and proceeds from license agreements.

During the three and nine months ended September 30, 2021, the Company raised capital through the PIPE Financing of \$155.0 million which netted \$145.4 million after financing expenses. Additionally, the Company assumed \$29.7 million of cash from Aerpio in the Merger, which netted to \$27.7 million after \$2.0 million of compensation related expenses for former Aerpio executives related to the Merger. The Company had cash and cash equivalents of \$161.4 million at September 30, 2021. Management believes that the Company's current cash and cash equivalents, including the aggregate net proceeds from the PIPE Financing, will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report.

COVID-19

In December 2019, a strain of coronavirus was reported in Wuhan, China and began to spread globally, including to the United States and Europe, in the following months. The World Health Organization has declared COVID-19 to be a global pandemic. The full impact of the COVID-19 pandemic is inherently uncertain at the time of this report. The COVID-19 pandemic has resulted in travel restrictions and, in some cases, prohibitions of non-essential

activities, disruption and shutdown of businesses, and greater uncertainty in global financial markets. As COVID-19 has spread, it has significantly impacted the health and economic environment around the world, and many governments have closed most public establishments, including restaurants, workplaces, and schools. Aadi's clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings can also make it more difficult to enroll new patients in ongoing or planned clinical trials. Any of these circumstances will potentially have a negative impact on our financial results and the timing of our clinical trials.

The COVID-19 pandemic has caused the Company to modify business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work, and cancelling physical participation in meetings, events, and conferences), and may take further actions as may be required by government authorities or that are determined to be in the best interests of the Company's employees, patients, and business partners.

The extent of the impact of the COVID-19 pandemic on Aadi's future liquidity and operational performance will depend on certain developments, including the duration and spread of the outbreak, the availability and effectiveness of vaccines, the impact on our clinical trials, patients, and collaboration partners, and the effect on our suppliers.

2. Related Party Transactions

Presented below are the details of a license agreement with Celgene, an entity which was a stockholder of Private Aadi prior to the Merger and became a stockholder of the Company as a result of the Merger.

Celgene License Agreement

On April 9, 2014, the Company's wholly owned subsidiary, Private Aadi, entered into a license agreement (the "Celgene License Agreement") with Celgene for exclusive rights for certain patents and a non-exclusive license for certain technology and know-how pertaining to ABI-009.

The Celgene License Agreement will remain in effect from the effective date of April 9, 2014 until expiration of all milestone and royalty payment obligations under the agreement, unless terminated by either of the parties upon giving an advance notice as specified in the Celgene License Agreement. Under the terms of the Celgene License Agreement, Celgene agreed to supply the Company with licensed products of ABI-009 necessary for clinical or non-clinical development.

Celgene had the option to terminate the Celgene License Agreement and all of the Company's related rights and licenses upon the occurrence of each of the following: (a) successful completion of the first Phase 2 Trial for a licensed product ("First Trigger Event"), or (b) if Celgene elects not to exercise its option upon the First Trigger Event, then upon the acceptance by the Food and Drug Administration or the European Medicines Agency, as applicable, of the first New Drug Application either in the United States or European Union, whichever occurs first, for a licensed product ("Second Trigger Event"). Celgene could also terminate the Celgene License Agreement upon written notice to the Company at any time following the occurrence of the First Trigger Event and prior to the occurrence of the Second Trigger Event (an "Early Exercise"). In each case, the termination would be subject to a payment to the Company by Celgene equal to the valuation of the Company as per the terms of the Celgene License Agreement. On October 3, 2016, the Celgene License Agreement was amended to include an option extension payment that allowed Celgene the option of paying \$3.0 million to the Company to extend the period of time that Celgene had to Early Exercise. The Company has certain milestones that it is required to meet as specified in the Celgene License Agreement. If the Company fails to meet these milestones and cannot agree upon new terms and conditions, Celgene may terminate the Celgene License Agreement.

Celgene is entitled to receive certain development milestone payments, royalties on net sales from licensed products under the agreement and any sublicense fees. No payments related to milestones or royalties under this agreement were paid during the three and nine months ended September 30, 2021 or 2020.

On May 1, 2019, Celgene terminated its rights to elect an option to terminate the Celgene License Agreement upon the occurrence of a First Trigger Event, Second Trigger Event or Early Exercise. As a result, the Company is free to negotiate and enter into any agreement with respect to an acquisition of all or substantially all of the business or assets of the Company whether by merger, sale of equity or assets, or otherwise and to consummate the same as it sees fit.

On November 15, 2019, Celgene and the Company entered into an amendment to the Celgene License Agreement (the "Amended Celgene License Agreement") to terminate certain of Celgene's ABI-009 product supply obligations and to transfer control over certain regulatory filings under the original Celgene License Agreement from Celgene to the Company. The Amended Celgene License Agreement also waived the obligations related to certain development milestone payments and waived the liability related to 2016 and 2017 licensed drug manufacturing costs of \$1.2 million and \$2.7 million, respectively.

On August 30, 2021, the Company and Celgene entered into Amendment No. 1 (the "Amendment") to the Amended Celgene License Agreement related to certain intellectual property rights of Celgene pertaining to the compound known as ABI-009. Under the terms of the Amendment, the Company paid Celgene \$5.8 million representing 50% of the previously outstanding payment obligation under the terms of the Amended Celgene License Agreement, following the Effective Time of the PIPE Financing. Pursuant to the terms of the Amendment, the remaining previously outstanding payment obligation of \$5.8 million, is due on the third anniversary of the Effective Time plus any accrued and unpaid interest due thereon ("Balloon Payment"). The Balloon Payment shall accrue interest, beginning as of the Effective Time until paid in full, at a rate equal to 4.0% per annum based on the weighted average amount outstanding during the applicable calendar quarter, and interest shall be payable quarterly in arrears. In addition, the parties agreed to amend the royalty rates payable to Celgene based on net sales of products subject to the Amended Celgene License Agreement.

On December 8, 2020, the Company entered into a license agreement ("EOC License Agreement") with EOC Pharma (Hong Kong) Limited ("EOC") under which the Company received \$14.0 million in January 2021 in non-refundable upfront consideration as partial payment for the rights and licenses granted to EOC by the Company for the further development and commercialization of ABI-009 in the People's Republic of China, Hong Kong Special Administration Region, Macao Special Administrative Region and Taiwan (the "Licensed Territory"). In accordance with the Celgene License Agreement, the Company is required to pay 20% of all sublicense fees to Celgene. As such, the Company recognized \$2.8 million of license expense in the fourth quarter of 2020 and had a corresponding \$2.8 million sublicense payable to Celgene on the balance sheet as of December 31, 2020. During the three and nine months ended September 30, 2021, the Company paid the \$2.8 million sublicense fee. Refer to Note 8 for additional information on the EOC License Agreement.

3. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements, and the related disclosures, have been prepared in accordance with U.S. Securities and Exchange Commission ("SEC") regulations and include all of the information and disclosures required by GAAP for interim financial reporting, and, in the opinion of management include all adjustments necessary for a fair presentation of the results of operations, financial position, changes in stockholders' equity and cash flows for each period presented. 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"). All adjustments are of a normal and recurring in nature. The Company's condensed consolidated financial statements are stated in U.S. Dollars.

On August 26, 2021, when the Company closed the Merger, all outstanding shares of common stock along with preferred stock of Private Aadi were exchanged for new shares of common stock of the Company and the approximately 8.1 million shares of Private Aadi capital stock held by stockholders of Private Aadi immediately prior to the Merger were exchanged for approximately 2.5 million shares of common stock of the Company based on the Exchange Ratio. The authorized number of shares of common stock was not reduced and remains at 300.0 million. The par value of the Company's common stock remains unchanged at \$0.0001 per share.

Also on August 26, 2021, and immediately prior to the closing of the Merger, Aerpio effected the Reverse Stock Split. Accordingly, all share and per share amounts for the period presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to shares of the Company's common stock and per share amounts have also been adjusted to reflect the Exchange Ratio.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics. All the assets and operations of the Company's sole operating and reportable segment are located in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. In the opinion of management, all adjustments, consisting of normal recurring accruals, considered necessary for a fair presentation

have been included. The most significant estimates in the Company's condensed consolidated financial statements relate to stock-based compensation expense and accrued research and development costs. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents and certain investments in money market funds. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since inception.

Cash and Cash Equivalents

The Company considers all highly liquid marketable securities purchased with original maturities of three months or less at the time of purchase date to be cash equivalents. As of September 30, 2021 and December 31, 2020, cash and cash equivalents included money market investments totaling \$152.5 million and \$3.0 million, respectively.

Fair Value Option

The Company has elected the fair value option to account for its convertible promissory notes issued. The Company records these convertible promissory notes at fair value with changes in fair value recorded in the statements of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in earnings as incurred and not deferred. As of September 30, 2021, there were no Convertible Notes outstanding as they were converted to shares of Private Aadi common stock immediately prior to the closing of the Merger.

Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs, such as quoted prices in active markets

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions which reflect those that a market participant would use

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

In determining the fair value of its financial instruments, the Company considers the source of observable market data inputs, liquidity of the instrument, the credit risk of the counterparty to the contract, and its risk of nonperformance. In the case fair value is not observable, for the items subject to fair value measurements, the Company applies valuation techniques deemed the most appropriate under the GAAP guidance based on the nature of the assets and liabilities being measured.

The carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued liabilities are reasonable estimates of their fair value because of the short maturity of these items.

The following table sets forth the fair value of the Company's financial assets and liabilities, allocated into the Level 1, Level 2 and Level 3 hierarchy that were measured at fair value on a recurring basis (amounts in thousands):

	Fair Value Measurements as of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	\$ 152,465	\$ —	\$ —	\$ 152,465
Liabilities:				
Convertible promissory notes	\$ —	\$ —	\$ —	\$ —
	Fair Value Measurements as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	\$ 3,041	\$ —	\$ —	\$ 3,041
Liabilities:				
Convertible promissory notes	\$ —	\$ —	\$ 10,131	\$ 10,131

(1) Included in cash and cash equivalents in the accompanying balance sheets.

As further described in Note 9, Private Aadi issued convertible notes in October 2019 and January 2020 (collectively the "Convertible Notes"). The Company elected the fair value option to account for the Convertible Notes. The fair value was estimated using a scenario-based analysis based on the probability-weighted value of expected future investment returns, considering possible outcomes available to the noteholders including conversions in subsequent equity financings, change of control transactions, settlement, and dissolution. The Company adjusts the carrying value of its Convertible Notes to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as a change in fair value of convertible promissory notes in the statements of operations and comprehensive loss.

As of September 30, 2021 there were no Convertible Notes outstanding as the Convertible Notes were converted to shares of Private Aadi common stock immediately prior to the closing of the Merger, which were concurrently exchanged for common stock of the Company based on the Exchange Ratio in connection with the closing of the Merger. As of December 31, 2020, the significant unobservable inputs used in the fair value measurement of the Convertible Notes included an expected settlement date in August 2021 and June 2021, respectively, and an estimated discount rate of 25%. Other significant unobservable inputs include the relative weighting applied to the possible outcomes available to the noteholders including conversions in subsequent equity financings, change of control transactions, settlement, and dissolution.

There are significant judgments, assumptions and estimates inherent in the determination of the fair value of the Convertible Notes described above. These include determination of a valuation method and selection of the possible outcomes available to the Company, including the determination of timing and expected future investment returns for such scenarios, as well as the likelihood of repayment, conversion, and dissolution. The related judgments, assumptions and estimates are highly interrelated and changes in any one assumption could necessitate changes in another. Any changes in the probability of a particular outcome would require a related change to the probability of another outcome.

The following table provides a reconciliation of the Convertible Notes (refer to Note 9) measured at fair value using significant unobservable inputs (Level 3) (amounts in thousands):

	Convertible Notes (Level 3)	
Balance as of December 31, 2020	\$	10,131
Issuance of convertible promissory notes		—
Accrual of interest		584
Change in fair value of convertible promissory notes		(1,585)
Conversion to common stock		(9,130)
Balance September 30, 2021	\$	—
	Convertible Notes (Level 3)	
Balance as of December 31, 2019	\$	8,165
Issuance of convertible promissory notes		1,000
Accrual of interest		585
Change in fair value of convertible promissory notes		—
Balance September 30, 2020	\$	9,750

There have been no transfers between levels during the reporting periods.

Accounts Receivable

Accounts receivable represents revenue recognized, but for which payment has not yet been received. Accounts receivable at December 31, 2020 includes \$14.0 million receivable related to the EOC upfront payment and \$0.1 million grant revenue. These amounts were subsequently collected in 2021. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations and historical payment patterns. No allowance for doubtful accounts was recorded as of September 30, 2021 and December 31, 2020.

Property and Equipment, Net

Property and equipment, consisting of computers, furniture and fixtures, and office equipment, are stated at cost, less accumulated depreciation. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally five years. Such costs are periodically reviewed for recoverability when impairment indicators are present.

Intangible Asset

The Company's intangible asset consists of a single asset, Aerpio's license agreement with Gossamer Bio., Inc. acquired in the Merger. The intangible asset is stated at fair value and is amortized using the straight-line method over its estimated useful life of 14.3 years. The intangible asset is reviewed for potential impairment when events or circumstances indicate that carrying amounts may not be recoverable.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property, equipment, and the intangible asset for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. An impairment was recorded for the long-lived intangible asset during three and nine months ended September 30, 2021 (see Note 5).

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months.

The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five

criteria: (i) the lease has a purchase option that is reasonably certain of being exercised, (ii) the present value of the future cash flows is substantially all of the fair market value of the underlying asset, (iii) the lease term is for a significant portion of the remaining economic life of the underlying asset, (iv) the title to the underlying asset transfers at the end of the lease term, or (v) if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term.

Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. For finance leases, depreciation expense is recognized for the leased asset acquired and interest expense is recognized related to the portion of the financing in the statements of operations. For operating leases, lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expense in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of September 30, 2021 and December 31, 2020.

Revenue Recognition

Grant Revenue

The Company's grant revenues are derived from federal grants with the U.S. Food and Drug Administration. The Company has determined that the government agencies providing grants to the Company are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. The Company recognizes grant revenues as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where the Company acts as principal with discretion to choose suppliers, bears credit risk, and performs part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

Revenue Under License Agreement

The Company generates revenues from payments received under a license agreement. Under such license agreement, the Company recognizes revenue when it transfers promised goods or services to partners in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with partners, the Company performs the following five steps: (i) identifies the promised goods or services in the contract; (ii) identifies the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determines the transaction price, including the constraint on variable consideration; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies the performance obligations.

For revenue from such license agreement, the Company generally collects an upfront license payment from the license partner and is also entitled to receive event-based payments subject to the license partner's achievement of specified development, regulatory and sales-based milestones. In addition, the Company is generally entitled to royalties if products under the license agreement are commercialized.

Transaction price for a contract represents the amount to which the Company is entitled in exchange for providing goods and services to the partner. Transaction price does not include amounts subject to uncertainties unless it is

probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment, all other fees the Company may earn under such license agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining regulatory approvals and successful completion of clinical trials. With respect to other development milestones, e.g. dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. The Company does not include any amounts subject to uncertainties into the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Because such agreements generally only have one type of performance obligation, a license, which is generally all transferred at the same time as agreement inception, allocation of the transaction price among multiple performance obligations is not required. Upfront amounts allocated to licenses are recognized as revenue when the licenses are transferred to the partners. Development milestones and other fees are recognized in revenue when their occurrence becomes probable.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, contract services, and other external development expenses. The Company records research and development activities conducted by third-party service providers, which include work related to preclinical studies, clinical trials, and contract manufacturing activities, to research and development expense as incurred. The Company is required to estimate the amount of services provided but not yet invoiced and include these expenses in accrued expenses on the balance sheet and within research and development expenses in the statements of operations and comprehensive loss. These expenses are a significant component of the Company's research and development expenses and require significant estimates and judgments. The Company accrues for these expenses based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. As actual expenses become known, the Company adjusts its accrued expenses

Share-Based Compensation

The Company recognizes all stock-based payments to employees, including grants of employee stock options in the consolidated statements of operations and comprehensive loss based on their fair values. All the Company's share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. The Company estimates the fair value of its stock-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Options granted during the year have a maximum contractual term of ten years. Forfeitures are recognized and accounted for as they occur.

Due to the historical lack of a public market for the trading of the Company's securities and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted to employees, officers, and directors using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

Net and Comprehensive Loss per Share Attributable to Common Stockholders

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities, which include convertible preferred stock, outstanding stock options and warrants under the Company's equity incentive plans have been excluded from the computation of diluted net loss per share as they would be anti-dilutive.

Net loss per share is presented as the more dilutive of the treasury stock and as-converted method or the two-class method required for participating securities. The Series A convertible preferred stock is considered a participating security and does not have a contractual obligation to share in Private Aadi's losses. As such, the two-class method was not required.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive (amounts in thousands):

	Nine Months Ended September 30,	
	2021	2020
Options to purchase common stock	1,298	374
Warrants to purchase common stock	37	—
Series Seed convertible preferred stock	—	734
Series A convertible preferred stock	—	7,212

Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options" (Subtopic 470-20) and "Derivatives and Hedging – Contracts in Entity's Own Equity" (Subtopic 815-40). This new guidance is intended to reduce the complexity of accounting for convertible instruments. The guidance also addresses how convertible instruments are accounted for in the diluted earnings per share calculation and requires enhanced disclosures about the terms of convertible instruments. Entities may adopt ASU 2020-06 using either a partial retrospective or fully retrospective method of transition. This ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years for smaller reporting companies. The Company is currently evaluating the impact the adoption of ASU 2020-06 will have on the Company's financial statements.

In April 2021, the FASB issued ASU 2021-04, which included Topic 260 "Earnings Per Share." This guidance clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options due to a lack of explicit guidance in the FASB Codification. ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2021-04 but does not expect this will have a material impact on the Company's financial statements.

4. Merger

The Merger was accounted for as a reverse asset acquisition because substantially all of the fair value was concentrated in cash, working capital, and a long-lived contract intangible asset (See Note 1).

The estimated fair value of total consideration given was \$110.4 million as detailed below and is based on 3,208,718 shares of common stock, after taking into account the Reverse Stock Split, outstanding immediately prior to the Effective Time.

Number of common shares of the combined company to be owned by Aerpio stockholders	3,208,718
Multiplied by the fair value per share of Aerpio common stock on August 26, 2021	\$ 33.00
Fair value of Aerpio common stock	105,887,694
Aadi transaction costs	4,500,864
Purchase price	<u>\$ 110,388,558</u>

The allocation of the purchase price is as follows (amounts in thousands):

	August 26, 2021
Cash and cash equivalents	\$ 29,700
Other current assets	2,709
Intangible asset (1)	78,062
Deposits	20
Accounts payable and accrued expenses	(103)
Net assets acquired	<u>\$ 110,388</u>

- (1) The long-lived intangible asset represents Aerpio's out-licensing agreement with Gossamer Bio., Inc. Should payment be received from the underlying license agreement, in accordance with milestones or royalties, the Company will retain 10% of the proceeds with the balance being distributed to the CVR Holders. In accordance with GAAP for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities was ascribed to the acquired contract intangible asset. See Note 5 below for additional discussion of the subsequent impairment recognized.

5. Intangible Asset

In conjunction with the Merger, the Company recorded a long-lived contract intangible asset related to Aerpio's license agreement with Gossamer Bio. Inc., which was assumed in the Merger. In accordance with GAAP, for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities was ascribed to the acquired contract intangible asset. Due to the significant excess purchase price being allocated over the fair value of the acquired contract intangible asset, the Company determined that an indicator of impairment was present. The contract intangible asset was assessed for recoverability using an undiscounted cash flow model, which resulted in undiscounted cash flows below the carrying amount. The Company therefore recognized an impairment of \$74.2 million to bring the carrying amount of the contract intangible asset down to its estimated fair value of \$3.9 million. The fair value estimate of the intangible asset relates to contingent cash flows expected from Aerpio's out-licensing arrangement, of which 90% of any future net cash proceeds will be remitted to CVR Holders and paid through the CVRs. The fair value determination of the intangible asset was based upon a discounted cash flow valuation of the milestone payments and Monte Carlo valuation for the sales royalties. The estimated useful life of the intangible asset is approximately 14.3 years. Amortization expense was \$26,000 for the three and nine months ended September 30, 2021. No intangible asset or amortization expense was recorded in 2020.

The estimated amortization expense related to this finite lived intangible asset for the five succeeding years is as follows (amounts in thousands):

	September 30, 2021
Intangible asset	\$ 3,906
Less amortization	(26)
Intangible asset, net	<u>\$ 3,880</u>
2021 (remaining)	\$ 68
2022	273
2023	273
2024	273
2025	273
Amounts thereafter	2,720
	<u>\$ 3,880</u>

As of September 30, 2021, all development milestones, sales-based milestones and royalty payments within the license agreement are constrained. There can be no assurance that any proceeds will be received under the license agreement.

6. Accrued Liabilities

Details of accrued liabilities are presented as follows (amounts in thousands):

	September 30, 2021	December 31, 2020
Accrued clinical	\$ 2,367	\$ 2,017
Accrued contract manufacturing	1,793	1,301
Accrued bonus	563	597
Accrued other	1,527	184
Total accrued liabilities	<u>\$ 6,250</u>	<u>\$ 4,099</u>

7. Operating Lease

In April 2019, the Company entered into a twenty-eight-month facility lease agreement for 2,760 square feet of office space in Los Angeles, California. The lease commenced on May 1, 2019, included four months of rent abatement and a rent escalation clause and was set to expire on August 31, 2021. In August 2021, the Company exercised its option to extend the term of the lease for an additional three-year period and entered into an amendment to the lease agreement (the "Lease Amendment"). Pursuant to the Lease Amendment, the Company and the landlord agreed to extend the term for an additional period of three (3) years and six (6) months, until February 28, 2025, with an option to renew for an additional three (3) years in accordance with the terms of the lease agreement. Included in the Lease Amendment were nine months of rent abatement and a rent escalation clause. Rent expense is being recorded on a straight-line basis. Rent expense related to this lease was \$47,000 and \$0.1 million for the three and nine months ended September 30, 2021, respectively. Rent expense related to the lease was \$46,000 and \$0.1 million for the three and nine months ended September 30, 2020, respectively.

The following table summarizes information related to the Company's lease (amounts in thousands):

	September 30, 2021	December 31, 2020
Assets:		
Operating lease right-of-use assets	\$ 597	\$ 119
Total right-of-use assets	<u>\$ 597</u>	<u>\$ 119</u>
Liabilities:		
Operating lease liabilities, current	\$ 90	\$ 125
Operating lease liabilities, non-current	523	—
Total operating lease liabilities	<u>\$ 613</u>	<u>\$ 125</u>

The future minimum lease payments required under the operating lease as of September 30, 2021, are summarized below (amounts in thousands):

Future Minimum Lease Payments:

Fourth quarter 2021	\$	9
2022		178
2023		231
2024		238
2025		40
Total minimum lease payments	\$	696
Less: amount representing interest		(83)
Present value of operating lease liabilities	\$	613
Less: operating lease liabilities, current		(90)
Operating lease liabilities, non-current	\$	523
Remaining lease term (in years)		3.42
Incremental borrowing rate		6.80%

8. EOC License Agreement

In December 2020, the Company entered into the EOC License Agreement with EOC for the further development and commercialization of ABI-009 in the Licensed Territory. Under the terms of the EOC License Agreement, the Company granted to EOC an exclusive, royalty-bearing license to develop and commercialize the product in the Licensed Territory.

Unless earlier terminated, the term of the EOC License Agreement continues until the expiration of the royalty obligations. EOC has the right to terminate the agreement for any reason upon 120 days advance written notice. Either party may terminate the EOC License Agreement in the event that the other party breaches the agreement and fails to cure the breach, becomes insolvent or challenges certain of the intellectual property rights licensed under the agreement.

The Company assessed the EOC License Agreement and concluded that EOC is a customer and identified the license of ABI-009 provided to EOC as the sole performance obligation. The \$14.0 million upfront payment received from EOC is non-refundable and non-creditable and is considered fixed consideration. The Company recognized revenue of \$14.0 million in December 2020 when the EOC License Agreement was signed, and the \$14.0 million upfront payment was received in January 2021.

The potential milestone payments and royalty payments under the EOC License Agreement are considered variable consideration and are constrained with respect to revenue recognition notification from EOC that the milestone and royalty payments have been achieved.

The Company is eligible to receive an additional \$257.0 million in the aggregate upon achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on net sales in the Licensed Territory. Under the terms of the EOC License Agreement, EOC will fund all research, development, regulatory, marketing and commercialization activities in the defined Licensed Territory.

9. Convertible Notes

Private Aadi received \$8.1 million in October 2019 and \$1.0 million in January 2020 for the proceeds from the issuance of Convertible Notes. The October 2019 Convertible Notes were issued to existing equity holders of Private Aadi. The Convertible Notes issued in October 2019 and January 2020 originally had a maturity date of one year from the date of issuance and bear an escalating interest rate of 6% per annum for the first four months following the effective date of the loan agreement, 8% per annum for the fifth and sixth months, and 10% per annum for the remaining six months of the note term until maturity at twelve months. The Convertible Notes contain certain redemption features, including conversion to preferred stock upon the closing of Private Aadi's next issuance of preferred stock resulting in net proceeds to the Company of at least \$25.0 million ("Qualified Financing"). The Convertible Notes will convert into a variable, whole number of preferred shares equal to the number obtained by dividing the principal plus accrued interest of the Convertible Notes by 80% of the price per share paid by cash investors in the Qualifying Financing if converted in the first four months following the effective date of the loan agreement, 75% if converted in months five or six, and 70% if converted later than six months. The Convertible Notes also contained a mandatory prepayment provision that required Private Aadi to pay the outstanding principal, plus accrued and unpaid interest together with a premium in the event that a qualified liquidity event occurred. The

premium was equal to 120% of the outstanding principal amount to be prepaid in the event the liquidity event occurs within four months of the note date, 130% between the fifth and sixth month, and 140% if after the sixth month but prior to maturity.

In November 2020, Private Aadi entered into an amendment to the October 2019 and January 2020 Convertible Notes, whereby the term was extended from one year to two years. The amendment was accounted for as a debt modification.

In May 2021, Private Aadi entered into an amendment to the October 2019 and January 2020 Convertible Notes, whereby upon the closing of the Merger (see Note 1), the outstanding principal amount of the Convertible Notes and all accrued and unpaid interest as of immediately prior to the closing of the Merger would automatically convert into fully paid and nonassessable shares of Private Aadi common stock at a price per share equal to \$4.80 and would be concurrently exchanged for shares of the Company's common stock based on the Exchange Ratio. In conjunction with the closing of the Merger on August 26, 2021, the outstanding Convertible Notes were converted into shares of Private Aadi common stock which were concurrently exchanged for 698,018 shares of the Company's common stock after taking into account the Exchange Ratio. At the date of conversion, the convertible notes were marked to market and valued at \$9.5 million, resulting in a gain of \$0.4 million.

10. Payroll Protection Program Loan

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act also appropriated funds for the Small Business Administration ("SBA") Paycheck Protection Program ("PPP") loans that are forgivable in certain situations to promote continued employment, as well as Economic Injury Disaster Loans to provide liquidity to small businesses harmed by COVID-19.

In May 2020, Aadi was approved for a \$0.2 million SBA PPP loan, as provided for in the CARES Act ("PPP Loan"). Under certain conditions, the PPP Loan and accrued interest are forgivable after a twenty-four-week covered period as long as the loan proceeds were used for eligible expenses, including payroll, benefits, rent and utilities, and the company maintains certain payroll levels. The amount of loan forgiveness is subject to reduction if the Company terminates employees or reduces salaries during the twenty-four-week covered period. The unforgiven portion of the loan is payable over two years at an interest rate of 1%, with a deferral of payments for the ten months following the end of the twenty-four-week covered period. On April 29, 2021, the Company received notification from the SBA that the Company's Forgiveness Application of the PPP Loan and accrued interest was approved in full, and the Company had no further obligations related to the PPP Loan. Accordingly, the Company recorded a gain on the forgiveness of the PPP Loan totaling \$0.2 million.

The SBA has stated that all PPP loans in excess of \$2 million, and other PPP loans as appropriate, will be subject to review by the SBA for compliance with program requirements. If the SBA determines in the course of its review that a borrower lacked an adequate basis for the required certification concerning the necessity of the loan request or the subsequent use of loan proceeds, the SBA will seek repayment of the PPP loan, including interest and potential penalties. While the Company believes the loan was properly obtained and forgiven, there can be no assurance regarding the outcome of an SBA review. The Company has not accrued any liability associated with the risk of an adverse SBA review.

11. Stockholders' Equity (Deficit)

Preferred Stock

As of September 30, 2021, under the Company's certificate of incorporation, as amended and restated, the Company has 10,000,000 shares of preferred stock, par value \$0.0001 per share, in authorized capital with no shares outstanding.

Series Seed Preferred Stock

On February 23, 2017, Private Aadi converted from a limited liability company to a corporation and at that time converted 734,218 membership units into shares of Series Seed Preferred Stock. All outstanding shares of Series Seed Preferred Stock were converted into Private Aadi's common stock and concurrently exchanged for the Company's common stock based on the Exchange Ratio in connection with the closing of the Merger.

Series A Preferred Stock

In February and March 2017, Private Aadi sold and issued in a private placement 5,847,940 shares of Series A Preferred Stock at \$3.42 per share (the “Series A Financing”). Upon the closing of the Series A Financing, convertible notes issued in 2015 converted into 482,426 shares of Series A Preferred Stock at 85% of the \$3.42 price per share (the “Series A Original Issue Price”) paid by the Series A Financing investors. Convertible notes issued in 2017 converted into 881,286 shares of Series A Preferred Stock at the Series A Original Issue Price. All outstanding shares of Series A Preferred Stock were converted into shares of Private Aadi common stock and concurrently exchanged for the Company’s common stock based on the Exchange Ratio in connection with the closing of the Merger.

Common Stock

As of September 30, 2021 and December 31, 2020, the Company had 300,000,000 and 20,000,000 shares of authorized common stock with par value of \$0.0001 per share, respectively, under the Company’s certificate of incorporation, as amended and restated. As of September 30, 2021 and December 31, 2020, the shares of common stock outstanding were 20,883,454 and 2,542,358, respectively.

In conjunction with the closing of the Merger, the Company issued an aggregate of 2,558,218 shares of common stock to holders of Private Aadi common stock in exchange for all of the Private Aadi capital stock outstanding immediately prior to the closing of the Merger. Concurrently with the closing of the Merger, the PIPE Investors purchased an aggregate of 11,852,862 shares of the Company’s common stock for an aggregate purchase price of \$155.0 million pursuant to the Subscription Agreement entered into with the Company on May 16, 2021. The aggregate net proceeds, after deducting certain expenses incurred that were direct and incremental to the issuance of the PIPE shares, was \$145.4 million.

Dividends

The holders of common stock are entitled to receive dividends, if and when declared by the board of directors of the Company (the “Board of Directors”). Since the Company’s inception, no dividends have been declared or paid to the holders of common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company’s assets.

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

12. Stock-Based Compensation

Stock Option Plan – 2014 Plan (“Private Aadi Plan”)

In connection with the Merger, the Company assumed Private Aadi Plan, which was amended and restated in February 2017, and the issued and outstanding stock options under the Private Aadi Plan (the Private Aadi common stock underlying the awards was adjusted for shares of the Company’s common stock pursuant to the Merger Agreement). The Private Aadi Plan allowed for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock unit awards and other stock awards. In connection with the closing of the Merger and the adoption of the 2021 Plan (as defined below), no further awards will be issued under the Private Aadi Plan.

The options that are granted from the Private Aadi Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The Private Aadi Plan stock options generally vest over a four-year term.

Stock Option Plan – 2011 Plan and 2017 Plan

In connection with the closing of the Merger, the Company assumed the Aerpio 2011 Equity Incentive Plan (the “2011 Plan”) and the Aerpio 2017 Stock Option and Incentive Plan (the “2017 Plan,” and collectively with the 2011 Plan, the “Prior Plans”). No new awards will be granted under the 2017 Plan effective upon the closing of the Merger and adoption of the 2021 Plan (as defined below).

Stock Option Plan – 2021 Plan

At the closing of the Merger, the Company adopted the Aadi Bioscience, Inc. 2021 Equity Incentive Plan (the “2021 Plan”), which also permits stock options and restricted stock unit grants to employees, members of the board of directors, and outside consultants.

Subject to the adjustment provisions contained in the 2021 Plan and the evergreen provision described below, a total of 2,070,784 shares of common stock were initially reserved for issuance pursuant to the 2021 Plan. In addition, the shares reserved for issuance under the 2021 Plan include any shares of common stock (i) subject to awards of stock options or other awards granted under the Prior Plans that expire or otherwise terminate without having been exercised in full and shares of common stock granted under the Prior Plans that are forfeited or repurchased by the Company, and (ii) any shares of common stock subject to stock options or similar awards granted under the Private Aadi Plan that were assumed in the Merger (provided that the maximum number of shares that may be added to the 2021 Plan pursuant to this sentence is 764,154 shares).

The number of shares available for issuance under the 2021 Plan also will include an annual increase, or the evergreen feature, on the first day of each of the Company's fiscal years, beginning with the Company's fiscal year 2022, equal to the least of:

- 2,070,784 shares of common stock;
- a number of shares equal to 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year; or
- such number of shares as the Board or its designated committee may determine.

Shares issuable under the 2021 Plan are authorized, but unissued, or reacquired shares of common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by the combined company due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2021 Plan (unless the 2021 Plan has terminated).

As of September 30, 2021, zero, 432,978, 195,737 and 669,731 shares were outstanding under the 2011 Plan, Private Aadi Plan, 2017 Plan and 2021 Plan, respectively.

The following table summarizes the stock option activity during the nine months ended September 30, 2021:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, January 1, 2021	390,949	\$ 2.00	7.26	\$ 505
Granted	727,620	26.58		
Assumed through Merger	248,258	29.20		
Exercised	(61,075)	12.20		
Expired/cancelled	(7,306)	36.47		
Outstanding, September 30, 2021	1,298,446	\$ 20.33	7.63	\$ 13,156
Options exercisable, September 30, 2021	493,890	\$ 13.79	3.46	\$ 9,646

As of September 30, 2021, the aggregate intrinsic value of options outstanding was \$13.2 million. The intrinsic value for stock options is calculated based on the difference between the exercise prices of the underlying awards and the quoted stock price of the Company's common stock as of the reporting date.

As of September 30, 2021, there was \$13.9 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 3.15 years.

As of September 30, 2021, zero and 1,845,971 shares were reserved for issuance under the Private Aadi Plan and 2021 Plan, respectively.

Option Awards

During the three months ended September 30, 2021 and 2020, option awards to purchase an aggregate of 669,731 and zero shares of common stock were granted, respectively.

During the nine months ended September 30, 2021 and 2020, option awards to purchase an aggregate of 727,620 and 53,131 shares of common stock were granted, respectively.

Compensation Expense Summary

The Company recognized the following compensation cost related to employee and non-employee stock-based compensation activity for the periods presented (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 124	\$ 23	\$ 180	\$ 67
General and administrative	524	11	543	33
Total	<u>\$ 648</u>	<u>\$ 34</u>	<u>\$ 723</u>	<u>\$ 100</u>

Included in the three and nine months ended September 30, 2021 is \$0.3 million of expense related to the acceleration of vesting associated with individual awards assumed in the Merger.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option pricing and models require the input of various assumptions, including the option's expected life, expected dividend yield, price volatility and risk-free interest rate of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the nine months ended September 30, 2021 and 2020 was \$19.24 and \$2.57 per share, respectively. The calculation was based on the following assumptions. No grants were issued during the three months ended September 30, 2020.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expected term (years)	5.27 - 6.08	—	5.08 - 6.25	5.27 - 6.25
Risk-free interest rate	0.84% - 1.15%	—	0.84% - 1.15%	0.34% - 0.80%
Expected volatility	86.02% - 87.27%	—	85.21% - 87.88%	89.57% - 92.52%
Expected dividend yield	—	—	—	—

Warrants to Purchase Common Stock

The Company had warrants outstanding for the purchase of 36,666 shares of the Company's common stock at September 30, 2021. There were no warrants outstanding as of December 31, 2020. These warrants were assumed in the Merger and were issued by Aerpio in October 2019, for the purchase of 40,000 shares (after taking into account the Reverse Stock Split) of the Company's common stock at an exercise price of \$7.29 per share (after taking into account the Reverse Stock Split). These warrants were fully vested as of the date of the Merger and expire on October 24, 2024. Prior to the closing of the Merger, 3,334 warrants were exercised. At the grant date, the fair value of these awards was determined using a Black-Scholes option pricing model.

The number of shares and the exercise price shall be adjusted for standard anti-dilution events such as stock splits, combinations, reorganizations, or issue shares as part of a stock dividend. The warrants meet the criteria to be classified within stockholders' equity (deficit).

13. Employee Stock Purchase Plan

On August 17, 2021, a special meeting of the Company's stockholders was held to approve the Merger and related matters which included, among others, an employee stock purchase plan ("Special Meeting"). At the Special Meeting, the Company's stockholders considered and approved the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP"). Upon approval of the 2021 ESPP by the stockholders, Aerpio's Amended and Restated 2017 Employee Stock Purchase Plan terminated. An aggregate of 310,617 shares of common stock (after taking into account the Reverse Stock Split) have been reserved and are available for issuance under the 2021 ESPP. The number of shares of common stock available for issuance under the 2021 ESPP will be increased on the first day of each fiscal year beginning with the 2022 fiscal year in an amount equal to the least of (i) 310,617 shares of common stock (after taking into account the Reverse Stock Split), (ii) one percent (1%) of the outstanding shares of all classes of common stock on the last day of the immediately preceding fiscal year, or (iii) an amount to be determined by the Board or its designated committee no later than the last day of the immediately preceding fiscal year. Shares of common stock issuable under the 2021 ESPP will be authorized, but unissued, or reacquired shares of common stock. If the Company's capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the 2021 ESPP will be appropriately adjusted. No shares under the 2021 ESPP are outstanding at September 30, 2021.

14. Income Taxes

The Company did not record a current or deferred income tax expense or benefit for the three and nine months ended September 30, 2021 and 2020, due to the Company's net losses and increases in its deferred tax asset valuation allowance.

15. Commitments and Contingencies

Legal Proceedings

From time to time, the Company could be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Regardless of the outcome, legal proceedings can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. Except as set forth below, as of the date of this Quarterly Report, the Company is not currently involved in any material legal proceedings.

Between June 30, 2021 and August 3, 2021, the following actions were filed by purported stockholders of Aerpio: *Dwayne Komurke v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05686 (S.D.N.Y.); *Matthew Whitfield v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05787 (S.D.N.Y.); *Robin Odach v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05802 (S.D.N.Y.); *Miah v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-03912 (E.D.N.Y.); *Weir v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-06456 (S.D.N.Y.); *Carlisle v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-01123 (D. Del.); *Adam Franchi v. Aerpio Pharmaceuticals, Inc., et al.*, 1:21-cv-06566 (S.D.N.Y.) and *Alex Ciccotelli v. Aerpio Pharmaceuticals, Inc., et al.*, 2:21-cv-03463 (E.D. Pa.). The complaints alleged that the Company's preliminary proxy statement filed with the U.S. Securities and Exchange Commission (the "SEC") in connection with the Merger on June 21, 2021, and its definitive proxy statement filed with the SEC in connection with the Merger on July 8, 2021, contained false and misleading statements and omissions, including relating to (i) the process leading up to the Merger; (ii) certain financial projections prepared by the Company's management and summarized in the preliminary and definitive proxy statements; (iii) the financial analyses conducted by Ladenburg in connection with Ladenburg's discounted cash flow analysis and fairness opinion to the Company's board of directors; and (iv) certain information concerning a second financial advisor. Following the closing of the Merger, all of these actions were voluntarily dismissed by each respective plaintiff.

As previously disclosed, the Company's Board of Directors also received a demand letter from a purported stockholder of the Company, requesting certain books and records of the Company concerning the Merger pursuant to Section 220 of the Delaware General Corporation Law. Thereafter, on August 16, 2021, the same purported stockholder filed a complaint in the Court of Chancery seeking books and records, captioned *Weiss v. Aerpio Pharmaceuticals, Inc.*, Case No. 2021-0699-KSJM (Del. Ch.). On September 29, 2021, the plaintiff voluntarily dismissed this action.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“Quarterly Report”) contains express or implied forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- our ability to obtain and maintain regulatory approval for ABI-009 in advanced malignant perivascular epithelioid cell tumors (“PEComa”) or any other product candidates we may develop in the future, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- the timing, scope or likelihood of regulatory filings and approvals;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the timing, progress and results of preclinical studies and clinical trials for our programs and product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the potential attributes and benefits of our product candidates;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- the implementation of our business model and our strategic plans for our business, product candidates, technology and our discovery engine;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our ability to contract with and rely on third parties to assist in conducting our clinical trials and manufacturing our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- our ability to obtain funding for our operations, including funding necessary to complete further development, approval and, if approved, commercialization of our product candidates;
- the period over which we anticipate our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to compete with other companies currently marketing or engaged in the development of treatments for the indications that we are pursuing for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our financial performance;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions, and projections about the business and future financial results of the pharmaceutical industry, and other legal, regulatory and economic developments. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “intend,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “potential,” “continue,” “likely,” and similar expressions (including their use in the negative) intended to identify forward-looking statements although not all forward-looking statements contain these identifying words. Actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including, but not limited to, those described in Part II, Item 1A, Risk Factors of this Quarterly Report.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with or furnished to the U.S. Securities and Exchange Commission (the “SEC”) completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes to those statements thereto appearing elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes thereto included in our Current Report on Form 8-K filed with the SEC on August 27, 2021, as amended on September 24, 2021. Some of the information contained in this discussion and analysis including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report. You should read this Quarterly Report completely, including the “Risk Factors” section under Part II, Item 1A of this Quarterly Report and the “Cautionary Statement Regarding Forward-Looking Statements” sections of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by our forward-looking statements contained in the following discussion and analysis. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a clinical-stage biopharmaceutical company developing precision therapies for genetically defined cancers with alterations in mTOR pathway genes. Our lead drug candidate, ABI-009 (FYARRO™, nab-sirolimus), is a form of sirolimus bound to albumin. Sirolimus is a potent inhibitor of the mTOR biological pathway, the activation of which pathway can promote tumor growth, and inhibits downstream signaling from mTOR. We are evaluating ABI-009 in cancers with known mTOR pathway activation, including tumor agnostic indications targeting specific genomic alterations that activate the mTOR pathway.

In May 2021, we completed the filing of a rolling new drug application (“NDA”) for ABI-009 to the U.S. Food and Drug Administration (the “FDA”), for approval to treat patients with advanced malignant PEComa, and the FDA accepted the NDA in July 2021 and granted us Priority Review designation with a Prescription Drug User Fee Act (“PDUFA”) target action date of November 26, 2021. Our NDA is based on results from our Phase 2 registrational study AMPECT (Advanced Malignant PEComa Trial), in advanced malignant PEComa for which there are currently no approved therapies in the U.S. and for which there has never been a prior prospective clinical trial. In November 2019, we announced top-line results from the AMPECT study, including that the study achieved its primary endpoint of overall response rate (“ORR”), as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors, RECIST v1.1.

We are actively engaged in commercial preparations to support the planned U.S. launch of ABI-009 for the treatment of patients with advanced malignant PEComa, if approved. We intend to build a specialist sales force to target physicians in the United States who treat advanced malignant PEComa in the first half of 2022.

In addition to advanced malignant PEComa, based on data from the completed AMPECT trial and our ongoing expanded access program, we are planning a registrational Phase 2 study (“PRECISION 1”) of ABI-009 in tumor-agnostic Tuberous Sclerosis Complex 1 and 2 (*TSC1* & *TSC2*) alterations. We have completed a Type B meeting with the FDA in which we discussed the initial trial design with the FDA. We plan to initiate the PRECISION 1 trial by the end of 2021, or in early 2022.

We have an exclusive license with Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation, now Bristol-Myers Squibb Company (“Celgene”), under which we obtained exclusive rights to develop, manufacture, and commercialize ABI-009, provided that we have granted to EOC Pharma (Hong Kong) Limited exclusive rights to develop and commercialize ABI-009 for the Greater China region.

Recent Developments

Merger and Reverse Stock Split

On August 26, 2021, we, formerly known as Aerpio, completed our previously announced merger transaction with Aadi Subsidiary, Inc. (formerly known as Aadi Bioscience, Inc., or “Private Aadi”) in accordance with the terms of the Agreement and Plan of Merger, dated as of May 16, 2021 (the “Merger Agreement”), by and among us, a wholly-owned subsidiary of ours (“Merger Sub”), and Private Aadi. Pursuant to the terms of the Merger Agreement, Merger Sub merged with and into Private Aadi, with Private Aadi surviving as our wholly owned subsidiary (the “Merger”).

On August 26, 2021, in connection with, and prior to the completion of, the Merger, we effected a 1-for-15 reverse stock split of our common stock (the “Reverse Stock Split”). Under the terms of the Merger Agreement, we issued common stock to holders of Private Aadi capital stock based on the Exchange Ratio of 0.3172, after giving effect to the Reverse Stock Split, for each share of Private Aadi capital stock outstanding immediately prior to the Merger. In connection with and immediately prior to the closing of the Merger, Private Aadi changed its name from “Aadi Bioscience, Inc.” to “Aadi Subsidiary, Inc.” and we changed our name from “Aerpio Pharmaceuticals, Inc.” to “Aadi Bioscience, Inc.” In connection with the closing of the Merger, our stock began trading on the Nasdaq Capital Market (“Nasdaq”) under the symbol “AADI” on August 27, 2021. Private Aadi was determined to be the accounting acquirer, and our historical financials will be those of Private Aadi and the business conducted by Private Aadi became the business conducted by us.

Also on August 26, 2021, and in connection with the closing the Merger, we entered into a contingent value rights agreement (the “CVR Agreement”) with a legacy director of Aerpio, as Holder Representative (as defined in the CVR Agreement), and American Stock Transfer & Trust Company, LLC, as Rights Agent (as defined in the CVR Agreement), in accordance with the terms of the Merger Agreement. Pursuant to the CVR Agreement, each holder of Aerpio common stock as of immediately prior to the Effective Time of the Merger is entitled to one contingent value right (“CVR”) for each outstanding share of Aerpio common stock held by such stockholder as of immediately prior to the closing of the Merger, each representing the right to receive contingent payments upon the occurrence of certain events set forth in, and subject to and in accordance with, the terms and conditions of the CVR Agreement. Each CVR entitles the holder thereof to receive 90% of the net proceeds (calculated as gross consideration minus certain permitted deductions), if any, under the CVR covered agreements. The CVRs are not transferable, except in certain limited circumstances as provided in the CVR Agreement, are not certificated or evidenced by any instrument and are not registered with the SEC or listed for trading on any exchange.

PIPE Financing and Subscription Agreement

On May 16, 2021, we entered into a subscription agreement (“Subscription Agreement”) with certain investors (the “PIPE Investors”), pursuant to which we sold shares of our common stock concurrently with the closing of the Merger (the “PIPE Financing”). At the closing of the PIPE Financing, we entered into a Registration Rights Agreement, dated August 26, 2021 (“Registration Rights Agreement”), with the PIPE Investors.

At the closing of the PIPE Financing, on August 26, 2021, we sold and issued to the PIPE Investors an aggregate of 11,852,862 shares of our common stock at a purchase price of \$13.077 per share. The total purchase price paid by the PIPE Investors in the closing of the PIPE Financing was approximately \$155.0 million. We intend to use the net proceeds from the PIPE Financing for commercialization and regulatory approval activities related to ABI-009 for advanced malignant PEComa, for research and development activities for ABI-009 in other indications, working capital and general corporate purposes.

COVID-19

The pandemic caused by an outbreak of a new strain of coronavirus, or COVID-19, and its variants, has resulted, and is likely to continue to result in, significant national and global economic disruption and may adversely affect our operations. Our clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings can also make it more difficult to enroll new patients in ongoing or planned clinical trials. We are actively monitoring the impact of COVID-19 and the possible effects on our financial condition, liquidity, operations, suppliers, industry and workforce. However, the full extent, consequences and duration of the COVID-19 pandemic and the resulting impact on us cannot currently be predicted. We will continue to evaluate the impact that these events could have on our operations, financial position, results of operations and cash flows during the remainder of fiscal year 2021.

Basis of Presentation

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the condensed consolidated balance sheets and the condensed consolidated statements of operation and comprehensive loss presented herein. The following discussion and analysis are based on the Company’s condensed consolidated financial statements contained in this Quarterly Report, which we have prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Loss

Revenue

Grant Revenue

Grant revenue is derived from federal grants, primarily with the FDA. We have determined that the government agencies providing grants to us are not customers. Grant revenue is recognized when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received. We recognize grant revenue as reimbursable grant costs are incurred. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

With respect to grant revenue derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts, where we act as principal with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we record revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the accompanying statements of operations and comprehensive loss.

EOC Pharma License Revenue

In December 2020, we entered into a license agreement (the “EOC License Agreement”) with EOC Pharma (Hong Kong) Limited (“EOC”) pursuant to which, we granted EOC exclusive rights to develop and commercialize ABI-009 in Greater China, including the Republic of China, Hong Kong, Macau and Taiwan (the “Licensed Territory”) for human use in specified indications. EOC is obligated to pay royalties to us on sales of licensed products in the Licensed Territory. Under the terms of the EOC License Agreement, EOC has agreed to use commercially reasonable efforts to develop and commercialize ABI-009 in the Licensed Territory and to obtain and maintain regulatory approval.

Unless earlier terminated, the EOC License Agreement will remain in effect until all milestones are achieved and royalty payment obligations are fulfilled as provided for in the EOC License Agreement. Prior to the expiration of the EOC License Agreement, EOC has the right to terminate the agreement for any reason upon a specified number of days advance written notice. Either party may terminate the EOC License Agreement in the event that the other party materially breaches the agreement and fails to cure the breach, or experiences certain events of financial distress. We may terminate the EOC License Agreement if EOC or its affiliates challenge the licensed patents in a legal, administrative or arbitration proceeding.

In January 2021, we received a \$14.0 million upfront payment and we are eligible to receive up to an additional \$257.0 million in the aggregate upon achievement of certain development, regulatory and sales milestones, as well as tiered royalties on net sales in the Licensed Territory, which royalties are potentially subject to various reductions. EOC is responsible for controlling the filing for and obtaining all regulatory approvals, with our reasonable cooperation, and for bearing all costs associated with those approvals.

We assessed the EOC License Agreement and concluded that EOC is a customer. Additionally, we identified the license of ABI-009 provided to EOC as the sole performance obligation. The \$14.0 million upfront payment received from EOC is non-refundable and non-creditable and is considered fixed consideration.

Both the milestones and royalty payments under the EOC License Agreement are considered variable consideration and, with respect to revenue recognition, are constrained until we receive notification from EOC that the milestones and royalty payments have been achieved.

Operating Expenses

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of: (i) employee related costs, including salaries, benefits and stock-based compensation expense for employees engaged in scientific research and development functions; (ii) third-party contract costs relating to research, formulation, manufacturing, nonclinical studies and clinical trial activities; (iii) external costs of outside consultants who assist with technology development, regulatory affairs, clinical development and quality assurance; (iv) payments made under our third-party licensing agreements; and (v) allocated facility-related costs.

Costs for certain activities, such as manufacturing, nonclinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators. Research and development activities are central to our business. We expect to increase our investment in research and development in order to advance our product candidates through clinical trials. As a

result, we expect that our research and development expenses will increase substantially in the foreseeable future as we continue to invest in research and development activities, pursue clinical development of our product candidates and expand our product candidate pipeline.

The process of commercialization and conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, to the extent that our product candidates continue to advance into clinical trials, including larger and later-stage clinical trials, our expenses will increase substantially and may become more variable.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development and other corporate functions. Other general and administrative expenses include professional fees for legal, auditing, tax and business consulting services, insurance costs, intellectual property and patent costs, facility costs and travel costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities. Additionally, we will incur significant additional expenses associated with being a public company that we did not incur as a privately-held company, including (i) costs to comply with the rules and regulations of the SEC and those of Nasdaq, (ii) legal, accounting and other professional services, (iii) insurance, (iv) investor relations activities and (v) other administrative and professional services.

Impairment of Acquired Contract Intangible Asset

Impairment of acquired contract intangible asset relates to a write down of the acquired contract intangible asset to fair value. The contract intangible asset was assessed for recoverability using an undiscounted cash flow model, which resulted in undiscounted cash flows below the carrying amount. We recognized an impairment of \$74.2 million to bring the carrying amount of the contract intangible asset down to its estimated fair value of \$3.9 million at August 26, 2021. The fair value determination of the contract intangible asset was based upon a discounted cash flow valuation of the milestone payments and Monte Carlo valuation for the sales royalties.

Other Income (Expense), Net

Other income (expense) consists of the change in fair value of convertible promissory notes and interest expense related to such notes. These expenses are partially offset by interest income earned on cash and cash equivalents.

Income Taxes

During the three- and nine-months ending September 30, 2021 and 2020, we recognized state tax payments as income tax expense on the income statement. Since our formation in 2011, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items.

Results of Operations:

The following table presents the results of operations for the periods indicated (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Grant revenue	\$ —	\$ 231	\$ 120	\$ 431
Total revenue	—	231	120	431
Operating expenses:				
Research and development	5,754	2,395	12,443	9,684
General and administrative	7,401	499	8,793	1,700
Impairment of acquired contract intangible	74,156	—	74,156	—
Total operating expenses	87,311	2,894	95,392	11,384
Loss from operations	(87,311)	(2,663)	(95,272)	(10,953)
Other income (expense), net	223	(228)	1,174	(544)
Loss before income taxes	(87,088)	(2,891)	(94,098)	(11,497)
Income tax expense	—	(1)	(2)	(1)
Net and comprehensive loss	\$ (87,088)	\$ (2,892)	\$ (94,100)	\$ (11,498)

Comparison of the Three and Nine Months ended September 30, 2021 and 2020

Grant Revenue

Grant revenue amounts can vary from period to period depending on the funding and work performed. Grant revenue decreased by \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2021, compared to the same periods in 2020, primarily due to a decrease in the eligible expenses for grant reimbursement incurred during the 2021 period compared to 2020.

Operating Expenses

Research and Development Expenses

The following table presents our research and development expenses for the periods indicated (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Clinical drug product manufacturing expense	\$ 2,455	\$ 120	\$ 4,967	\$ 2,886
External clinical development expense	1,537	1,429	3,820	3,776
Personnel and other expenses	1,762	846	3,656	3,022
Total research and development expenses	<u>\$ 5,754</u>	<u>\$ 2,395</u>	<u>\$ 12,443</u>	<u>\$ 9,684</u>

Research and development expenses for the three months ended September 30, 2021, were \$5.8 million, an increase of \$3.4 million, compared to \$2.4 million for the three months ended September 30, 2020. The increase was primarily driven by \$2.3 million increase in clinical drug manufacturing costs, \$0.1 million for external clinical development and \$1.0 million increase in headcount, consultants, and other expenses.

Research and development expenses for the nine months ended September 30, 2021, were \$12.4 million, an increase of \$2.7 million, compared to \$9.7 million for the nine months ended September 30, 2020. The increase was primarily driven by \$2.1 million in clinical drug manufacturing costs and \$0.6 million in personnel and other expenses.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2021, were \$7.4 million, an increase of \$6.9 million, compared to \$0.5 million for the three months ended September 30, 2020. The increase was primarily driven by \$2.1 million of compensation related expenses to former Aerpio executives related to the Merger, \$0.9 million of personnel expenses related to increased headcount, incentive bonuses and share-based compensation, \$1.5 million of consulting expenses, \$1.7 million of commercialization readiness and marketing expenses, and \$0.7 million of legal, insurance and office related expenses.

General and administrative expenses for the nine months ended September 30, 2021, were \$8.8 million, an increase of \$7.1 million compared to \$1.7 million for the nine months ended September 30, 2020. The increase was primarily driven by \$2.0 million of compensation related expenses to former Aerpio executives related to the Merger, \$1.0 million of personnel expenses related to increased headcount, incentive bonuses and share-based compensation expense, \$1.7 million of consulting expenses, \$1.8 million of commercialization readiness and marketing expenses, and \$0.6 million of legal, insurance and office related expenses.

Impairment of Acquired Contract Intangible Asset

During the three and nine months ended September 30, 2021, as a result of the excess fair value ascribed to the acquired contract intangible asset related to the Merger, we recorded a \$74.2 million impairment charge to reduce the carrying value of the intangible asset to its fair value at August 26, 2021. No impairments were recognized during the three or nine months ended September 30, 2020.

Other Income (Expense), Net

Other income (expense), net for the three months ended September 30, 2021 was \$0.2 million of income, compared to \$0.2 million of expense, for the three months ended September 30, 2020. The change was primarily driven by \$0.4 million non-cash income related to the change in fair value of the convertible promissory notes.

Other income (expense), net for the nine months ended September 30, 2021 was \$1.2 million of income, compared to \$0.5 million of expense, for the nine months ended September 30, 2020. The change was primarily driven by a

\$1.6 million increase in the change in fair value of the convertible promissory notes and a \$0.2 million gain recognized on the extinguishment of the PPP loan forgiven by the SBA in April 2021.

Liquidity and Capital Resources

Overview

We have incurred net losses in each year since inception and as of September 30, 2021, we had an accumulated deficit of \$126.7 million. Our net losses were \$87.1 million and \$2.9 million for the three months ended September 30, 2021 and 2020, respectively, and \$94.1 million and \$11.5 million for the nine months ended September 30, 2021 and 2020, respectively. These losses have resulted principally from costs incurred in connection with research and development activities, general and administrative costs associated with our operations, and costs associated with the Merger. Additionally, during the three and nine months ended September 30, 2021, we recognized a non-cash impairment charge of \$74.2 million on the contract intangible asset acquired in the Merger. We expect to continue to incur significant expenses and operating losses for the foreseeable future due to the cost of research and development, including identifying and designing product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. We expect our expenses, and the potential for losses, to increase substantially as we conduct clinical trials of our lead product candidates, seek to expand our pipeline and operate as a public company.

From inception through September 30, 2021, we received funding of \$25.4 million from our initial seed financing and the sale of Series A convertible preferred stock, \$9.1 million from the issuance of convertible promissory notes, \$145.4 million, net from the PIPE Financing in connection with the Merger and \$29.7 million of cash assumed in the Merger. As of September 30, 2021, we had \$161.4 million of cash and cash equivalents. Based on our current plans, we believe our existing cash and cash equivalents will enable us to conduct our planned operations into 2024.

The following table presents our cash flows for the periods indicated (amounts in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (9,995)	\$ (9,426)
Net cash provided by investing activities	25,199	—
Net cash provided by financing activities	141,716	1,194
Net increase (decrease) in cash and cash equivalents	<u>\$ 156,920</u>	<u>\$ (8,232)</u>

Operating Activities

Our net cash used in operating activities primarily results from our net loss adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct our clinical programs and employee-related expenditures for research and development and general and administrative activities. Our cash flows from operating activities will continue to be affected by spending to advance and support our product candidates in the clinic and other operating and general administrative activities, including operating as a public company.

For the nine months ended September 30, 2021, cash used in operating activities was \$10.0 million and resulted from (i) our net loss of \$94.1 million offset by non-cash adjustments totaling \$73.8 million, which was primarily related to impairment of the acquired contract intangible asset of \$74.2 million, and (ii) \$10.3 million net decrease in our working capital accounts, primarily driven by the receipt of the \$14.0 million upfront payment from EOC under the EOC License Agreement.

For the nine months ended September 30, 2020, cash used in operating activities was \$9.4 million and resulted from (i) our net loss of \$11.5 million, offset by (ii) \$0.8 million in non-cash expenses related to interest expense on convertible promissory notes, stock-based compensation expense, lease expense and depreciation and amortization expense and (iii) a \$1.3 million net decrease in our working capital accounts.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2021 related to cash acquired in connection with the Merger partially offset by transaction related expenses. There were no investing activities during the nine months ended September 30, 2020.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2021 includes \$155.0 million gross cash proceeds from our PIPE Financing and \$0.7 million from exercise of stock options, partially offset by \$9.6 million of issuance costs related to the PIPE Financing, and \$4.4 million of dividends paid to preferred stockholders.

Net cash provided by financing activities for the nine months ended September 30, 2020 includes \$1.0 million related to the issuance of convertible promissory notes and \$0.2 million related to proceeds from our PPP Loan.

Contractual Obligations and Commitments

In August 2021, we entered into an amendment to extend the lease of our 2,760 square feet of office space in Los Angeles, California. We exercised an option, under our prior lease agreement, to extend the term of the lease for an additional three-year period. Included in the renewal were nine months of rent abatement and a rent escalation clause. Rent expense is being recorded on a straight-line basis. Rent expense related to this lease was \$47,000 and \$0.1 million for the three and nine months ended September 30, 2021, respectively. Rent expense related to the lease was \$46,000 and \$0.1 million for the three and nine months ended September 30, 2020, respectively.

We also have contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities and manufacturing companies to manufacture the drug product used in the clinical trials. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice. In the event of a cancellation, we would be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

With respect to our obligations under the CVR Agreement, certain events specified in the CVR Agreement need to occur for us to receive funds, and it is currently uncertain whether any funds will be received under the CVR Agreement. We do not have any commitment or obligation under the CVR Agreement unless and until funds are received.

Off-Balance Sheet Arrangements

As of September 30, 2021 and December 31, 2020, we did not have, and we currently do not have, any off-balance sheet arrangements as defined by applicable SEC regulations.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which are prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis and base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for the judgments we make about the carrying value of assets and liabilities that are not readily apparent from other sources. Because these estimates can vary depending on the situation, actual results may differ from these estimates. Making estimates and judgments about future events is inherently unpredictable and is subject to significant uncertainties, some of which are beyond our control. Our actual results could differ from these estimates.

Other than the policies noted in Part 1, Item 1, Note 3, "Significant Accounting Policies," in the notes to our condensed consolidated financial statements in this Quarterly Report, we consider the following critical accounting policies and estimates.

Merger and Acquired Contractual Intangible Asset

Aerpio issued common stock in the Merger based on the terms of the Merger Agreement. For accounting purposes, however, we concluded under GAAP that Private Aadi has acquired Aerpio. We based this conclusion having evaluated the terms of the Merger Agreement and other factors including: (i) the stockholders of Private Aadi owned approximately 66.8% of the voting rights of the Company as of immediately following the Merger (but prior to the PIPE Financing); (ii) three (3) of seven (7) members of the board of directors of the Company post-Merger were composed of directors designated by Private Aadi under the terms of the Merger Agreement, and one (1) member of the board of directors of the Company post-Merger was a director mutually designated by Private Aadi and Aerpio;

(iii) existing members of Private Aadi's management became the management of the Company post-Merger; (iv) the PIPE Investors consist of individuals and funds, and for purpose of this analysis, while they owned approximately 55.6% on a fully-diluted basis, as of immediately following the Merger (and after giving effect to the PIPE Financing), no one individual or fund held more shares than the holders of Private Aadi collectively owned immediately following the Merger and they are not considered to be a single voting group; and (v) following the Merger, the Company is headquartered in Pacific Palisades, California, and all ongoing operations of the combined company are those of Private Aadi.

Further, under GAAP we have accounted for the Merger as a reverse asset acquisition rather than a business combination. Accounting as an asset acquisition is significantly different than the accounting for a merger transaction as a business combination. Among other things, we have not recognized any goodwill on our consolidated balance sheet as there may have been had the Merger been accounted for as a business combination. A central element to the accounting model conclusion is the determination of whether a business or an asset or a group of assets is acquired. A business is defined in ASC 805, Business Combinations, as an integrated set of inputs and processes that are capable of generating outputs that have the ability to provide a return to its investors or owners. Typical inputs include long-lived assets (including intangible assets or rights to use long-lived assets), intellectual property and the ability to obtain access to required resources. Typical processes include strategic, operational and resource management processes that are typically documented or evident through an organized workforce. We considered all of the above factors when determining whether a business was acquired in the Merger and concluded that Aerpio did not meet the definition of a business.

Upon closing of the Merger, substantially all of the fair value is concentrated in cash, working capital and a long-lived contract intangible asset related to Aerpio's license agreement with Gossamer Bio. Inc., under which 90% of any future net cash proceeds will be remitted to CVR Holders and paid through the CVRs. In accordance with GAAP for asset acquisitions, the excess purchase price over the fair value of the acquired assets and liabilities (\$78.1 million) was ascribed to the acquired contract intangible asset. However, due to the significant excess purchase price being allocated over the fair value of the acquired contractual intangible asset, we determined that an indicator of impairment was present, and we assessed the contract intangible asset as compared to expectations of contingent future cash flows. We concluded that our estimate of gross cash flows potentially accruing to us under the license agreement is likely to be less than the excess purchase price of the fair value of the acquired assets and liabilities ascribed to the acquired contract intangible asset. As a result, we performed a valuation of the acquired contract intangible asset and recognized an impairment of \$74.2 million to adjust the carrying amount of the contractual intangible asset to its estimated fair value of \$3.9 million.

The license agreement with Gossamer Bio. Inc. includes potential payments to us in the event of certain development and commercialization milestones and sales-based royalties. Our fair value determination of the intangible asset utilized a scenario-based, risk-adjusted, discounted cash flow model with respect to the potential development milestone payments and a Monte Carlo option-pricing model with respect to the sales-based milestone and royalty payments:

- We determined fair value of the potential development milestone payments under the license agreement with inputs based on certain subjective assumptions, including (a) the probability of clinical success determined with reference to various academic studies reporting probabilities of approval for clinical trials; (b) an estimate of the time to achievement of the clinical milestones; and (c) a counterparty credit risk premium determined with reference to the borrowing costs of a benchmark group of comparable market participants.
- Application of the Monte Carlo simulation model in valuing the potential sales-based milestone and royalties involves making assumptions for (a) the probability of clinical success determined with reference to various academic studies reporting probabilities of approval for clinical trials; (b) our forecast of potential revenues, revenue uptake rate and the period of time from a prospective commercial launch to peak sales, and an estimate of peak sales for each successfully commercialized product covered under the license agreement; (c) drift equal to the risk free rate on revenues following a multivariate Geometric Brownian Motion; (d) a counterparty credit risk premium determined with reference to the borrowing costs of a benchmark group of comparable market participants; and (e) a revenue metric risk premium determined with reference to a long-term risk-free rate, a weighted-average cost of capital, revenue volatility and asset volatility.

Research and Development Costs

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires us to exercise significant estimates in regard to the timing

and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include, the conduct of preclinical studies, contract manufacturing activities and clinical activities. The diverse nature of services being provided under CRO and other vendor arrangements, the different terms and milestone arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses, as applicable, on the balance sheets and within research and development expense on the consolidated statements of operations. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, payment arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our estimates and related accounts on the balance sheet. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Revenue Recognition

We account for revenue related to the EOC License Agreement and Grant Revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, we recognize revenue when the defined customer, under ASC 606, transfers promised goods or services in an amount that reflects the consideration to which we expect to be entitled in exchange for goods or services. To determine revenue recognition for contracts with customers, we perform the following five steps: (i) identify the promised goods or services in the contract; (ii) identify the performance obligation in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation. We recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. We only apply the five-step model to contracts when it is probable that we will collect consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

Stock-Based Compensation

We recognize all stock-based payments to employees, including grants of employee stock options in the consolidated statements of operations and comprehensive loss based on their fair values. All of our share-based awards, to employees, non-employees, officers, and directors, are subject only to service-based vesting conditions. We estimate the fair value of its stock-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options and (iv) expected dividends. Options granted during the year have a maximum contractual term of ten years. Forfeitures are recognized and accounted for as they occur.

Due to the historical lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to our, including stage of product development and life science industry focus. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of us.

We have limited historical stock option activity and therefore estimate the expected term of stock options granted to employees, officers, and directors using the simplified method, which represent the average of the contractual term of the stock option and its weighted-average vesting period, to calculate the expected term, as we do not have

sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilize the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population.

Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term. For the three and nine months ended September 30, 2021, we recognized stock-based compensation expense, net of estimated forfeitures, in the statements of operations and comprehensive loss as follows (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 124	\$ 23	\$ 180	\$ 67
General and administrative	524	11	543	33
Total	\$ 648	\$ 34	\$ 723	\$ 100

As of September 30, 2021, total unamortized stock-based compensation was \$13.9 million which we expect to recognize over a weighted average period of 3.15 years. The intrinsic value of all outstanding stock options as of September 30, 2021 was \$13.2 million.

Income Taxes

We have accounted for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. We recognize interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

During the nine months ending September 30, 2021 and 2020, we recognized state tax payments as income tax expense on the income statement. Since our formation in 2011, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned tax credits, due to our uncertainty of realizing a benefit from those items. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, or NOLs. Utilization of NOLs may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code of 1986, as amended. Similar rules may apply under state tax laws. Our ability to use our remaining NOLs may be further limited if we experience future changes in our stock ownership.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.***Management's Evaluation of our Disclosure Controls and Procedures***

Under the supervision of and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2021, the end of the period covered by this Quarterly Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate.

Based on this evaluation, our principal executive officer and principal financial officer concluded that our internal controls over financial reporting were effective at the reasonable assurance level as of September 30, 2021.

Changes in Internal Control over Financial Reporting

Other than the transition of internal control over financial reporting in conjunction with the Merger, there were no changes in our internal control over financial reporting during the quarter ended September 30, 2021 that were identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we could be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. Except as set forth below, as of the date of this Quarterly Report, we are not currently involved in any material legal proceedings.

Between June 30, 2021 and August 3, 2021, the following actions were filed by purported stockholders of Aerpio: *Dwayne Komurke v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05686 (S.D.N.Y.); *Matthew Whitfield v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05787 (S.D.N.Y.); *Robin Odach v. Aerpio Pharmaceuticals Inc., et al.*, Case No. 1:21-cv-05802 (S.D.N.Y.); *Miah v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-03912 (E.D.N.Y.); *Weir v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-06456 (S.D.N.Y.); *Carlisle v. Aerpio Pharmaceuticals, Inc., et al.*, Case No. 1:21-cv-01123 (D. Del.); *Adam Franchi v. Aerpio Pharmaceuticals, Inc., et al.*, 1:21-cv-06566 (S.D.N.Y.) and *Alex Ciccotelli v. Aerpio Pharmaceuticals, Inc., et al.*, 2:21-cv-03463 (E.D. Pa.). The complaints alleged that our preliminary proxy statement filed with the SEC in connection with the Merger on June 21, 2021, and our definitive proxy statement filed with the SEC in connection with the Merger on July 8, 2021, contained false and misleading statements and omissions, including relating to (i) the process leading up to the Merger; (ii) certain financial projections prepared by management and summarized in the preliminary and definitive proxy statements; (iii) the financial analyses conducted by Ladenburg in connection with Ladenburg's discounted cash flow analysis and fairness opinion to our Board of Directors; and (iv) certain information concerning our second financial advisor. Following the closing of the Merger, all of these actions were voluntarily dismissed by each respective plaintiff.

Our Board of Directors also received a demand letter from a purported stockholder of the Company, requesting certain books and records of the Company concerning the Merger pursuant to Section 220 of the Delaware General Corporation Law. Thereafter, on August 16, 2021, the same purported stockholder filed a complaint in the Court of Chancery seeking books and records, captioned *Weiss v. Aerpio Pharmaceuticals, Inc.*, Case No. 2021-0699-KSJM (Del. Ch.). On September 29, 2021, the plaintiff voluntarily dismissed this action.

Item 1A. Risk Factors

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem immaterial may also impair our business operations. Please see page 25 of this Quarterly Report for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- We are a clinical stage biopharmaceutical company, have a limited operating history, have not initiated or completed any large-scale clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.
- Even following the Merger and PIPE financing, we will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- We are substantially dependent on the success of our lead product candidate, ABI-009, which requires significant clinical testing before submitting a new drug application for regulatory approval and potentially launching commercial sales if approval is granted. If we are unable to complete development of, obtain approval for and commercialize ABI-009 for one or more indications in a timely manner, our business will be harmed.
- In addition to ABI-009, our prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Results from early preclinical studies and clinical trials of our product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials of our product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.
- We have limited resources and are currently focusing our efforts on developing ABI-009 for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.
- The market opportunities for ABI-009 and other product candidates we develop, if approved, may be limited to certain smaller patient subsets.
- The recent global COVID-19 outbreak has affected and is expected to continue to affect our business and operations.
- If the FDA does not conclude that FYARRO for the treatment of advanced malignant PEComa satisfies the requirements under the 505(b)(2) regulatory pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for ABI-009 may take longer, cost

more or entail greater complications and risks than anticipated, which may delay or prevent the approval of FYARRO for commercial use.

- We may be unable to obtain United States or foreign regulatory approval for ABI-009 or our other product candidates and, as a result, may be unable to commercialize ABI-009 or our product candidates and our business will be substantially harmed.
- Even if our product candidates receive regulatory approval, they will be subject to significant ongoing post- marketing regulatory requirements and oversight.
- We may face difficulties from changes to current regulations and future legislation.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees.
- If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.
- If we do not obtain patent term extension for our product candidates, our business may be materially harmed.
- The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We contract with qualified third parties for the production of ABI-009 for preclinical studies and clinical trials and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of ABI-009 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We are dependent on a single-source supplier for the drug product ABI-009, and the loss of such supplier could harm our business.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.
- We entered into a collaboration agreement with EOC Pharma (“EOC”), and we may form or seek additional strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.
- We depend on EOC to develop and commercialize ABI-009 within the EOC Territory, and we have limited control over how EOC will conduct development and commercialization activities for ABI-009.
- Our stock price is expected to be volatile.
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical stage biopharmaceutical company, have a limited operating history, have not initiated or completed any large-scale clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk.

Our Phase 2 registrational study of our drug FYARRO (ABI-009, nab-sirolimus) (the “AMPECT trial”) for advanced (metastatic or locally advanced) malignant perivascular epithelioid sarcoma (“PEComa”) has been completed. A rolling New Drug Application (an “NDA”) submission for our lead product candidate, ABI-009, was completed in May 2021, and the U.S. Food and Drug Administration (the “FDA”) accepted our NDA in July 2021 and granted us Priority Review status with a Prescription Drug User Fee Act (“PDUFA”) target action date of November 26, 2021. Based on the AMPECT trial and emerging data for ABI-009 in other solid tumors with tumor-agnostic Tuberous Sclerosis Complex 1 and 2 (“TSC1 & TSC2”) alterations, and following discussions with the FDA, we plan to initiate a tumor-agnostic registrational trial in cancers harboring TSC1 & TSC2 inactivating alterations by the end of 2021, or in early 2022. Our other programs are in early clinical research stages. To date, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

We have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We may also need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have not generated any revenue from product sales to date and has financed our operations principally through private placements of our convertible preferred stock, federal grants and proceeds from licenses. Our net losses were \$94.1 million for the nine months ended September 30, 2021 and \$3.5 million for the year ended December 31, 2020. We had an accumulated deficit of \$126.7 million as of September 30, 2021 and \$32.6 million as of December 31, 2020. These losses have resulted primarily from a non-cash impairment charge of \$74.2 million related to the acquired contract intangible asset, costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant operating expenses for the foreseeable future due to the cost of research and development, including identifying and designing additional product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. We expect our expenses, and the potential for losses, to increase substantially as we conduct clinical trials of our lead product candidates and seek to expand our pipeline. The amount of our future expenses and potential losses is uncertain.

Even if we succeed in receiving regulatory approval for and commercializing one or more of our current and future product candidates, we expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital, our ability to fund the development of our product candidates, our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.

Our ability to generate product revenue sufficient to achieve profitability depends on the successful discovery, development and eventual commercialization of one or more of our current and future product candidates. To date, we have no products approved for commercial sale and do not anticipate generating any revenue from product sales until after we have received regulatory approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including, but not limited to:

- timely review and regulatory approval of our NDA submission for FYARRO for the treatment of advanced malignant PEComa by the FDA;
- demonstrating the safety and efficacy of ABI-009 to the satisfaction of the FDA and obtaining regulatory approval for ABI-009 and other current and future product candidates, if any, for which there is a commercial market;
- completing development activities, including planned clinical trials for ABI-009, successfully and on a timely basis;
- our ability to complete investigational new drug application (an "IND") enabling studies and successfully submit INDs or IND supplements or comparable applications, which become effective without any objections by the FDA or comparable regulatory authorities before commencing a clinical trial for any of our product candidates;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development of ABI-009 and our other future product candidates;
- timely receipt of regulatory approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing or contracting for an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- launching and successfully commercializing product candidates following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- negotiating and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- a continued acceptable safety profile following any regulatory approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-regulatory approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into and maintaining, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business or continue our operations and could cause a decline in the value of our common stock.

Even following the Merger and PIPE financing, we will require additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing and planned activities, particularly as we seek regulatory approval for, and the potential commercialization of, ABI-009. Our expenses could increase beyond our current expectations if we are required by the FDA, the European Medicines Agency (the “EMA”) or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical trials or the development of any of our product candidates. Other unanticipated costs may also arise. In addition, even if we obtain regulatory approval for any of our product candidates, including ABI-009, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution activities and ongoing compliance activities. Because the outcome of our NDA submission for the PEComa indication and the design and outcome of our planned and anticipated clinical trials is uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of ABI-009 for the PEComa indication, if approved, or any other product candidates or other indications we develop. We are not permitted to market or promote ABI-009, or any other product candidate, in the United States before we receive regulatory approval from the FDA. In addition, in connection with the completion of the Merger, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2021, we had \$161.4 million in cash and cash equivalents. Based on our current operating plan, we believe that our cash and cash equivalents will enable us to fund our planned operating expenses and capital expenditures into 2024. Our estimate as to how long we expect our cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our cash and cash equivalents to fund the commercialization of ABI-009 for the PEComa indication, if approved, ongoing and planned clinical trials of ABI-009 for other indications such as the TSC1 & TSC2 indications, for manufacturing operations and to fund our other research for other product candidates and development activities, as well as for working capital and other general corporate purposes. Advancing the development of ABI-009 and any other product candidate will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of ABI-009.

We will be required to obtain further funding to support our continuing operations through public or private equity offerings, debt financings, third-party funding, marketing and distribution arrangements, collaborations with third parties and licensing arrangements or other sources or a combination of these approaches, which may dilute our stockholders or restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our product candidates. Adequate additional financing may not be available to us in sufficient amounts or on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder and the possibility of such issuance may cause the market price of our shares to decline. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the conduct of our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to certain of our technologies or our product candidates, or grant licenses on terms that

are not favorable to us, which may have a material adverse effect on our business, operating results and prospects. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to significantly delay, reduce the scope of, suspend or eliminate one or more of our research or development programs, clinical trials or future commercialization efforts.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, ABI-009. If we are unable to complete development of, obtain approval for and commercialize ABI-009 for one or more indications in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely and successfully obtain regulatory approval for, and then successfully commercialize, ABI-009, our lead product candidate. We are investing the majority of our efforts and financial resources in the research and development of ABI-009 for multiple indications. ABI-009 is an injectable, albumin-bound nanoparticle form of sirolimus bound to albumin, for the treatment of malignant PEComa, as well as other cancer types with mTOR pathway alterations in the *TSC1* & *TSC2* genes that are most likely to respond to mTOR treatment.

In May 2021, we completed the filing of a rolling NDA for ABI-009 to the FDA for approval to treat patients with advanced malignant PEComa, and the FDA accepted our NDA in July 2021 and granted us Priority Review status with a PDUFA target action date of November 26, 2021. Our NDA is based on results from our AMPECT trial, involving patients for whom there are currently no approved therapies in the United States. In November 2019, we announced top-line results from the AMPECT trial, including that the study achieved its primary endpoint of objective response rate (the “ORR”) as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors (“RECIST”). ABI-009 will require additional clinical development, expansion of manufacturing capabilities, regulatory approval from the FDA and other regulatory authorities in jurisdictions where we plan to market ABI-009, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote ABI-009, or any other product candidate, before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of ABI-009 will depend on several factors, including the following:

- the timely receipt of regulatory approval for ABI-009 from applicable regulatory authorities;
- the extent of any required post-regulatory approval commitments to applicable regulatory authorities;
- the successful and timely completion of the required preclinical studies and clinical trials of ABI-009 for current and future indications;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of ABI-009;
- the successful launch of commercial sales following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- INDs going into effect with the FDA for our planned and future clinical trials;
- the initiation and successful patient enrollment and completion of additional clinical trials of ABI-009 on a timely basis, including the planned registrational Phase 2 study (“**PRECISION 1**”) of ABI-009 in patients with tumor-agnostic *TSC1* & *TSC2* alterations;
- maintaining and establishing relationships with CROs and clinical sites for the development of ABI-009 both in the United States and internationally;
- the type, frequency and severity of adverse events in clinical trials;
- demonstrating efficacy and safety profiles that are satisfactory to the FDA and any comparable foreign regulatory authority for regulatory approval obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;

- the protection of our rights in our intellectual property portfolio;
- a continued acceptable safety profile following any regulatory approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

In addition to advanced malignant PEComa, based on data from the completed AMPECT trial and our ongoing expanded access program, we are planning a registrational Phase 2 study, PRECISION 1, of ABI-009 in TSC1 & TSC2 alterations. We completed a Type B meeting with the FDA in which we discussed the initial trial design with the FDA. We plan to file the IND for ABI-009 in tumor-agnostic TSC1 & TSC2 alterations and initiate a registrational clinical trial by the end of 2021, or in early 2022. Our product development costs could increase if we experience delays. Significant trial delays also could shorten any periods during which we may have the exclusive right to commercialize ABI-009 or allow our competitors to bring products to market before we do, which would impair our ability to successfully capitalize on ABI-009 and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of clinical development of ABI-009 include, among other things:

- unexpectedly high rate of patients withdrawing consent or being lost to follow-up;
- feedback from the FDA and foreign regulatory authorities, institutional review boards (“IRBs”), or a data safety monitoring board, or results from clinical trials that might require modification to a clinical trial protocol;
- imposition of a clinical hold by the FDA or other regulatory authorities, a decision by the FDA, other regulatory authorities, IRBs or us, or a recommendation by a data safety monitoring board to suspend or terminate trials at any time for safety issues or for any other reason;
- deviations from the trial protocol by clinical trial sites and investigators or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of ABI-009 to the clinical trial sites;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse drug reactions;
- failure to demonstrate the efficacy of ABI-009 in this clinical trial;
- changes in government regulations or administrative actions or lack of adequate funding to continue the trials; or
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters and public health epidemics, such as the COVID-19 outbreak.

An inability by us to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of our current or any future collaborators. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize ABI-009, which would materially harm our business. If we do not receive regulatory approvals for ABI-009 or other product candidates, we may not be able to continue our operations.

In addition to ABI-009, our prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates other than ABI-009. All of our current product candidates other than ABI-009 are in research or preclinical development. Prior to initiating clinical trials with our other product candidates, we will need to file an IND or similar application to the FDA or regulatory authorities in other

jurisdictions. we may not be able to file future INDs for our product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory clearance for our trials may prevent us from developing our product candidates on a timely basis, if at all. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient preclinical data to support the initiation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct preclinical studies and clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- generating sufficient safety and efficacy data to warrant continued development and which are satisfactory to the FDA or any other regulatory authority for marketing approval.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

The preclinical studies and clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results, which would prevent, delay, or limit the scope of development, regulatory approval and commercialization.

Before obtaining regulatory approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we, among other requirements, must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product candidates. Each product candidate must demonstrate an adequate risk versus benefit profile in our intended patient population and for our intended use. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is inherently uncertain. A failure of one or more preclinical studies or clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies in the biopharmaceutical industry that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that require us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;

- clinical trial sites or our CRO failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- delays due to the recent COVID-19 pandemic, including starting any clinical trials for other indications or programs.

For instance, we do not know whether ABI-009 will perform in current or future clinical trials as it has performed in preclinical studies or prior clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Additionally, while we are aware of several other approved and clinical-stage mTOR inhibitors being developed by multiple other companies, to our knowledge, there are no mTOR inhibitors approved specifically for the treatment of advanced malignant PEComa. As such, the development of ABI-009 and our stock price may be impacted by inferences, whether correct or not, that are drawn between the success of our product candidate and those of other companies' mTOR inhibitors. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may (i) incur unplanned costs, (ii) be delayed in seeking and obtaining regulatory approval, if we receive such approval at all, (iii) receive more limited or restrictive regulatory approval, (iv) be subject to additional post-marketing testing requirements or (v) have the drug removed from the market after obtaining regulatory approval. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit their commercial potential.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with serious adverse events or other undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to conduct additional studies to further evaluate the product candidates' safety, interrupt, delay or abandon their development or halt clinical trials or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in a more restrictive label, delay or denial of regulatory approval or potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate, could substantially increase the costs of commercializing our product candidates and significantly impact our

ability to successfully commercialize our product candidates and generate revenues, and may harm our business, financial condition and prospects significantly. For example, in our AMPECT trial of ABI-009, most treatment-related adverse events were mild or moderate, with the most commonly reported adverse events being anemia, edema, infections, mucositis, pain, nail changes, vomiting, thrombocytopenia, hypertension and nausea. Treatment-related adverse events in our other oncology and PAH trials of ABI-009 included thrombocytopenia, diarrhea, fatigue, mucosal inflammation, nausea, anemia, and rash. Additionally, in our first- in-human study of ABI-009 in solid tumors, one patient died of dyspnea which was deemed possibly related to ABI-009.

Patients in our completed and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed or anticipated based on our preclinical studies or previous clinical trials. ABI-009 or other product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, ABI-009 is being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with ABI-009 or our other product candidates may also be undergoing surgical, radiation and/or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our ABI-009 clinical trials will die or experience major adverse clinical events either during the course of our clinical trials or after such trials, which has occurred in the past.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an institutional review board may suspend or terminate clinical research at any time for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development.

Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains regulatory approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to (i) conduct additional clinical safety trials, (ii) add additional contraindications, warnings and precautions to the drug label, (iii) significantly restrict the use of the product, (iv) change the way the product is distributed or administered, (v) implement a risk evaluation and mitigation strategy, or create a medication guide outlining the risks of such side effects for distribution to patients, or (vi) suspend or withdraw the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical trials.

Results from early preclinical studies and clinical trials of our product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our product candidates. If we cannot replicate the results from our earlier preclinical studies and clinical trials of our product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any results from early preclinical studies and clinical trials of our product candidates may not necessarily be predictive of the results from later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies and clinical trials of our product candidates according to our current development timeline, the results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies

that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

Additionally, some of our ongoing, planned and future clinical trials utilize an open-label study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a controlled environment with a placebo or active control.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the preliminary data from our completed AMPECT trial of ABI-009 in patients with malignant PEComas. The preliminary data is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, ABI-009 or any other product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Adverse results of clinical trials conducted by third parties investigating the same product candidates as us in different territories could adversely affect our development of such product candidate.

Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating the same product candidates as us in different territories for the same or different indications. For example, pursuant to the exclusive license agreement (the “EOC License Agreement”) with EOC Pharma (Hong Kong) Limited (“EOC”) for the development and commercialization of ABI-009 in Greater China, including the Republic of China, Hong Kong, Macau and Taiwan (collectively, the “EOC Territory”), EOC has been granted the right to develop and commercialize the same compounds licensed to us, as specified in the EOC License Agreement, including ABI-009, in the EOC Territory and, subject to certain restrictions, to collaborate with others for such development and commercialization. We do not have control over

EOC's clinical trials or development program, and adverse findings from or EOC's conduct of clinical trials could adversely affect our development of ABI-009 or the viability of ABI-009 as a product candidate. We may be required to report EOC's adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of ABI-009.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Orphan indications, in particular, have small populations, and it may be difficult for us to locate and enroll sufficient patients in trials for orphan-designated indications. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to identify and enroll eligible patients for clinical trials may be limited or may result in slower enrollment than we anticipate. For instance, patients for our trials for the TSC1 & TSC2 study are screened using genomic information to identify alterations in the TSC1 & TSC2 genes and utilizing such criteria and/or certain highly specific criteria related to the cancer sub-types may limit patient populations eligible for our clinical trials. In particular, because we are focused on patients with specific genetic mutations for certain of our development programs, our ability to enroll eligible patients may be limited or may result in slower enrollment than anticipated. For example, with respect to ABI-009, we cannot be certain how many patients will harbor the TSC1 & TSC2 mutations that ABI-009 is designed to target or that the number of patients enrolled for each mutation will suffice for regulatory approval and inclusion of each such mutation in the approved label. We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. If our strategies for patient identification prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for ABI-009.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment for one or more of our trials. Patient enrollment and retention for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol or as mandated by regulatory agencies;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- the ability to recruit clinical study investigators with the appropriate competencies and experience;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and

- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, there is a risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials. As a result, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

We expect to develop ABI-009 and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop ABI-009 and potentially other product candidates, in combination with one or more currently approved or unapproved therapies to treat cancer or other diseases. Patients may not be able to tolerate ABI-009 or any of our other product candidates in combination with other therapies or dosing of ABI-009 in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates, the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions requiring additional clinical trials, or our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain regulatory approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with ABI-009 or any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop. These unapproved therapies face the same risks described with respect to our product candidates currently in development, including serious adverse effects and delays in their clinical trials. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited resources and are currently focusing our efforts on developing ABI-009 for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately prove to be more profitable or to have a greater likelihood of success.

We are currently focusing our resources and efforts on developing ABI-009 for particular indications and advancing our preclinical programs for certain other product candidates. As a result, because we have limited financial and managerial resources, we may forgo or delay pursuit of opportunities for other indications or with

other product candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research and development activities for ABI-009 and other programs may not yield any commercially viable drugs. If we do not accurately evaluate the likelihood of clinical trial success, commercial potential or target markets for ABI-009 or any of our other product candidates, we may relinquish valuable rights to that product candidate or program through collaboration, licensing or other strategic or royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or achieve regulatory approval before we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates and products, if approved. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with drugs that physicians currently use to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, government agencies, universities and other research institutions. We also compete with these organizations to recruit and retain management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We are not aware of any FDA- or EMA -approved products indicated specifically for the treatment of advanced malignant PEComa. Patients with malignant PEComa commonly receive chemotherapy regimens and currently mTOR inhibitors including sirolimus, everolimus, and temsirolimus are recommended in the National Comprehensive Cancer Network (the "NCCN") guidelines for treatment of advanced malignant PEComa based on published retrospective data. For tumor agnostic TSC1 & TSC2 inactivating alterations, there are no existing FDA- or EMA-approved products indicated for such use. If ABI-009 receives regulatory approval, it may face competition from other drug candidates in clinical trials that target the mTOR pathway. These may include dual mTORC1/2 inhibitors in clinical trials or next generation mTOR inhibitors in development. Any potential competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than us. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in the field before us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may

develop. Our competitors also may obtain regulatory approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve regulatory approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any products we may develop, if approved, could be adversely affected.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical studies and clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce alternative formulations or dosage forms of ABI-009 into the planned PRECISION 1 trial. Such material changes will require regulatory approval before implementation and carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success, which would limit the revenue that we generate from our sales.

Even if our product candidates receive regulatory approval, the approved product candidates may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, among others:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities or the willingness of patients to pay out-of-pocket in the absence of third-party payor coverage;
- the availability of an approved product candidate for use as a combination therapy;
- the prevalence and severity of any adverse effects associated with any approved product candidate;
- any restrictions on the use of our product candidates together with other medications;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, in addition to treating target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

The market opportunities for ABI-009 and other product candidates we develop, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.) and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor- targeted therapies, more invasive forms of surgery and new technologies. Our completed and planned clinical trials for ABI-009 are with patients who may have received one or more prior treatments. There is no guarantee that product candidates that we develop, even if approved, would be approved for first-line or second-line therapy, including FYARRO for the treatment of advanced malignant PEComa, and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates, which may prove to be incorrect. Additionally, the potentially addressable patient population for ABI-009 and other product candidates may be limited or may not be amenable to treatment with our product candidates. Regulatory approval may limit the market of a product candidate to target patient populations when such biomarker-driven identification and/or highly specific criteria related to the stage of disease progression are utilized. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

Even if we obtain significant market share for any approved product, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We may not be successful in growing our product pipeline through acquisitions and in-licenses.

We believe that accessing external innovation and expertise is important to our success; and while we plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio, we may not be able to identify suitable licensing or acquisition opportunities, and even if we do, we may not be able to successfully secure such licensing and acquisition opportunities. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully license or acquire additional product candidates to expand our portfolio, our pipeline, competitive position, business, financial condition, results of operations, and prospects may be materially harmed.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive regulatory approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not

be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain regulatory approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products, which would include any product candidates for which we may obtain regulatory approval. Market acceptance and sales of our product candidates will depend on reimbursement policies and may be affected by healthcare reform measures. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance. Third-party payors decide which drugs they will pay for and establish reimbursement levels. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor’s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. Factors that payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under our health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (an “ASP”) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to prescription drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, the U.S. Department of Health and Human Services, our (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such laws once we begin commercialization after obtaining regulatory approval for any of our products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any

new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives regulatory approval. To obtain favorable reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be unavailable or reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If reimbursement is conditioned upon our completion of additional clinical trials, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products, the prices of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have a material adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with our product candidates. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend against them, we could incur substantial liabilities. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our (or third-party) manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain or maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline.

The recent global COVID-19 outbreak has affected and is expected to continue to affect our business and operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. To date, the COVID-19 pandemic has caused significant disruptions to the United States and global economy. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates. The COVID-19 pandemic caused us to modify business practices (including but not limited to curtailing or modifying employee travel, curtailing or modifying our clinical trials, moving to full remote work, and cancelling physical participation in meetings, events, and conferences). For example, we have experienced some clinical development disruptions due to the pandemic, including closures at certain lab facilities, which led to longer than anticipated clinical development times. In addition, our clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings can also make it more difficult to enroll new patients in ongoing or planned clinical trials.

As a result of the evolving COVID-19 pandemic, we have experienced and expect to continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- continued delays or difficulties in enrolling and retaining an adequate number of patients in our clinical trials;
- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations (“CMOs”) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including as a result of the COVID-19 pandemic;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require changes in the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The extent of the impact of the COVID-19 pandemic on our future liquidity and operational performance will depend on certain developments, including the duration and spread of the outbreak, the availability and effectiveness of vaccines, the impact on our clinical trials, patients, and collaboration partners, and the effect on our suppliers.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If the FDA does not conclude that FYARRO for the treatment of advanced malignant PEComa satisfies the requirements under the 505(b)(2) regulatory pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for ABI-009 may take longer, cost more or entail greater complications and risks than anticipated, which may delay or prevent the approval of FYARRO for commercial use.

We submitted a Section 505(b)(2) NDA to the FDA in May 2021 for FYARRO for the treatment of advanced malignant PEComa, and the FDA has assigned a PDUFA target action date of November 26, 2021 as the goal to complete its review of the NDA. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the “FDCA”) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”) and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA’s previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA is not required to meet the PDUFA goal date, and the FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. If the FDA determines FYARRO does not meet the requirements of Section 505(b)(2), or that additional information is needed to support a marketing application for FYARRO, we could experience delays in obtaining marketing approval. Moreover, even if FYARRO is approved under the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which we may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We may be unable to obtain United States or foreign regulatory approval for ABI-009 or our other product candidates and, as a result, may be unable to commercialize ABI-009 or our product candidates and our business will be substantially harmed.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We submitted an NDA under Section 505(b)(2) to the FDA in May 2021 for FYARRO for the treatment of advanced malignant PEComa, and the FDA has assigned a PDUFA target action date of November 26, 2021 as the goal to complete its review of the NDA. We have not previously submitted an NDA or similar application for approval to the FDA or any other regulatory authority and we cannot assure that any of our product candidates will receive marketing approval. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon numerous factors, including the type, complexity and novelty of the product candidate. The standards that the FDA and our foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Additionally, as of March 18, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue, and our business will be substantially harmed.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Even if we eventually complete clinical testing and receives approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not obtained regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval.

Further, regulatory approval may be delayed for reasons beyond our control. For example, a United States federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, or the current diversion of resources to handle the COVID-19 public health emergency and pandemic may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to obtain regulatory approval for our product candidates. In addition, the impact of COVID-19 may cause the FDA to allocate additional resources to product candidates focused on treating related illnesses, which could lead to longer approval processes for our product candidates. Finally, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any of our NDAs.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;

- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us from obtaining regulatory approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- We may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests for our product candidates, if required; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Our clinical trials have been and may in the future be undertaken in the United States. We may choose to conduct additional clinical trials internationally as well. For example, we may conduct our PRECISION 1 trial of ABI-009 in the United States, Europe and other countries. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for regulatory approval in foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Brexit and uncertainty in the regulatory framework as well as future legislation in the United Kingdom (the "UK"), European Union, and other jurisdictions can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the European Union and/or the UK and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may

have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The regulatory approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States, as well as other risks. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Following Brexit, to the extent we conduct any operations in the UK, we will be subject to applicable regulatory requirements in the UK. Although the UK is no longer a member of the European Union, European Union law remains applicable in Northern Ireland. There are a number of new marketing authorization routes available in the UK, Great Britain (England, Scotland and Wales) or Northern Ireland, in addition to the national procedure. As with the European Union position, a company can only start to market a medicine in the UK once it has received a marketing authorization. The main legislation that applies to clinical trials in the UK is the UK Medicines for Human Use (Clinical Trials) Regulations 2004, which transposes the Clinical Trials Directive into domestic law. Consequently, the requirements and obligations that relate to the conduct of clinical trials in the UK currently remain largely aligned with the European Union position. It is unclear how future regulatory regime in the UK will impact regulations of products, manufacturers, and approval of product candidates in the UK. In the immediately foreseeable future, the UK regulatory approval process is likely to remain similar to that applicable in the European Union, albeit that the processes for applications will be separate. Longer term, the UK is likely to develop its own legislation that diverges from that in the European Union.

Even if our product candidates receive regulatory approval, they will be subject to significant ongoing post- marketing regulatory requirements and oversight.

Even if we receive regulatory approval for our product candidates, they will be subject to ongoing regulatory obligations and continued review by regulatory authorities, which may include imposing significant restrictions on our product candidates, indicated uses or marketing, or imposing ongoing requirements for potentially costly post-approval studies. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. For example, the FDA may require the submission of a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices (“cGMPs”), good laboratory practices (“GLPs”) and good clinical practices (“GCPs”) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the product, manufacturers or manufacturing process;
- warning letters or untitled letters that would result in adverse publicity;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The holder of an approved NDA or comparable regulatory approval must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process and the FDA or comparable foreign regulatory authority may refuse to approve pending applications or supplements to approved applications filed by us.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of the company and our operating results will be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies, including the U.S. Department of Justice, strictly regulate the post-approval marketing and promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. As such, we may not promote our products for indications or uses for which they do not have approval. For example, if we receive regulatory approval for ABI-009 as a treatment for advanced malignant PEComa, physicians may, in their practice of medicine, use drug products for their patients in a manner that is inconsistent with the approved label. If we, or any of our contractors or agents acting on behalf of us, are found to have promoted such off-label uses, we may become subject to significant liability. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic product in connection with approval of any future product in candidates or new indication that we may develop, and if we fail to obtain or faces delays in obtaining FDA approval of such companion diagnostic product, we will not be able to commercialize such product candidate intended for use with such companion diagnostic product and our ability to generate revenue from such product candidate will be materially impaired.

In connection with the development of any future product candidates or new indication we may develop or work with collaborators to develop or obtain access to companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our programs. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of any future product candidates or new indication we may develop. To be successful in developing and commercializing such product candidate in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any future product candidate or new indication that we may develop, whether before or concurrently with approval of such product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/ specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for any future product candidate or new indication, or experience delays in doing so, the development of such product candidate may be adversely affected, the product candidate may not obtain marketing approval, and we may not realize the full commercial potential of such product candidate after obtaining marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of any such future product candidate or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements

with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of any such future product or new indication, or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of any such future product candidate we may develop.

A Fast Track or Breakthrough Therapy designation for ABI-009 may not lead to a faster development or review process, or we may be unable to maintain or effectively utilize such a designation. We may also seek additional Fast Track designations from the FDA for ABI-009 or any of our other product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

In October 2018, we announced that the FDA granted Fast Track designation for ABI-009 for the investigation of the treatment of patients with advanced malignant PEComa. This Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures or that it will ultimately obtain regulatory approval of ABI-009. Even though we received this Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw the Fast Track designation if it believes that the Fast Track designation is no longer supported by data from our clinical development program. We may also seek Fast Track designation for additional cancer indications or other diseases, and we may not be successful in securing such additional designation or in expediting development if such designations were received.

Fast Track designation is designed to facilitate the development and expedite the review of therapies intended for the treatment of a serious or life-threatening condition which demonstrate the potential to address unmet medical needs for the condition. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. The FDA may withdraw any Fast Track Designation at any time. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

In December 2018, we announced that the FDA granted Breakthrough Therapy designation for ABI-009 for the treatment of patients with advanced malignant PEComa. We may also seek a Breakthrough Therapy designation for ABI-009 for various cancer indications or other diseases. Breakthrough Therapy designation is for a product candidate that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request the FDA to designate our product candidate as a Breakthrough Therapy at the time of, or any time after, the submission of an IND for the product candidate. For product candidates that have been designated as a Breakthrough Therapy, the FDA may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the product candidate; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

The FDA has broad discretion in determining whether to grant a Fast Track or Breakthrough Therapy designation for a drug. Obtaining a Fast Track or Breakthrough Therapy designation does not change the standards for product approval but may expedite the development or approval process. There is no assurance that the FDA will grant either such designation for any other indication or product candidate that we may pursue. Even if the FDA does grant either such designation, it may not actually result in faster clinical development or regulatory review or

approval. Furthermore, such a designation does not increase the likelihood that ABI-009 will receive regulatory approval in the United States.

We may not be able to obtain or maintain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, such exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if orphan drug designation is granted for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain regulatory approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, that the orphan drug exclusivity may not effectively protect an approved product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

We received orphan drug designation from the FDA for ABI-009 for the treatment of advanced malignant PEComa. We may be unable to obtain regulatory approval for ABI-009 for this orphan population or any other orphan population, or we may be unable to successfully commercialize ABI-009 for such orphan population due to risks that include:

- the orphan patient populations may change in size;
- there may be changes in the treatment options for patients that may provide alternative treatments to ABI-009;
- the development costs may be greater than projected revenue of drug sales for the orphan indications;
- the regulatory agencies may disagree with the design or implementation of our clinical trials;
- there may be difficulties in enrolling patients for clinical trials;
- ABI-009 may not prove to be efficacious in the respective orphan patient populations;
- clinical trial results may not meet the level of statistical significance required by the regulatory agencies; and
- ABI-009 may not have a favorable risk/benefit assessment in the respective orphan indication.

If we are unable to obtain regulatory approval for ABI-009 for advanced malignant PEComa or any orphan population for which we obtain orphan drug designation or is unable to successfully commercialize ABI-009 for such orphan population, it could harm our business prospects, financial condition and results of operations.

We may not be able to obtain orphan drug exclusivity for ABI-009 or for one or more of our product candidates that we may develop in the future, and even if we do, that exclusivity may not prevent the FDA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan product candidates by the EMA in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for another similar product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates. Under the accelerated approval provisions in the FDCA, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that generally provides a meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the “ACA”), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the United States pharmaceutical industry. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the former Trump administration to repeal or replace certain aspects of the ACA. In June 2021, the Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this decision and other healthcare reforms will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional congressional action is taken. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Additionally, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public

list. In 2020, at the federal level, under the former Trump administration, HHS and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, importation of prescription drugs from Canada and other countries, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of these new rules. In January 2021, the Biden administration issued a “regulatory freeze” memorandum that directs department and agency heads to review new or pending rules of the prior administration. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at increasing competition for prescription drugs. In response to this executive order, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Implementation of cost containment measures or other healthcare reforms that affect the pricing and/or availability of drug products may impact our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act), was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA’s approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or in other jurisdictions. If we or our collaborators are slow or unable

to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Additionally, the collection and use of health data in the European Union is governed by the General Data Protection Regulation (the “GDPR”), which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals. Failure to comply with the GDPR and the applicable national data protection laws of the European Union Member States may result in fines up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (the “CCPA”), which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General, with fines set at \$2,500 per violation (i.e., per person) or \$7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and certain clinical trials data, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Some observers note that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Inadequate funding for the FDA, the Securities and Exchange Commission and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (the “SEC”) and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the United States government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products as well as routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and based on updated guidance issued in May 2021, FDA continues to conduct mission-critical inspections on a case-by-case basis, or, where possible to do so safely, has, since July 2020, resumed prioritized domestic inspections, which generally include pre-approval, pre-license, surveillance, and for-cause inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA’s inability to complete

required inspections for their applications. While the FDA indicated that it will consider alternative methods for inspections and exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities on a timely basis, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with other United States healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. Further, our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;

- the federal HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance effort;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value made to covered recipients in the previously year, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Additionally, beginning with data collected in 2021 and reported to CMS in 2022, such reporting obligations with respect to payments or other transfers of value made in the previous year to covered recipients have been extended to include new provider types: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse- midwives. our failure to submit required information timely, accurately, and completely may result in significant civil monetary penalties and may increase our liability under other federal laws or regulations; and
- additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance effort.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions or safe harbors, it is possible that some of our activities, including those of our contractors or agents who conduct business for or on behalf of us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal

expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Any of the foregoing consequences could seriously harm our business and our financial results. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraud, misconduct or other improper activities. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with federal and state health care fraud and abuse laws and regulations and similar foreign fraudulent misconduct laws; accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, certain customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we or any contract manufacturers and suppliers we engage fails to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures, the generation, handling, use, storage, treatment and disposal of hazardous and regulated

materials and wastes, the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. The operations of our contractors may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, including any contamination at our current or past facilities and at third-party facilities, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the United States Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as United States and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees are employed by the government and would be considered foreign officials under the FCPA, and often the purchasers of pharmaceuticals are government entities; therefore, our dealings with these doctors, hospital employees and purchasers are subject to regulation under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, collaborators, or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. If we fail to comply with export and import regulations, and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any

decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to our Business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers, key scientific personnel and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers or key scientific personnel could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than us. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with these advisors or they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team or infrastructure for distribution of product candidates. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services and we may not be successful in accomplishing these required tasks, which may negatively impact the successful commercialization of FYARRO for advanced malignant PEComa, if approved.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. If the commercial launch of a product candidate for which we recruit a sales team and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Alternatively, if we chooses to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on its own. If we are unable to enter into such arrangements when needed, on

acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 5, 2021, we had 21 full-time employees, including 14 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, development, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for ABI-009 and any other product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize ABI-009 and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of ABI-009 and any other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize ABI-009 and other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. To the extent that any disruption or security breach

were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information or individually identifiable health information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which it has formed strategic relationships. Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/ or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach of our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our current operations are located in California, and we or the third parties upon whom we depend, may be adversely affected by earthquakes, wildfires and other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 outbreak, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidate or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that

otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our ability to utilize our NOL carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under United States tax law. Our NOLs generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 taxable years under applicable United States federal tax law, and therefore could expire unused. Under the Tax Cuts and Jobs Act of 2017 (the “Tax Act”), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), Our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of our current year taxable income. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation and will continue to have a two-year carryback and twenty-year carryforward period. California recently enacted legislation limiting our ability to use our state NOLs for taxable years 2020, 2021, and 2022. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2020, we had federal NOL carryforwards of approximately \$3.5 million, which will begin to expire in 2037. In addition, we have \$27.4 million federal NOL carryforwards which do not expire. We also have available California NOL carryforwards of approximately \$27.4 million as of December 31, 2020, which begin to expire in 2037.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change” (generally defined as a cumulative change in the corporation’s ownership by “5-percent stockholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of the Merger or subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize our NOLs and certain other tax attributes could be limited by an “ownership change” as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

United States federal income tax reform could materially adversely affect our financial condition.

Legislation or other changes in United States and international tax laws could increase our tax liability and adversely affect after-tax profitability. For example, the Biden administration has proposed to increase the United States corporate income tax rate to 28% from 21%, increase the United States taxation of international business operations and impose a global minimum tax on corporate income. Such proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may have significant impacts on our effective tax rate, cash tax expenses and net deferred tax assets in future periods.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries for our product candidates, proprietary technologies and their uses, and know-how related to our business, as well as our ability to operate without infringing upon the valid and enforceable patents and proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our licensors will result in additional patents being issued in any particular jurisdiction or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for us and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although we own or license ten (10) issued patents in the United States, we cannot be certain that the claims in our other United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the United States Patent and Trademark Office (the "USPTO"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- if clinical trials encounter delays, the period of time during which we could market our current or future product candidates under patent protection would be reduced;
- patents may be challenged, invalidated, modified, narrowed, revoked, circumvented, found to be unenforceable, found to be not infringed or otherwise may not provide any competitive advantage;
- Our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that could limit, interfere with or eliminate our ability to make, use and sell our potential product candidates or design around any of our owned, co-owned, or licensed patents;
- since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product; or (ii) invent any of the inventions claimed in our patents or patent applications;
- even when laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, complex, and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our (or such licensor's) research and development output before it is too late to obtain patent protection. If we are unable to obtain or maintain patent protection with respect to any of our proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of some foreign countries do not protect our proprietary rights to the same

extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our pending and future patent applications and those of our licensors may not result in patents being issued that protect our product candidates or effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in-licenses currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-licenses may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents.

Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review (“PGR”) and *inter partes* review (“IPR”), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights or put its patent applications at risk of not issuing, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If any of our patents, if and when issued, covering our product candidates are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. We may not prevail in any lawsuits that we or any third-party initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- We or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- We may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement or misappropriation of the patents, intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, and because patent claims can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe or which such third parties claim are infringed by our technologies. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If a patent holder believes one or more of our product candidates infringes such holder's patent rights, the patent holder may sue us even if we have received patent protection. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this Quarterly Report, others may hold proprietary rights that could prevent our product candidates from being marketed. For example, various patent offices periodically grant mode of action patents and a third party may have or obtain a patent with claims covering modes of action relevant to our product candidates. While these mode of action patents may be difficult to enforce, the third party may assert a claim of patent infringement directed at one of our product candidates. Any patent-related legal action or any claim relating to intellectual property infringement that is successfully asserted against us claiming damages and seeking to enjoin commercial activities relating to our products or processes could subject us to significant liability for damages, including treble damages and attorney's fees if it was determined that we willfully infringed, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our current or future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent or delay us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We may also be unable to license or acquire third-party intellectual property rights on terms that would be favorable to us or allow us to make an appropriate return on our investment or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or intellectual property or our licensors' patents or intellectual property, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors and other third parties may infringe, misappropriate, or otherwise violate our patents and other intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the attention of our management and key personnel

from our business operations. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution of the patent application.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents or our licensors' patents in such a way that such patents no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patents or our licensors' patents invalid. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or the patents and patent applications of our licensors has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of

technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that our former employees or our licensors or other third parties have an ownership interest in our patents or other intellectual property. Confidentiality and intellectual property assignment agreements may not be honored and may not effectively assign intellectual property rights to us. The assignment of intellectual property rights under these agreements may not be automatic upon the creation of the intellectual property or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against it, to determine the ownership of what we regard as our intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional effective filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to us.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates, one or more of our United States patents or those of our licensors may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be

reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we own, co-own, or have licensed at least ten (10) issued patents in the United States and pending patent applications in the United States and other countries, filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, the statutory deadlines for pursuing patent protection in individual foreign jurisdictions, are based on the priority date of each of our patent applications and we may not timely file foreign patent applications.

Competitors may use our technologies in jurisdictions where we do not pursue or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed patents and/or applications will be due to be paid to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our licensors and any patent rights we may own or license in the future. We have systems in place to remind us to pay these fees, and, in certain instances, we rely on our licensor partners to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and over the lifetime of our owned patents and applications. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, competitors or other third parties might be able to enter the market earlier than would

otherwise have been the case and it could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market our self and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We may also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. However, trade secrets are difficult to protect. For example, we may be required to share our trade secrets with third-party licensees, collaborators, consultants, contractors, or other advisors and we have limited control over the protection of trade secrets used by such third parties. Although we have taken steps to protect our trade secrets and unpatented know-how, including by entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed or that they have been obtained in all circumstances, and it is possible that any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Enforcing a claim that a party illegally obtained, disclosed, used or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. If any of these events occurs or if we otherwise lose protection for our trade secrets or confidential or proprietary information, the value of this information may be greatly reduced, and our competitive position in the marketplace, business, financial condition, results of operations and prospects may be materially adversely affected. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees, consultants or advisors inadvertently or otherwise breached the agreements

and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including competitors or our potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into license agreements with third parties and we may enter into additional license agreements in the future with others to advance our research or allow commercialization of product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we had licensed may be reduced or eliminated, and our rights to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experiences disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us and our licensors and partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensors or collaboration partners, including those licensed to us under our license agreements. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any invention that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for United States-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-United States manufacturers.

Our licensed patent applications may have been or may be in the future supported through the use of United States government funding awarded by the National Institute of Health or the FDA Office of Orphan Products Development, and the Army Medical Research and Development Command. Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we have licensed, or may acquire or license in the future, intellectual property rights that have been generated through the use of United States government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. These United States government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (“march-in rights”). The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

Risks Related to Our Reliance on Third Parties

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and highly regulated and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and efficacy. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or efficacy of the products before and after such changes. If microbial, viral or other contaminations or impurities are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination or impurity, which could delay clinical trials and adversely harm our business. If our third-party manufacturers are unable to produce sufficient quantities of consistent quality for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We entered into a license agreement with Abraxis BioScience, LLC pursuant to which we have licensed exclusive global rights to intellectual property and know-how related to ABI-009. We are required to use commercially reasonable efforts or diligent efforts to commercialize products based on the licensed rights and to pay certain royalties based off our net sales, certain sublicense fees (such as with respect to our license agreement with EOC) and certain other fees. We may not meet these requirements, which could result in a loss or termination of any

rights under such agreements. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to commercialize our product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described above under “Risks Related to Our Intellectual Property.” If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We contract with qualified third parties for the production of ABI-009 for preclinical studies and clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties, some of which are sole source suppliers, increases the risk that we will not have sufficient quality and quantities of ABI-009 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of ABI-009, we rely on a single third-party manufacturer, Fresenius-Kabi, and currently has no alternative manufacturer in place. We do not currently have any long-term supply agreements, and, to date, we have obtained our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. We have supply agreements in place for key raw materials used in the manufacture of ABI-009 such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. In addition, we are presently negotiating a supply agreement with Fresenius-Kabi for the commercial manufacture of ABI-009, but there is no assurance that we will be able to enter into such agreement on acceptable terms, or if at all. If we were to engage another third-party manufacturer, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a bridging study, that any new manufacturing process will produce our product candidate or product, if approved, according to the specifications previously submitted to the FDA or another regulatory authority. If we were to experience an unexpected loss of supply of ABI-009 or any other product candidates we may develop in the future for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials or commercialize our product candidates, including FYARRO for advanced malignant PEComa, if approved, in a timely manner or on budget.

We expect to rely on third-party manufacturers for the commercial supply of ABI-009, if approved, and the continued development of ABI-009 in other indications or any other product candidates we may develop in the future for which we obtain regulatory approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Further, any delay in identifying and qualifying a manufacturer for commercial production could delay the potential commercialization of ABI-009, and, in the event that we do not have sufficient product to complete our planned clinical trials, it could delay such trials. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture ABI-009 or any of our other product candidates that we may develop in the future according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates, are constrained by the recent COVID-19 pandemic or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including manufacturing drug supply pursuant to strictly-enforced cGMPs;
- the failure of the third-party contractor to manufacture ABI-009 or any of our other product candidates that we may develop in the future according to our specifications;

- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients (“API”) and finished drug products. To date, we have obtained drug substance and drug product from third-party manufacturers to support preclinical and clinical testing of ABI-009. For example, we have obtained our supplies of ABI-009 from a single source supplier, Fresenius-Kabi. We have supply agreements in place for key raw materials used in the manufacture of ABI-009 such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product. We are in the process of developing our supply chain for ABI-009 and are presently negotiating a supply agreement with Fresenius-Kabi for the commercial manufacture of ABI-009. As we advance our product candidates through development, we will consider redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to pass a pre-approval inspection or secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we do not have control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, many of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our CMOs facilities generally. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of ABI-009 or any of our other product candidates that we may develop in the future or if we withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain regulatory approval for or market ABI-009 or any of our other product candidates that we may develop in the future, if approved. Our reliance on CMOs also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on the parties, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of ABI-009 or any of our other product candidates or drugs that we may develop in the future and harm our business and results of operations.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of ABI-009 or in our third-party manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any stability or other issues relating to the manufacture of our product candidates may occur in the future. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders,

shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at our third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for ABI-009 or any of our product candidates that we may develop in the future. Further, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects. Our current and anticipated future dependence upon others for the manufacture of ABI-009 and any of our other product candidates that we may develop in the future may adversely affect our future profit margins and our ability to commercialize ABI-009, if approved, or any other product candidates that we may develop in the future that receives regulatory approval on a timely and competitive basis.

We are dependent on a single-source supplier for the drug product ABI-009, and the loss of such supplier could harm our business.

We rely on a single-source supplier, Fresenius-Kabi for our drug product ABI-009. While we have supply agreements in place for key raw materials used in the manufacture of ABI-009 such as for the drug substance sirolimus and for human albumin, which are key ingredients in the drug product, we place purchase orders from Fresenius-Kabi on an as-needed basis. Our suppliers could discontinue the manufacturing or supply of ABI-009 at any time. We do not carry a significant inventory of ABI-009 or our key raw materials used in the manufacture of ABI-009. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us either entirely or for a particular territory. The loss of any of the foregoing would require significant time and effort to locate and qualify an alternative source of supply. Though we do not currently have contracts for third parties to provide manufacturing capabilities for ABI-009, if we are successful in reaching the point of manufacturing our products for commercialization, we may rely on a single company for such manufacturing. Any contractual disputes between us and such manufacturer or loss of manufacturing ability by such manufacturer could similarly require significant time, effort and expense to locate and qualify an alternative source of manufacturing, which could materially harm our business.

In addition, we might not be able to identify and qualify additional or replacement suppliers for the drug product ABI-009 or for the key raw materials used in the manufacture of ABI-009 quickly or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. In addition, we do not currently have arrangements in place for redundant supply of the drug product ABI-009 or for the key raw materials used in the manufacture of ABI-009.

Establishing additional or replacement suppliers for the drug product ABI-009 or for the key raw materials used in the manufacture of ABI-009, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis. Our inability to obtain sufficient quantities of the drug product ABI-009 or for the key raw materials used in the manufacture of ABI-009 also could adversely affect clinical development of the ABI-009. If we are not able to identify alternate sources of supply for the drug product ABI-009 or for the key raw materials used in the manufacture of ABI-009, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct all of our preclinical studies and clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct, supervise and monitor our current or planned preclinical studies and clinical trials of ABI-009, and we expect to continue to rely upon third parties to conduct additional preclinical studies and clinical trials of ABI-009 and other product candidates we may develop in the future. We enter into agreements with third parties that have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the conduct of such third party, the amount or timing of resources that any such third party will devote to our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. The third parties we rely on for these services may also (i) have staffing difficulties, (ii) fail to comply with contractual obligations, (iii) experience regulatory compliance issues, (iv) undergo changes in priorities or become financially distressed, or (v) have relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies and clinical trials being delayed or unsuccessful. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, we would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and legal, regulatory, and scientific requirements and standards. Moreover, the FDA requires us and our third parties to comply with applicable GLP and GCP standards, regulations for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to assure that the data and reported results are reliable and accurate and for clinical trials that the rights, integrity and confidentiality of trial participants are protected and that they are adequately informed of the potential risks of participating in clinical trials. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies and clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product candidates produced under current cGMP regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not successfully carry out their contractual duties or perform preclinical studies and clinical trials in a satisfactory manner, meet expected deadlines or conduct our preclinical studies and clinical trials in accordance with legal and regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We entered into a collaboration agreement with EOC Pharma, and we may form or seek additional strategic alliances or collaborations in the future. Such alliances and collaborations may inhibit future opportunities, or we may not realize the benefits of such collaborations or alliances.

In December 2020, we granted to EOC exclusive rights to develop and commercialize ABI-009 in the EOC Territory, pursuant to the EOC License, and we may form or seek strategic alliances, joint ventures or collaborations or enter into licensing arrangements with other third parties that we believe will complement or augment our development and commercialization efforts with respect to ABI-009 or any future product candidates that we may develop. Under the EOC License Agreement, we received an upfront payment and are eligible to receive regulatory and sales-based milestone payments upon the occurrence of certain milestone events

totaling \$257 million. we are also eligible to earn tiered royalties based on annual net sales of ABI-009 based upon the royalties we are obligated to pay Abraxis for sales of products in the EOC Territory pursuant to the Abraxis License, plus an additional single-digit percentage that is variable based on the level of annual net sales. EOC will be responsible for development, regulatory submissions, and commercialization in the EOC Territory. We retain our rights outside of the EOC Territory.

Future efforts for additional alliances or collaborations may also require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Furthermore, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

We depend on EOC to develop and commercialize ABI-009 within the EOC Territory, and we have limited control over how EOC will conduct development and commercialization activities for ABI-009.

Under the EOC License Agreement, we rely on EOC for a substantial portion of the financial resources and for the development, regulatory, and commercialization activities for ABI-009 in the EOC Territory, and we have limited control over the amount and timing of resources that EOC devotes to ABI-009. In addition, payments associated with development, regulatory and commercial milestones that we may be eligible to receive, as well as royalties, will be dependent upon further advancement of the ABI-009 by EOC. If these milestones are not met and if ABI-009 is not commercialized in the EOC Territory, we will not receive future revenues from the collaboration. EOC may fail to develop or effectively commercialize ABI-009 for a variety of reasons and the EOC License Agreement subjects us to a number of risks, including:

- EOC may not commit sufficient resources to the development, regulatory approval, marketing, or distribution of ABI-009;
- EOC may be unable to successfully complete the clinical development of ABI-009 or obtain all necessary approvals from foreign regulatory agencies in the EOC Territory required to market ABI-009;
- EOC may terminate their agreement with us prior to completing development or commercialization of the ABI-009 under the collaboration, in whole or in part, adversely impacting the potential approval and our revenue from the licensed product;
- EOC may fail to manufacture ABI-009 in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand;
- there may be disputes between us and EOC, including disagreements regarding the EOC License Agreement with us, that may result in (1) the delay of (or prevent entirely) the achievement of development, regulatory and commercial objectives that would result in milestone payments, (2) the delay or termination of the development or commercialization of ABI-009 in the EOC Territory, costly litigation or arbitration that diverts our management's attention and resources; and/or
- termination of the underlying license agreement;
- EOC may not comply with applicable regulatory guidelines with respect to developing or commercializing ABI-009, which could adversely impact the development of or sales of ABI-009 and could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;
- EOC may experience financial difficulties;
- business combinations or significant changes in either the business strategy of EOC may also adversely affect EOC's ability to perform its obligations under its license agreement with us;
- EOC may not properly maintain our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- EOC may develop or commercialize ABI-009 in a manner that may adversely impact our development or commercialization of ABI-009 and/or future product candidates outside of such collaboration; and

- Although EOC is subject to a limited non-compete obligation, EOC could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

If EOC does not perform in the manner we expect or fulfill our responsibilities in a timely manner, or at all, the development, regulatory approval, and commercialization efforts related to ABI-009 could be delayed. It may be necessary for us to assume the responsibility at our own expense for the development of ABI-009 in the EOC Territory. In that event, we would likely need to seek additional funding and our potential to generate future revenues from ABI-009 could be significantly reduced and our business could be materially and adversely harmed.

We have entered into collaborations with third parties in connection with the development of ABI-009. Even if we believe that the development of such product candidate is promising, our partners may choose not to proceed with such development.

Our existing agreement with EOC, and any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances, including, in the case of EOC, without cause subject to a specified notice period. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, we may not receive additional milestones or royalties under those collaborations. In addition, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us.

We are also at risk that our current and any potential collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- Our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their efforts under their collaboration agreement with us;
- Our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- Our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- Our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition, and operating results may be adversely affected.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property, and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- Our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

If we decide to establish additional collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business

combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than us;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product, if approved, relative to other products;
- We may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from us collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

General Risks

Our stock price is expected to be volatile.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- Our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- the failure of any of our product candidates, if approved for marketing and commercialization, to achieve commercial success;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements;
- adverse regulatory authority decisions;

- the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- changes in laws or regulations applicable to our product candidates;
- the results of current, and any future, nonclinical or clinical trials of our product candidates;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our potential products;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the loss of key employees;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in the structure of health care payment systems;
- adverse regulatory decisions;
- trading volume of our common stock; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management's attention and resources, which could significantly harm our profitability and reputation.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We must maintain effective internal controls over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, and therefore will be able to take advantage of certain exemptions from various reporting requirements that are applicable to other companies that are not “emerging growth companies” including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We rely heavily on direct management oversight of transactions, along with the use of legal and outsourced accounting professionals. As we grow, we plan to hire additional personnel and engage in external temporary resources and may implement, document, and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management’s review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company. If we fail to staff our accounting, finance and information technology functions adequately or maintain internal control over financial reporting adequate to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States are expensive and time- consuming, and our management will be required to devote substantial time to compliance matters.

Following the recently completed Merger, we have incurred and expect to continue to incur significant additional legal, accounting and other expenses as a publicly-traded company that we did not incur as a privately-held company, including costs associated with public company reporting requirements. The obligations of being a public company in the United States require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) and the Nasdaq listing requirements. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. For example, our management team consists of executive officers and other personnel of the operating company that survived the Merger prior to the Merger, some of whom have not previously managed and operated a public company. Thus, our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems. In addition, these rules and regulations may also make it difficult and expensive for us to obtain and maintain director’s and officer’s liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence in and could cause our business or stock price to suffer.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq’s listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;

- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of new and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our principal stockholders and management own a significant percentage of our common stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant portion of our outstanding voting stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact the elections of directors, amendments to our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholder and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

A significant portion of our total outstanding shares of common stock are restricted from immediate resale in connection with the closing of the Merger but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of the completion of the Merger, (i) the Private Aadi stockholders owned, collectively, approximately 29.2% of the outstanding shares of our common stock, on a fully-diluted basis, (ii) Aerpio’s stockholders owned, collectively, approximately 15.2% of the outstanding shares of our common stock, on a fully-diluted basis, and (iii) the PIPE Investors owned, collectively, approximately 55.6% of the outstanding shares of common stock, on a fully-diluted basis. Concurrently with the execution of the Merger Agreement, certain of the Aerpio directors who continue to serve on our board of directors and certain stockholders of Private Aadi, which collectively owned or controlled an aggregate of approximately 96.08% of Private Aadi’s voting securities, entered into lock-up agreements with us, pursuant to which such parties have agreed not to, except in limited circumstances, sell or transfer, or engage in swap or similar transactions with respect to, shares of our common stock, including, as applicable, shares received in the Merger and issuable upon exercise of certain warrants and options, from the closing of the Merger until 180 days from the closing date of the Merger. Pursuant to the Merger Agreement, certain directors and executive officers of ours also executed lock-up agreements prior to the closing of the Merger. However, these shares of common stock may be sold after the expiration of the respective applicable lock-up agreement. Pursuant to the Merger Agreement and the Subscription Agreement with the PIPE Investors, respectively, we were required to file one or more registration statements to provide for the resale of the shares issued in the Merger and the PIPE Financing. As restrictions on resale end and these registration statements are available for use, the market price of our common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds.

We are a “smaller reporting company” under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed second fiscal quarter, has an aggregate market value of the company’s voting stock held by non-affiliates, or public float, of less than \$250 million, or has at least \$100 million in revenue and at least \$700 million in public float. SEC rules provide that companies with a non-affiliate public float of less than \$75 million may only sell shares under a Form S-3 shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the public float. If we do not meet this public float requirement, any offering by us under a Form S-3 will be limited to raising an aggregate of one-third of our public float in any 12-month period. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings, is exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting if its public float is less than \$75

million, and has certain other reduced disclosure obligations in our SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain, if any, for the foreseeable future.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We will be highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and by-laws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated by-laws provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the DGCL, or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, our amended and restated certificate of incorporation or our by-laws (including the interpretation,

validity or enforceability thereof), or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the by-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our by-laws described above

We are a California-domiciled public company and will be required to have at least two or three women on our board of directors by the end of 2021, depending on the size of our board at the time.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we will be required to have two or three women on our board of directors by the end of 2021, depending on the size of our board of directors at the time. We have seven seats on our board of directors which will require us to have at least three women on our board of directors by the end of 2021. While we currently have two women on the board of directors, recruiting and retaining board members carries uncertainty, and failure to comply with this California requirement will result in financial penalties, ranging from \$100,000 to \$300,000. To date, the Secretary of State of the State of California has neither adopted regulations regarding fines or imposed fines for violations.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Employees may also unintentionally or willfully disclose our proprietary and/or confidential information to competitors. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending our self or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There have been no sales of unregistered securities other than previously disclosed by us in our Current Reports on Form 8-K, as filed with the SEC.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit Number	Description
2.1	<u>Agreement and Plan of Merger, dated May 16, 2021, by and among the registrant, Aadi Bioscience, Inc. and Aspen Merger Subsidiary, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on May 17, 2021).</u>
3.1	<u>Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
3.2	<u>Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.1	<u>Contingent Value Rights Agreement dated August 26, 2021, by and between Aerpio Pharmaceuticals, Inc., Cheryl Cohen, as Holder Representative, and American Stock Transfer & Trust Company, LLC, as Rights Agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.2	<u>Subscription Agreement, dated May 16, 2021, by and among Aerpio Pharmaceuticals, Inc. and each purchaser identified on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on May 17, 2021).</u>
10.3	<u>Registration Rights Agreement dated August 26, 2021, by and between Aadi Bioscience, Inc. (formerly known as Aerpio Pharmaceuticals, Inc.) and certain purchasers listed therein (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.4+	<u>Amended and Restated Employment Agreement, dated August 26, 2021, by and between Aadi Bioscience, Inc. and Neil Desai, Ph.D. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.5+	<u>Consulting Agreement dated July 20, 2021, by and between Aadi Bioscience, Inc. and Danforth Advisors, LLC (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.6+	<u>Aadi Bioscience, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.7+	<u>Form of Stock Option Agreement under the Aadi Bioscience, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.8+	<u>2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.9+	<u>Aadi Bioscience, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.10+	<u>Form of Stock Option Agreement under the Aadi Bioscience, Inc. Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.11	<u>Form of Indemnification Agreement between Aadi Bioscience, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 27, 2021).</u>
10.12#	<u>Asset Purchase Agreement dated August 17, 2021, by and between Aerpio Pharmaceuticals, Inc. and EyePoint Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on August 23, 2021).</u>

10.13*#	Amended and Restated License Agreement by and between Abraxis BioScience, LLC and Aadi Bioscience, Inc. dated November 15, 2019
10.14*#	Amendment No. 1 to the Amended and Restated License Agreement between Abraxis BioScience, LLC and Aadi Bioscience, Inc.
10.15*	First Amendment to Office Lease dated August 30, 2021 by and between BRE Sunset Coast, LLC and Aadi Bioscience, Inc.
10.16+	Employment Agreement dated September 14, 2021, by and between Brendan Delaney and Aadi Bioscience, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38560) filed with the SEC on September 20, 2021).
10.17*#	Employment Agreement dated October 19, 2021, by and between Loretta Itri and Aadi Bioscience, Inc.
10.18*#	License Agreement by and between Aadi Bioscience, Inc. and EOC Pharma (Hong Kong) Limited dated December 8, 2020
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

104 Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates them by reference.

+ Indicates a management contract or compensation plan, contract or arrangement.

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

AMENDED AND RESTATED LICENSE AGREEMENT

This AMENDED AND RESTATED LICENSE AGREEMENT (this “*Restated Agreement*”), is made as of November 15, 2019 (the “*Restatement Effective Date*”), by and between Abraxis BioScience, LLC, a Delaware limited liability company, a wholly owned subsidiary of Celgene Corporation (“*Abraxis*”), and AADi Bioscience, Inc., a Delaware corporation, formerly known as AADi LLC (“*AADi*”). Abraxis and AADi are sometimes herein each referred to as a “*Party*” and collectively the “*Parties*.” As of the Restatement Effective Date, this Restated Agreement amends and restates in its entirety that certain License Agreement between Abraxis and AADi, dated as of April 9, 2014 (the “*Effective Date*”), as amended by that certain First Amendment to the License Agreement between Abraxis and AADi, dated as of October 3, 2016 (such amendment, the “*First Amendment*” and such agreement together with the First Amendment, the “*Original Agreement*”).

RECITALS

A. Abraxis Controls (as defined below) certain intellectual property rights pertaining to ABI-009 (as defined below), including proprietary know-how directed to or concerning manufacturing of ABI-009.

B. AADi desired to obtain a license to such intellectual property rights, to develop and commercialize Licensed Products for the Field (as defined below) and Abraxis was willing to grant such a license to AADi, on and subject to the terms and conditions set forth in the Original Agreement.

C. Abraxis and AADi also desired that AADi would have access to [***] (as defined below) in connection with the Original Agreement.

D. The Parties previously entered into the Original Agreement.

E. The Parties now desire to amend certain terms of the Original Agreement to, among other matters, terminate certain of Abraxis’s supply obligations with respect to the Licensed Products and transfer control over certain portions of regulatory filings for Licensed Products from Abraxis to AADi, on the terms and conditions set forth in this Restated Agreement; and to restate the Original Agreement in its entirety in this Restated Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the premises, the covenants and obligations expressed herein and other valuable consideration, the receipt and sufficiency of which is acknowledged by the Parties, the Parties agree as follows:

1. DEFINITIONS

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

When used in this Restated Agreement, whether in the singular or plural, each of the following capitalized terms shall have the meanings set forth in this Article 1.

1.1 “**AADi**” has the meaning set forth in the preamble.

1.2 “**AADi Indemnitees**” has the meaning set forth in Section 10.2.

1.3 “[***]” means any and all inventions, discoveries, know-how, data and improvements, whether or not patentable, made, conceived or reduced to practice prior to the Restatement Effective Date in the exercise of rights or performance of obligations under this Agreement by or on behalf of AADi, its Affiliates or Sublicensees (except by Abraxis), including by their respective employees, consultants and agents.

1.4 “**ABI-009**” means albumin-bound rapamycin known as nab-rapamycin as described in [***], as of the Effective Date.

1.5 “**ABI-009 Patent**” has the meaning set forth in Section 5.1(c).

1.6 “**Abraxis**” has the meaning set forth in the preamble.

1.7 “**Abraxis Indemnitees**” has the meaning set forth in Section 10.1.

1.8 [***].

1.9 “**Accounting Standards**” means GAAP (United States Generally Accepted Accounting Principles), consistently applied.

1.10 [***].

1.11 “**Affiliate**” means a Person that, during the Term, directly or indirectly, through one or more intermediates, controls, is controlled by or is under common control with, the Person specified. For the purposes of this definition, control shall mean the direct or indirect ownership of (a) in the case of corporate entities, securities authorized to cast more than 50% of the votes in any election for directors, (b) in the case of non-corporate entities, more than 50% ownership interest with the power to direct the management and policies of such non-corporate entity, or (c) such lesser percentage as may be the maximum percentage allowed to be owned by a foreign corporation under the applicable laws or regulations of a particular jurisdiction outside of the United States) of the equity having the power to vote in the election of directors or to direct the management and policies of another entity.

1.12 “**Agreement**” shall mean the Original Agreement, as in effect from the Effective Date until the Restatement Effective Date, together with the Restated Agreement, which replaces the Original Agreement in its entirety as of the Restatement Effective Date.

1.13 “**Celgene**” means Celgene Corporation, a Delaware corporation.

1.14 “**CMC**” has the meaning set forth in Section 3.1.2.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

1.15 **“Combination Product”** means any product that comprises a Licensed Product sold in conjunction with another active component (whether packaged together or in the same therapeutic formulation or otherwise) or service.

1.16 **“Commercially Reasonable Efforts”** means that level of efforts and resources that a similarly situated biopharmaceutical company, in the exercise of its commercially reasonable business practices, would normally devote to the research, development or commercialization as the case may be, of a product owned by it or to which product it has rights of the type it has hereunder, which is of a similar commercial potential at a similar stage in its lifecycle, in each case taking into account [***].

1.17 **“Confidential Information”** means all secret, confidential or proprietary information, data or material, whether provided in written, oral, graphic, video, computer, digital or other form, provided by one Party (the **“Disclosing Party”**) to the other Party (the **“Receiving Party”**) pursuant to this Agreement or generated pursuant to this Agreement, including information relating to the Disclosing Party’s existing or proposed research, development efforts, Patent applications, business or products and any other materials that have not been made available by the Disclosing Party to the general public. [***] shall also be deemed Confidential Information of Abraxis. [***] is Abraxis’ Confidential Information. Notwithstanding the foregoing sentences, Confidential Information shall not include any information, data or material that:

(a) was already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party to the extent such Receiving Party has documentary evidence to that effect;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of a Party in breach of such Party’s confidentiality obligations under this Agreement;

(d) was subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others;

(e) was independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party and the Receiving Party has documentary evidence to that effect; or

(f) is approved for release by the Disclosing Party in writing.

Information, data or material shall not be deemed to be within any of the foregoing exceptions merely because such information, data or material is embraced by more general information, data or material in the public domain or in the possession of the Receiving Party, nor shall information, data or material be deemed to be within any of the foregoing exceptions merely because the individual items thereof are in such exceptions, unless the combination of such individual items and the principle of operation (if any) are in such exceptions.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

1.18 “**Controls**” or “**Controlled**” means with respect to any Technology and/or Patent, the ownership thereof or the possession by a Party (or its Affiliates, as the case may be) of the ability to grant a license or sublicense of such Technology or Patent as provided for herein without violating the terms of any agreements between such Party (or its Affiliates) and any Third Party existing as of the date on which such license or sublicense is granted and without being required to make any additional payments or royalties to a Third Party in connection with such license or sublicense, unless the other Party agrees to pay the additional payments or royalties to the Third Party.

1.19 [***].

1.20 [***].

1.21 “**Desai**” means Dr. Neil Desai; an individual.

1.22 “**Designee**” has the meaning set forth in Section 3.2

1.23 “**Disclosing Party**” has the meaning set forth in Section 1.17.

1.24 “**DMF**” has the meaning set forth in Section 3.1.2.

1.25 “**Restatement Effective Date**” has the meaning set forth in the preamble.

1.26 “**EMA**” means the European Medicines Agency, or any successor agency thereto.

1.27 “**Executive Officers**” means Abraxis’ [***] (or the officer or employee of Abraxis then serving in a substantially equivalent capacity) or her designee and AADi’s [***] (or the officer or employee of AADi then serving in a substantially equivalent capacity) or his designee; provided that any such designee must have decision-making authority on behalf of the applicable Party.

1.28 “**FDA**” means the United States Food and Drug Administration, or any successor agency thereto.

1.29 “**Field**” means treatment, prevention, palliation and diagnosis of condition(s) or disease state(s) in humans, subject to Section 2.8(b) below. “Field” expressly excludes any and all other uses and applications.

1.30 “**Force Majeure**” means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder, if such occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident; or war, revolution, civil commotion, acts of public enemies, terrorist attack, blockade or embargo; or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government (to the extent such government has ruling authority over such Party) or of any subdivision, authority or representative of any such government; or other similar event, beyond the reasonable control of such Party, if and only if the Party affected shall have used reasonable efforts to avoid such occurrence.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

1.31 “**FTE**” means a full-time scientific or technical person, or in the case of less than a full-time scientific or technical person, a full-time equivalent scientific or technical person, in each case, assigned to perform specific tasks under this Agreement and carried out by an appropriately qualified employee of Abraxis or its Affiliates, based on [***].

1.32 “**FTE Costs**” means the actual number of FTEs employed by Abraxis or its Affiliates in the conduct of performing services for AADi pursuant to Section 6.4 hereunder multiplied by the FTE Rate.

1.33 “**FTE Rate**” means [***].

1.34 “**Fully Loaded Cost**” means all costs actually incurred by Abraxis in the development, manufacture or supply of applicable therapeutic ingredients, finished products, related inputs and services (a) by a Third Party or (b) directly by Abraxis or its Affiliates. It is understood and agreed that, in the case of costs referred to in clause (a) of this sentence where a Third Party is the developer, manufacturer or supplier, Fully Loaded Cost will equal [***]. It being understood and agreed that, in the case of costs referred to in clause (b) of this sentence where Abraxis or its Affiliate is the developer, manufacturer or supplier, Fully Loaded Cost will equal [***]. For purposes of determining reasonable overhead with respect to the manufacture of Licensed Product, the Parties agree that (i) with respect to the manufacture of Licensed Product by Abraxis’ current Third Party supplier, overhead will be equal to [***]; and (ii) with respect to the manufacture of Licensed Product by Abraxis itself, [***]. Costs to be included in the calculation of “Fully Loaded Costs” for the supply of Licensed Product include [***].

1.35 “**IMPD**” means a Medicinal Product Dossier (or an equivalent dossier in any jurisdiction of the Territory outside of the United States and European Union).

1.36 “**IND**” means an Investigational New Drug Application, as defined in the Food, Drug and Cosmetics Act, or similar application or submission that is required to be filed with any global Regulatory Authority before initiating the clinical testing of Licensed Product in human subjects.

1.37 “**Indemnitee**” means an AADi Indemnitee or Abraxis Indemnitee as the context requires.

1.38 “**Intellectual Property**” means all Patents, copyrights, trademarks, trade secrets, Technology and documentation and related applications.

1.39 “**Licensed IP**” means the Licensed Patents and Licensed Technology.

1.40 “**Licensed Patents**” means (a) solely to extent of claims necessary for the development, manufacture and commercialization of Licensed Products in the Field and the Territory, (i) the United States and foreign patents and patent applications (x) Controlled by Abraxis as of the Restatement Effective Date as set forth in Exhibit 1.40 or (y) Controlled by Abraxis and added to Exhibit 1.40 as provided in Section 2.4, (ii) divisionals, continuations, continuations-in-part (to the extent of claims entitled to priority of the earliest parent application included in (i)) of such patent applications; and (iii) patents issuing on any of the foregoing patent applications, together with all registrations, reissues,

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

substitutions, re-examinations, renewals, extensions and supplementary protection certificates of such patents or of any patents included in Exhibit 1.40; and (b) solely to extent of claims necessary for the development, manufacture and commercialization of Licensed Products in the Field and the Territory, any [***] that constitute Patents.

1.41 “**Licensed Products**” means (a) a pharmaceutical product in the injectable form and in the dosage strength(s) described in [***] as of the Restatement Effective Date that contains ABI-009 as the sole active ingredient and is labeled for use (or, in the case of product for clinical use, specified in the applicable IND for use) solely in the Field and (b) [***] labeled for use (or, in the case of product for clinical use, specified in the applicable IND for use) solely in the Field.

1.42 “**Licensed Technology**” means, solely to the extent pertaining directly to ABI-009 and/or Licensed Products and/or their use in the Field and the Territory, (a) Technology Controlled by Abraxis as of the Restatement Effective Date that is necessary for the development, manufacture and commercialization of Licensed Products and is listed in Exhibit 1.42, (b) Technology Controlled by Abraxis during the Term that is developed by or on behalf of Abraxis or its Affiliate in performing activities pursuant to Section 6.4 or 6.5 of this Restated Agreement and is necessary for the development, manufacture and commercialization of Licensed Products, and (c) any [***] that constitute Technology.

1.43 [***].

1.44 “**Losses**” has the meaning set forth in Section 10.1.

1.45 [***].

1.46 “**NDA**” means a New Drug Application, supplemental New Drug Application, Marketing Application, or Biologics License Application (BLA), as applicable, filed with the FDA, or a foreign equivalent of the FDA, required for the regulatory and marketing approval for the applicable Licensed Product in a given jurisdiction.

1.47 “**Net Sales**” means, for each Net Sales Measuring Period, the sum of, without any duplication, the gross amounts invoiced for the Licensed Products sold by AADi, its Affiliates or its Sublicensees to Third Parties (other than AADi, its Affiliates or its Sublicensees) during such Net Sales Measuring Period, including wholesale distributors, less deductions from such amounts calculated in accordance with Accounting Standards so as to arrive at “net sales” under Accounting Standards as reported by AADi, its Affiliate or its Sublicensee, as applicable, in such Person’s financial statements, and further reduced by write-offs of accounts receivables or increased for collection of accounts that were previously written off.

Any and all set-offs against gross invoice prices shall be calculated in accordance with Accounting Standards. [***]. Notwithstanding the foregoing, if a Licensed Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm’s length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be [***]. Such amount that would have been invoiced shall be determined, wherever possible, by reference to [***].

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Notwithstanding the foregoing, in the event a Licensed Product is sold as a Combination Product in a particular country, Net Sales shall be calculated [***]. If no such separate sales are made by AADi, its Affiliates or Sublicensees in a country, Net Sales of the Combination Product shall be calculated [***].

1.48 **“Net Sales Measuring Period”** means the one-year period beginning January 1st of each year during the Term and ending December 31st of each year during the Term; provided that the first Net Sales Measuring Period will begin on the Effective Date and end on December 31, 2019.

1.49 **“Party”** and **“Parties”** have the meaning set forth in the preamble.

1.50 **“Patents”** means patents, patent applications (provisional and non-provisional), utility models, applications for utility models and statutory invention registrations, including reissues, divisions, continuations, continuations-in-part, extensions, supplementary protection certificates and re-examinations thereof, all inventions disclosed therein and improvements thereto and all rights therein provided by international treaties and conventions.

1.51 **“Person”** means any individual, firm, corporation, partnership, limited liability company, trust, unincorporated organization or other entity or a government agency or political subdivision thereto and shall include any successor (by merger or otherwise) of such Person.

1.52 **“Phase 2 Trial”** means a human clinical trial conducted on study subjects with the disease or condition being studied for the principal purpose of achieving a preliminary determination of efficacy or appropriate dosage ranges, as further described in 21 C.F.R. §312.21(b) (including any such clinical study in any country other than the United States to ensure compliance within those local requirements to initiate the phase 2 trial).

1.53 **“Phase 3 Trial”** means a pivotal clinical trial in humans performed to gain evidence with statistical significance of the efficacy of a product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of an NDA or Marketing Application by a Regulatory Authority that would provide an adequate basis for physician labeling, as described in 21 C.F.R. § 312.21(c) or the corresponding regulation in jurisdictions other than the United States.

1.54 **“Prosecution”** means the preparation, filing, prosecution, issuance and maintenance (including, without limitation, interference, opposition and similar third party proceedings before the relevant patent office) of any Patent applications and Patents in Licensed Patents.

1.55 **“Receiving Party”** has the meaning set forth in Section 1.17.

1.56 **“Regulatory Approval”** means the technical, medical and scientific licenses, registrations, authorizations and approvals (including, without limitation, approvals of NDAs, marketing applications, supplements and amendments, biologic license applications, pre- and post-approvals, pricing and Third Party reimbursement approvals and labeling approvals) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the development (including the conduct of clinical trials),

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

manufacture, distribution, marketing, promotion, offer for sale, use, import, reimbursement, export or sale of a Licensed Product in a regulatory jurisdiction.

1.57 **“Regulatory Authority”** means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of Regulatory Approval in any country.

1.58 **“Restated Agreement”** has the meaning set forth in the preamble.

1.59 **“Royalty Term”** has the meaning set forth in Section 7.2.2.

1.60 **“Serious Adverse Drug Experience”** means any of an “adverse drug experience,” a “life-threatening adverse drug experience,” a “serious adverse drug experience,” or an “unexpected adverse drug experience,” as those terms are defined at either 21 C.F.R. §312.32 or 21 C.F.R. §314.80 or in similar relevant foreign regulations applicable to one or more jurisdictions.

1.61 **“Sublicense”** means an agreement into which AADi enters with a Third Party for the purpose of (i) granting certain rights; (ii) granting an option to certain rights; or (iii) forbearing the exercise of any rights in each case, granted to AADi under this Agreement. For clarity, a contract for services to be performed solely for AADi (or its Affiliate) and under which the contractor obtains no independent right to conduct any activity with Licensed IP or Licensed Products shall not be considered a “Sublicense.”

1.62 **“Sublicense Fees”** means any [***] that AADi receives from a Third Party Sublicensee in consideration of and associated with the grant of a Sublicense to such Third Party by AADi pursuant to Section 2.2 of the exclusive rights granted to AADi under Section 2.1; provided, however, that “Sublicense Fees” shall exclude [***].

1.63 **“Sublicensee”** means a Third Party or an AADi Affiliate with whom AADi enters into a Sublicense.

1.64 **“Technology”** means any and all compounds, materials, equipment, specifications, designs, formulae, methods, techniques, processes, procedures, inventions, know how, results, data and information, documentation and other technology, whether or not Patentable or protectable as a trade secret.

1.65 **“Term”** means the term of this Agreement as provided in Section 11.1.

1.66 **“Territory”** means worldwide except the following countries: [***].

1.67 **“Third Party”** means any Person other than a Party and its Affiliates.

1.68 **“Third Party Claim”** has the meaning set forth in Section 10.1.

1.69 **“Valid Claim”** means an issued and unexpired claim of a Patent that (a)(i) has not been held permanently revoked, unenforceable or invalid by a decision of a governmental entity, which decision is unappealable or has not been appealed within the time allowed for appeal, and (ii) has not

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been admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) a claim of pending application for a Patent; [***].

2. LICENSES AND EXCLUSIVITY

2.1 **Grant.** Subject to the terms and conditions of this Agreement, Abraxis hereby grants to AADi, during the Term, (i) an exclusive license in the Territory under the Licensed Patents, and (ii) a non-exclusive license in the Territory to use the Licensed Technology, in each case, to make, have made, use, sell, offer for sale and import Licensed Products solely in and for the Field and Territory. Notwithstanding anything in this Agreement to the contrary, in no event shall AADi have any right to market or sell Licensed Products outside the Territory.

2.2 **Sublicenses.** AADi shall have the right to grant Sublicenses of its rights granted in Section 2.1; [***]. Notwithstanding anything else in this Section 2.2 or otherwise in this Agreement, in no event will AADi be permitted to enter into a Sublicense or other agreement for any Licensed IP or Licensed Product (including a subcontracting agreement under Section 2.12) [***].

2.3 **Conditions for Sublicenses.** AADi acknowledges and agrees that the grant of a Sublicense to a Sublicensee shall not relieve AADi from its obligations under this Agreement and AADi shall, under each Sublicense agreement with a Sublicensee, obligate the Sublicensee to be bound by all of the applicable terms and conditions of this Agreement. The Sublicense agreement must be in the English language and must (i) [***], (ii) [***], (iii) [***] hereunder, and (iv) include terms and conditions substantially identical to those of [***] hereunder. AADi shall be [***]. AADi shall provide Abraxis with a copy of the Sublicense agreement with each Sublicensee within [***] of its execution. AADi agrees that, if it [***] Sublicenses, [***], AADi shall pay to Abraxis the Sublicense Fees as set forth in Section 7.6.

2.4 Additional License Rights.

2.4.1 At any time during the Term, AADi may provide written notice to Abraxis requesting that a patent or patent application in the Territory Controlled by Abraxis having claims necessary for the development, manufacture or commercialization of ABI-009 or Licensed Products be included in Licensed Patents. Such written notice shall [***]. Abraxis shall consider AADi's request in good faith and may, in its sole discretion, include such patent/patent application in Licensed Patents; provided, however, that, if such patent or patent application is [***] and was Controlled by Abraxis as of the Effective Date, Abraxis will include such patent/patent application in Licensed Patents to the extent that Abraxis is legally able to do so [***]. If a patent or patent application is added as a Licensed Patent pursuant to this Section 2.4, Abraxis will amend Exhibit 1.40 to reflect such addition. The Parties acknowledge and agree that Abraxis, in accordance with this Section 2.4, will update Exhibit 1.40 from time-to-time to reflect the issuance of patent claims that specifically claim the Licensed Product and which are considered Licensed Patents pursuant to this Agreement.

2.4.2 In addition, at any time during the Term, AADi may provide written notice to Abraxis requesting that [***]. Such written notice shall identify the relevant patent/patent application or Technology and shall explain briefly why AADi, in good faith, considers it necessary to use, offer for sale, sell, make or have made Licensed Products. Abraxis shall consider AADi's request in good

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faith and may, in its sole discretion, include such patent/patent application or Technology in Licensed Patents or Licensed Technology, as applicable.

2.5 No Implied Licenses. Only the licenses expressly granted herein shall be of legal force and effect. Except as set forth in Sections 2.1 and 2.2, no license rights under any Intellectual Property of Abraxis or any its Affiliates, subsidiaries or assigns shall be created hereunder by implication, estoppel or otherwise, whether such Intellectual Property is subordinate, dominant or otherwise useful for the practice of the Licensed IP.

2.6 Retained Rights. Notwithstanding the license granted in Section 2.1, Abraxis shall have the right, under the Licensed IP, to make, have made, use and import the Licensed Products solely for research purposes (which rights may be sublicensed by Abraxis only for such research purposes). Abraxis retains the right to use and/or license others to use the Licensed IP for every purpose except for those uses specifically licensed to AADi in Section 2.1. Notwithstanding the foregoing, during the Term, neither Abraxis nor any of its Affiliates shall: (a) conduct any activities directed towards the clinical development or commercialization of any product containing (i) ABI-009 or (ii) [***], in either case, for use in the Field in the Territory; or (b) grant any license or other rights to any Third Party under any Patents owned or controlled by Abraxis or any of its Affiliates to do the foregoing; in each case, except for those activities to be conducted for AADi involving ABI-009 or Licensed Products pursuant to this Agreement.

2.7 Prohibitions. In furtherance of Abraxis' reservations of rights and the protection of Abraxis' Confidential Information and without limiting anything else herein, the following will apply:

2.7.1 Neither AADi nor any of its Affiliates shall, directly or indirectly: (a) conduct any research, development, commercialization, or other activity with ABI-009, the Licensed IP, [***] or any Licensed Product outside the scope of the rights and license granted under this Agreement, (b) conduct any clinical study on ABI-009 or any Licensed Product whose primary endpoint is for [***], (c) seek or obtain Regulatory Approval or any label claim for ABI-009 or any Licensed Product indicated for the [***] or outside the Territory, (d) seek or obtain Regulatory Approval or marketing approval for ABI-009 or any Licensed Product in any jurisdiction in which [***], (e) refer to or use any clinical data of Abraxis or its Affiliates related to ABI-009, the Licensed IP, [***] or any Licensed Product for seeking or obtaining Regulatory Approval of any product, except for Licensed Products as provided herein, in any jurisdiction, or (f) market or promote (including by publishing any results, data or observations on) ABI-009 or any Licensed Product for any use or indication outside the Field or outside the Territory. Neither AADi nor any of its Affiliates shall assist or encourage any Third Party to engage in or conduct any of the foregoing prohibited activities.

2.7.2 AADi further agrees that, in any agreement with any Sublicensee or any other Third Party involving Licensed IP, ABI-009 or Licensed Product, such Sublicensee or other Third Party:

(i) shall agree (a) to not use any Confidential Information of Abraxis or its Affiliates except in the performance of rights and/or exercise of obligations under such Person's agreement with AADi with respect to ABI-009 or Licensed Product and (b) without limiting

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the foregoing, to not use any Confidential Information of Abraxis or its Affiliates for any purposes described in clauses (a) through (g) of Section 2.7.2(ii) below; and

(ii) shall acknowledge that any sublicense of rights from AADi or its Affiliates does not include a license under the Licensed Technology to: (a) conduct any research, development, commercialization, or other activity with ABI-009, the Licensed IP, [***] or any Licensed Product outside the scope of the rights and license granted under this Agreement, (b) conduct any clinical study on ABI-009 or any Licensed Product whose primary endpoint [***], (c) seek or obtain Regulatory Approval or any label claim for ABI-009 or any Licensed Product indicated for the [***] or outside the Territory, (d) seek or obtain Regulatory Approval or marketing approval for ABI-009 or any Licensed Product in any jurisdiction in which [***], (e) refer to or use any clinical data of Abraxis or its Affiliates related to ABI-009, the Licensed IP, [***] or any Licensed Product for seeking or obtaining Regulatory Approval of any product, except for Licensed Products as provided herein, in any jurisdiction, or (f) market or promote (including by publishing any results, data or observations on) ABI-009 or any Licensed Product for any use or indication outside the Field or outside the Territory;

provided that, notwithstanding the foregoing, any Third Party provided access to [***] (including any Permitted Party with respect to whom Abraxis has approved disclosure of [***]) must abide by the restrictions in Section 2.7.1 as applicable to AADi and not the restrictions set forth in this Section 2.7.2.

2.8 Combination Products; Companion Diagnostics.

(a) The license granted under Section 2.1 does not include the right to include ABI-009 or any Licensed Product as part of a Combination Product consisting of another active component in the same formulation. AADi will be permitted to package the Licensed Product as part of a Combination Product for use in the Field, including the right to create a Combination Product consisting of a device and a Licensed Product in the Field of [***]; provided that (i) the license granted under Section 2.1 does not include rights under the Licensed Technology with respect to any product other than a Licensed Product, and AADi will be required to separately obtain any rights to any products or services included with the Licensed Product as part of a Combination Product; and (ii) Abraxis' obligations under this Agreement (including Articles 3 and 6) will not apply to the Combination Product or the other product or service included with the Licensed Product as part of a Combination Product, instead Abraxis' obligations are limited solely to the Licensed Product.

(b) AADi will be permitted to develop and commercialize [***] for use in connection with the Licensed Products in the Field; provided that (i) such companion diagnostic must be directed to [***]; and (ii) except for Licensed Patents or Licensed Technology added hereunder pursuant to Section 2.4.2(b) or any [***], the Licensed Technology licensed to AADi hereunder will not include any Patents or Technology related to companion diagnostics.

2.9 [***] and Ownership of [***].

2.9.1 All [***] shall be owned by [***]. In furtherance of the foregoing, except as otherwise permitted in Section 2.12(b), [***] shall cause any of its contractors or Sublicensees and

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their respective employees, consultants and agents to automatically assign to [***], its or their respective right, title and interest in and to all [***], together with all Intellectual Property rights therein. With respect to any [***] described in Section 2.12(b)(ii), [***] hereby grants [***] a non-exclusive, irrevocable, perpetual, fully paid up, transferable, sublicensable [***] right and license to practice any such [***] (and any Intellectual Property rights therein) for any purpose whatsoever and hereby transfers to [***] the right to negotiate for an exclusive license to such [***] (and any Intellectual Property rights therein). [***] shall own any other inventions made by or for [***], except that (a) during the Term, [***] shall notify [***] in writing of any such inventions that pertain to [***] or Licensed Product and (b) [***] hereby grants to [***] a fully paid up, worldwide, irrevocable, perpetual, sublicensable, transferable, non-exclusive license to practice such inventions (i) during the Term for any purpose, subject to the rights and licenses granted to [***] hereunder, and (ii) upon expiration or termination of this Agreement for any reason, in all fields.

2.9.2 To facilitate the provisions of Section 2.9.1, [***] will cooperate with [***] to effectuate ownership of [***] in [***], including taking any and all actions necessary to perfect [***] rights in and to such inventions, as provided herein, executing and recording documents, and, subject to Section 5.1, assisting in the Prosecution of any Patent and copyright applications at [***] direction and expense, as well as assisting in the enforcement and defense of Patents within [***]. If for any reason, [***] is unable to obtain [***] signature on any document or consent necessary for any of the foregoing activities after reasonable efforts, [***] hereby appoints the [***], or his/her designee and grants him/her a power of attorney to transact all business worldwide, including in the United States Patent and Trademark Office in connection with such [***], to the extent permitted by law. [***] understands and agrees that such power of attorney is irrevocable.

2.10 Trademark. This Agreement does not grant AADi any rights in, and AADi shall have no rights to use, any Abraxis trademarks. AADi is responsible, at its own expense, for developing and obtaining trademarks for use in connection with its commercialization of Licensed Products.

2.11 Government Rights. The Parties acknowledge that the U.S. government retains certain rights in Intellectual Property funded in whole or in part under any contract, grant or similar agreement with a U.S. federal agency. [***] covenants and agrees that it will take all reasonable steps and actions required or necessary to perfect [***] ownership interest, as required by Section 2.9, in any [***] that was funded in whole or in part under any contract, grant or similar agreement with a federal agency.

2.12 Subcontracting. AADi may perform research and development permitted under this Agreement activities through subcontracting to Third Parties, including Third Party contractors, contract service organizations, and academic or government collaborators; provided that: (a) any such Third Party subcontractor to whom AADi discloses Confidential Information will enter into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on disclosure and use of such Confidential Information that are no less restrictive than the obligations set forth in [***]; (b) [***]; (c) AADi shall notify Abraxis promptly following execution of any such subcontracting agreement during the Term and shall provide Abraxis with a copy of the subcontracting agreement, the financial terms of which may be redacted; and (d) AADi will at all times be responsible for the performance of such subcontractor.

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3. REGULATORY MATTERS

3.1 IND; DMF.

3.1.1 AADi acknowledges that Abraxis has provided AADi with a letter of cross reference to [***], and AADi has already filed with the FDA an IND regarding ABI-009 with such letter of cross-reference (such IND, the “**AADi IND**”). Abraxis acknowledges that AADi has provided Abraxis with a copy of the AADi IND.

3.1.2 Abraxis [***] provide to AADi certain information and data related to [***] in Abraxis’s possession or control as of the Restatement Effective Date identified by the FDA or reasonably anticipated by AADi to be necessary for submission of the NDA for the Licensed Product or otherwise to apply for or obtain Regulatory Approvals for the Licensed Product in the United States for use in the Field. Such information includes studies, reports, and documentation reasonably required to file eCTD Module 3 of the NDA for the Licensed Product in accordance with applicable FDA guidance documents, information required by the FDA to be submitted in the CMC section of the NDA for the Licensed Product, the Drug Master File(s) relevant to the Licensed Product (“**DMF**”), and master batch records and process and product characterization reports for the Licensed Product. Abraxis shall not be required to generate new information in connection with this paragraph. All of the costs incurred by Abraxis pursuant to fulfilling its obligations under this Section 3.1 will be included as costs incurred by Abraxis for the supply of Licensed Product to AADi pursuant to Article 6 for purposes of determining “Fully Loaded Costs” and will be subject to AADi’s payment obligations associated therewith, including Section 7.2.

3.1.3 AADi’s and AADi’s officers shall comply with Section 9.7 with respect to any [***] provided under this Section 3.1.

3.1.4 AADi represents and warrants to Abraxis that AADi has not included any [***] or other proprietary information (including CMC information) of Abraxis in the AADi IND.

3.1.5 Abraxis shall withdraw any DMF containing CMC information relevant to a Licensed Product [***] or at such earlier time as mutually agreed by the Parties, provided that if Abraxis determines, in its reasonable discretion, that it is reasonably practicable to transfer the DMF to AADi, Abraxis shall so notify AADi and upon AADi’s request, Abraxis will transfer the DMF to AADi instead of withdrawing such DMF.

3.1.6 Abraxis represents and warrants to AADi that it has withdrawn [***] and that all development activities conducted under such IND have ceased.

3.2 Regulatory Matters.

3.2.1 Unless otherwise agreed by the Parties from time to time, after the Restatement Effective Date, as between Abraxis and AADi, AADi shall control filing for and obtaining all Regulatory Approvals and interactions with all Regulatory Authorities with respect to the Licensed Product, at its sole expense. Abraxis shall [***] provide reasonable support for AADi’s first NDA submission for a Licensed Product, including by providing reasonably necessary reports, studies,

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information and data and assisting in the preparation of CMC information and reports for such NDA submission upon request by AADi, until the earlier of: (i) the first date on which the FDA has approved an NDA for a Licensed Product, and (ii) [***] following AADi's receipt of acceptance of filing of an NDA for a Licensed Product, provided that if the FDA designates the Licensed Product as a Fast Track Product (as set forth in 21 U.S.C. § 356), such time period shall be reduced to [***] following AADi's receipt of acceptance of filing of an NDA for such Licensed Product. [***] and will be subject to AADi's payment obligations associated therewith, including Section 7.2. Abraxis shall not be required to generate new information in connection with this paragraph.

3.2.2 At least [***] prior to a submission to a Regulatory Authority, Abraxis will be entitled to review for Abraxis Confidential Information (a) any IND and application for Regulatory Approval, (b) any amendments to an IND or Regulatory Approval or other submissions to Regulatory Authorities that contain any CMC information or toxicology information, and (c) any submission to Regulatory Authorities that contains Abraxis Confidential Information, and Abraxis will be entitled to approve the content of any disclosures of any Abraxis Confidential Information and approve the content of any CMC disclosure as it relates to the manufacturing process used by Abraxis. If Abraxis fails to respond to a submission properly provided pursuant to Section 12.5 within [***] after Abraxis' receipt of such submission from AADi, AADi may proceed with such submission in the form provided to Abraxis, unless Abraxis objects prior to AADi's delivery of the submission to the applicable Regulatory Authority; provided that such failure to respond will not be deemed Abraxis' consent to the disclosure of any Abraxis Confidential Information. With respect to any draft submissions required to be reviewed under this Section 3.2.2, AADi will also provide Abraxis with copies of the final versions actually submitted by AADi.

3.2.3 Notwithstanding anything to the contrary in this Agreement, the information contained in any portions of the [***] (or portions thereof) or any equivalent thereof relating to or based on ABI-009, [***], or any Licensed Product will be [***] or otherwise the Confidential Information of Abraxis, and any such information that Abraxis may make available to AADi shall be made available solely through [***], each of whom is approved in advance in writing by Abraxis (a "**Designee**"). Each Designee, if any, [***] must be bound in writing by a Confidentiality Agreement in the form attached hereto as Exhibit 9.7 prior to receiving the Abraxis Confidential Information contained in the [***]. Abraxis may make such information available to [***] the Designees through means designed to protect the confidentiality of such information, including through the use of security protocols, passwords, encryption, secure servers and other means of controlling and restricting access, and Abraxis may require AADi to take reasonable steps to protect the confidentiality of such information and limit access to such information.

3.3 Adverse Event Reporting. [***].

3.4 Regulatory Review. Without limiting anything herein to the contrary, AADi will provide Abraxis with drafts of any documents or other correspondence to be submitted to any Regulatory Authorities pertaining to a Licensed Product to the extent that statements made in such documents or other correspondence describe preclinical and clinical studies performed (including clinical trial protocols and investigator brochures), describe [***], or include [***]. Such documents or other correspondence will be provided sufficiently in advance of submission for Abraxis to review

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any such submissions (but at least [***] in advance). Abraxis may comment on such documents or other correspondence to the extent that statements made in such documents or other correspondence may affect the Prosecution of any Licensed Patents or disclose [***], in which case AADi will consider in good faith all such comments; provided that AADi may not make a statement in any such documents or correspondence that contradicts statements made in connection with the Prosecution of the Licensed Patents or disclose [***] without Abraxis' prior consent. AADi may redact information that would not affect the Prosecution of Licensed Patents. With respect to any draft submissions required to be reviewed under this Section 3.4, AADi will also provide Abraxis with copies of the final versions actually submitted by AADi.

4. DILIGENCE

4.1 Diligence and Development Plan. AADi, itself and/or through its Affiliates and Sublicensees, will [***] clinically develop and commercialize [***] indication and [***] indication and [***] to sell the Licensed Products with respect to which Regulatory Approval has been obtained.

4.2 Milestones. AADi, itself and/or through its Affiliates or Sublicensees, will accomplish the following tasks with respect to Licensed Products for the Territory:

Activity	Date
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The Parties acknowledge and agree that as of the Restatement Effective Date, Milestones A, B and C have been achieved in accordance with this Section 4.2.

4.3 First Commercial Sale. If AADi, itself and/or through its Affiliates or Sublicensees, has not completed the First Commercial Sale of a Licensed Product in the United States before [***], Abraxis will be entitled to (a) [***]; or (b) [***]. For this purpose, "**First Commercial Sale**" means the date of the first arm's length transaction, transfer, or disposition for value by or on behalf of AADi or any Affiliate or Sublicensee of AADi to a Third Party of a Licensed Product for end use or consumption of such Licensed Product; [***].

4.4 Progress Reports. Beginning [***] after Effective Date and ending on [***], AADi shall report to Abraxis progress covering AADi's (and its Affiliates' and Sublicensees') activities (against the development plan) for the preceding [***] to develop and test the Licensed Products and obtain Regulatory Approvals necessary for marketing the same. Such [***] reports shall be due within [***] of the reporting period and include a summary of work completed, summary of work in progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Products, and summary of resources (dollar value) spent in the reporting period.

4.5 Milestone Extensions. If AADi fails to achieve any of its obligations specified in Sections 4.2 hereof, through no fault of Abraxis, AADi shall have the right, [***]. [***]. Thereafter, if AADi fails to achieve any of the [***] milestones, through no fault of Abraxis, then, subject to the

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cure provisions of Section 11.4(b) hereunder, [***]. This right to [***], if exercised by Abraxis, supersedes the rights granted in Article 2 hereof. [***].

5. INTELLECTUAL PROPERTY

5.1 Prosecution of Licensed Patents.

(a) [***] shall have the right, but not the obligation, to prosecute Licensed Patents.

(b) [***] shall be entitled to use patent counsel selected by it, and such counsel shall take instructions only from [***], and patents and patent applications in Licensed Patents shall be assigned to [***]. [***] shall control all patent filings and all patent prosecution decisions and related filings (e.g., responses to office actions) shall be at [***] final discretion. [***] (i) shall keep [***] reasonably informed with respect to the overall status of Prosecution of the ABI-009 Patents and the Licensed Patents involving [***], (ii) shall reasonably consult with [***] on Prosecution matters with respect to the ABI-009 Patents and the Licensed Patents involving [***], (iii) shall provide [***] with copies of material correspondence (including applications, office actions, responses, etc.) related to such Prosecution on the ABI-009 Patents and the Licensed Patents involving [***], and any proposed responses thereto by Abraxis prior to any filing or response deadlines, and (iv) upon [***] reasonable request, shall update [***] with respect to the overall status of Prosecution of the Licensed Patents. [***] shall promptly provide [***] with any related comments, and [***] shall [***] or requests to amend to address [***] commercial interests; provided that, if any [***] comments are not received by [***] sufficiently in advance of any deadline for taking action, [***] may take action without considering [***] comments. In any event, [***] shall have final decision making authority with respect to such Prosecution matters.

(c) If [***] decides to discontinue Prosecution of an [***] within Licensed Patents or any other Licensed Patent that contains only claims solely directed to ABI-009, a Licensed Product or their use in the Field (an “**ABI-009 Patent**”), not file a continuation application requested to be filed by [***] within such [***] or ABI-009 Patents or not maintain an issued patent on an [***] within the Licensed Patents or ABI-009 Patents, [***] shall provide [***] with notice of such decision at least [***] prior to any pending lapse or abandonment (or last possible filing date) thereof, or if earlier, promptly after its election not to file such continuation application or maintain such patent, as applicable. In such event [***]. If [***], [***] shall reimburse [***] reasonable out-of-pocket costs, including outside counsel’s fees, within [***] after request for reimbursement from [***]. If [***] declines to do so, [***]. [***] Prosecution rights with respect to ABI-009 Patents under this Section 5.1(c) (whether through requesting [***] to continue Prosecution at [***] expense or [***] in its sole discretion providing [***] with Prosecution responsibility) will be limited to pursuing only claims solely directed to ABI-009, a Licensed Product or their use in the Field, and [***] may not pursue any other claims without the prior written consent of [***].

(d) If [***] decides to discontinue Prosecution of any Licensed Patent (other than a Patent related to an [***] or an ABI-009 Patent), not file a continuing application requested to be filed by [***] or not maintain an issued Patent on any such Licensed Patent, [***] shall provide [***] with notice of such decision at least [***] prior to any lapse or abandonment (or

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last possible filing date) thereof, or if earlier, promptly after its election not to file such application or maintain such patent, as applicable. In such event [***]. If [***] request, [***] shall reimburse [***] out-of-pocket costs, including outside counsel's fees, within [***] after request for reimbursement from [***]. If [***].

(e) If [***] assumes Prosecution responsibility pursuant to Section 5.1(c), [***] shall [***] and provide [***] with copies of material correspondence (including applications, office actions, responses, etc.) relating to Prosecution of any [***] or ABI-009 Patent being prosecuted by [***]. [***] may provide [***] with respect to any material actions to be taken by [***], and [***] with respect to ABI-009 Patents. [***] shall consult with [***] before taking any action that would have a material adverse impact on the scope of claims within [***] or ABI-009 Patents and [***] shall take [***]. To facilitate the [***] right to [***], [***] shall provide copies of all such material correspondence and any proposed responses thereto by [***] at least [***] prior to any filing or response deadlines, or within [***] of [***] receipt of any official correspondence if such correspondence only allows for [***] or less to respond, and [***] shall provide [***] promptly and in sufficient time to allow [***] to meet applicable filing requirements. [***] shall give due consideration to any [***] request to amend the [***]; provided that, if any [***] are not received by [***] sufficiently in advance of any deadline for taking action, [***] may take action without considering [***] comments or instructions, as the case may be.

(f) Although the following Patent families have claims that are not solely directed to ABI-009, a Licensed Product or their use in the Field, Abraxis agrees that the [***] set forth on Exhibit 1.40 may be treated as ABI-009 Patents under this Agreement.

5.2 Patent Marking. AADi agrees to mark all Licensed Products or, if the marking on the products is impracticable, the packaging of such Licensed Products, in such manner conforming with the applicable patent laws, using content, form, location and language in accordance with the laws and practices of the country where such markings are used and as reasonably requested by Abraxis. On Abraxis' request, AADi agrees to cease so marking any batches of Licensed Products manufactured after the date specified by Abraxis in its request.

5.3 Third Party Infringement.

(a) Notice re Infringement of the Licensed Patents. If AADi becomes aware of infringement of any Patent included in the Licensed Patents by a Third Party, AADi shall promptly notify Abraxis in writing to that effect and provide a summary of the relevant facts and circumstances known to such Party relating to such infringement. The notice shall specify if the infringement is based on the manufacture, use or sale of a Licensed Product (an "***Infringing Product***").

(b) Suits by [***] for Infringement. As between Abraxis and AADi, [***] shall have the right, but not the obligation, to initiate, prosecute and control any action or proceeding to restrain infringement of [***] hereunder to the extent such patent covers a Licensed Product, at [***] expense. [***] agrees to be joined as a party if necessary to prosecute the action or proceeding and shall provide all reasonable cooperation, including any necessary use of its name, required to prosecute such litigation, provided that [***] shall reimburse [***] in connection with the foregoing. [***] shall control any such action or proceeding; provided that [***] shall (i) notify [***] prior to

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initiating any action to enforce a Licensed Patent against an Infringing Product, (ii) keep [***] reasonably informed with respect to such action or proceeding and reasonably consult with [***] with respect to [***] conduct of such action or proceeding, and (iii) [***]. [***] shall also control negotiations and settlement or compromise of such action or proceeding; provided that [***] consent [***] shall be required for any settlement or compromise that imposes any liability on [***]; provided further that [***] shall [***] comments with respect to any settlement or compromise that materially adversely affects the scope, validity or enforceability of any ABI-009 Patent or any Licensed Patent that involves an [***] invention and that, in either case, covers a Licensed Product, except that [***] shall have final decision making authority with respect to such settlement or compromise. Notwithstanding the foregoing, on [***] request but not more than [***], [***] agrees to consider in good faith and discuss granting [***].

(c) Costs and Recoveries from Infringement Action. [***] shall assume and pay its out-of-pocket costs incurred in connection with any litigation or proceedings described in this Section 5.3, including the fees and expenses of counsel. Any recovery obtained by any Party as a result of any proceeding described in this Section 5.3, by settlement or otherwise, shall be applied in the following order of priority: (i) first, [***]; (ii) second, to [***]; (iii) third, [***]; and (iv) third, [***]. Notwithstanding the foregoing, in the event a portion of the recovery is required to be paid pursuant to the [***], such portion(s) will [***].

(d) Declaratory Actions and Counterclaims Against Abraxis or AADi. In the event that an action alleging invalidity or non-infringement of any of the Licensed Patents shall be brought against Abraxis or AADi that is related to a Licensed Product, [***] shall have the right to take and control the action, in accordance with the provisions of Section 5.3(b) hereof. Any costs incurred or recovery obtained with respect to such litigation, proceeding or settlement shall be borne or retained by [***].

5.4 Infringement of Third Party Rights. With respect to any and all claims instituted by Third Parties for Patent infringement involving the manufacture, use, offer for sale, sale or importation of a Licensed Product covered by the Licensed Patents during the Term, AADi shall promptly notify Abraxis of such claim and [***] shall have the first right, but not the obligation, to defend and control any action or proceeding with respect to such claim, at [***] sole expense and otherwise in accordance with the provisions of Section 5.3(b) hereof. If [***] elects not to defend and control such action, [***] may do so at its expense, provided, however, that [***] may [***] participate in such suit and be represented by counsel of its choice, at its own expense.

6. SUPPLY OF LICENSED PRODUCT

6.1 Limited Obligation to Supply. Abraxis agrees to [***] supply AADi with Licensed Products solely as set forth in this Article 6 and in accordance with the supply terms attached hereto as Exhibit 6.1. Abraxis agrees to [***] manufacture and supply [***], as agreed by the parties prior to the Restatement Effective Date, for clinical or non-clinical development for the development activities currently contemplated by AADi to support submission of an NDA for a Licensed Product. All costs incurred by Abraxis for such manufacture, supply and stability testing will be included as costs

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incurred by Abraxis for the supply of Licensed Product to AADi pursuant to Article 6 in the calculation of “Fully Loaded Costs” and will be subject to AADi’s payment obligations under Section 7.2.

6.2 Commercial Supply. AADi shall be solely responsible for commercial supply of Licensed Product.

6.3 Transition Assistance. Abraxis agrees to [***] provide certain transition assistance set forth in Exhibit 6.3. All such transition services, whether performed by Abraxis or a Third Party on behalf of Abraxis, shall be paid by AADi to Abraxis in advance.

6.4 [***]. AADi understands and agrees that Licensed Product shall be supplied in the form and dosage strength described in [***]. In no event will Abraxis be obligated to modify the Licensed Product in any way, including dosage form or strength except as expressly set forth in this Section 6.4. Upon AADi’s written request, if agreed to by Abraxis in its sole discretion, and at AADi’s sole expense at Abraxis’ [***], Abraxis shall use [***], to develop and manufacture for AADi [***] products as follows: (a) [***] as of the Effective Date, (b) [***], and (c) [***]. Such [***]. In addition, AADi can develop [***] with the prior written approval of Abraxis. Any [***] developed by Abraxis or AADi pursuant to Section 6.4 shall be deemed a Licensed Product hereunder.

6.5 Services. In furtherance of developing the Licensed Product, from time to time during the Term, AADi may request that Abraxis perform specified development services and activities related to manufacturing and supply of Licensed Products and any additional activities as may be required by a Regulatory Authority to obtain or maintain any Regulatory Approval, IND or other regulatory filing with respect to a Licensed Product (collectively, “Services”). Such Services, if agreed to by Abraxis, in its sole discretion, shall be performed by Abraxis for AADi on a fee for services basis in accordance with a scope of services agreement executed by the Parties (each a “Scope of Services Agreement”). Upon execution by the Parties, each such Scope of Services Agreement shall be subject to all of the terms and conditions of this Restated Agreement and shall be incorporated herein by reference. With respect to any agreed upon Services, the Parties shall agree in advance in writing on a work plan, timeline, any deliverables, budget and cost. All such Services, whether performed by Abraxis or a Third Party on behalf of Abraxis, shall be paid by AADi to Abraxis in advance.

6.6 Other Matters. AADi acknowledges and agrees, as follows:

6.6.1 As set forth in Section 2.5 of Exhibit 6.1, Abraxis may subcontract any of its obligations with respect to the manufacture or testing of Licensed Product, and the current expectation is that a Third Party will be used for such activities. As such, the scope of Abraxis obligations to AADi under this Agreement will be subject to the rights of Abraxis under the applicable agreement with the Third Party (the “Third Party Agreement”); provided that Abraxis will [***] enforce the terms and of the Third Party Agreement, at [***] cost (but Abraxis will not be required to institute any litigation). For example, (a) if AADi disputes any payments owed to such Third Party, Abraxis will [***] dispute such obligations with the Third Party; however, [***] will be responsible for any payments that such Third Party demands are owed, but [***] will also receive the benefit of any refunds from such Third Party (as described in the definition of “Fully Loaded Costs”); (b) if AADi rejects any Licensed Product pursuant to Section 4.2 of Exhibit 6.1, notwithstanding the procedure set

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forth in such Section 4.2, the procedure for rejection under the Third Party Agreement will govern rejection of Licensed Product, and AADi will abide by the outcome of such determination; (c) any audit or inspection rights under this Agreement or the GMP Agreement will be limited to audit and inspection rights Abraxis is able to pass onto, or exercise on behalf of, AADi under the Third Party Agreement; and (d) Abraxis' liability for damages for breaches of this Agreement caused by such Third Party and Abraxis' indemnification obligations under Article 10 with respect to Losses caused by such Third Party will be limited to [***]. To the extent permitted, Abraxis will make a copy of any Third Party Agreement available to AADi, upon its reasonable request, which copy may be redacted with respect to matters that are not related to this Agreement or otherwise confidential.

6.6.2 In determining what constitutes [***] for purposes of Abraxis fulfilling its obligations under this Article 6, Abraxis will not be required to [***]; and Abraxis may take into account such things as [***], in each case, of the Licensed Product and Abraxis' products when making determinations as to how to prioritize products.

6.7 Termination of Supply Obligations. Except as set forth herein, Abraxis' supply obligations hereunder are terminated. Abraxis will continue to manufacture (or have manufactured) and supply to AADi Licensed Products only in accordance with Section 6.1 of this Agreement, for delivery of [***]. Although the Parties do not currently anticipate any supply beyond [***], only to any extent Section 6.1 of this Agreement might somehow result in any supply beyond [***], any and all such obligations shall terminate, regardless, upon the earlier of (i) [***] and (ii) [***].

7. CONSIDERATION

7.1 Initial Fee.

7.1.1 Initial Fee. AADi shall pay to Abraxis \$[***], of which amount: (a) \$[***] shall be paid by AADi within [***] following the Effective Date in partial consideration of the rights granted to AADi hereunder, and (b) (i) \$[***] shall be paid by AADi within [***] following the Effective Date and (ii) \$[***] shall be paid by AADi within [***] following the Effective Date, and the amounts in each of clause (b)(i) and (b)(ii) shall be reimbursement for [***]. The Parties acknowledge and agree that AADi paid to Abraxis \$[***] pursuant to [***].

7.2 Cost for Supply of Licensed Product. Abraxis will supply to AADi Licensed Products pursuant to Section 6.1 and Exhibit 6.1 at [***]. Abraxis shall invoice AADi for the amount due for the Licensed Product with or promptly [***] of Licensed Product. Notwithstanding the foregoing, Abraxis hereby [***] and [***], and [***].

7.2.1 Royalties. In consideration of the rights granted to AADi hereunder, AADi shall pay to Abraxis a royalty on Net Sales of Licensed Products in the percentages set forth below, as set forth in this Section during the applicable Royalty Term, in addition to the [***] in accordance with Section 7.5 below. AADi will pay to Abraxis the royalties due hereunder simultaneously with each such report submitted under Section 8.12.2. AADi will pay a royalty of [***] on Annual Net Sales of [***]. AADi will pay a royalty of [***] of Annual Net Sales [***]. AADi will pay a royalty of [***] on Net Sales [***]. AADi will pay a royalty of [***] of Net Sales [***]. For such purposes,

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“**Annual Net Sales**” means the total Net Sales of Licensed Products in a particular calendar year by AADi, its Affiliates and Sublicensees.

7.2.2 On a Licensed Product-by-Licensed Product basis, royalties shall be due commencing with the first commercial sale of the Licensed Product in a particular country of the Territory until the later of [***] (such period, on a country-by-country basis, the “**Royalty Term**”).

7.2.3 In the event there are no longer (or never were) any Valid Claims of Licensed Patents in the applicable country and there no longer is (or never was) any marketing or data exclusivity for the Licensed Product in the applicable country, at such time, the applicable royalty rate will be reduced by [***] until the expiration of [***] from the first commercial sale of such Licensed Product in such country of the Territory.

7.3 Royalty Stacking. If AADi, its Affiliate or Sublicensee licenses any Third Party Patent right that is necessary to avoid infringement of such Third Party Patent by using, offering for sale or sale of a Licensed Product, the royalties owed to Abraxis under Section 7.3 with respect to such Licensed Product may be reduced by the royalty payments made to such Third Party; provided that such royalty payments owed to Abraxis shall not be reduced by more than [***] of the amount that would otherwise be payable to Abraxis under such Sections.

7.4 Third Party Payments.

7.4.1 In addition to any royalties and other amounts due pursuant to this Agreement, AADi agrees to pay any royalties owed by Abraxis under [***] that are owed with respect to activities of AADi in exercising its license under this Agreement ([***]), including payments on sales of Licensed Products triggered by AADi’s activities that would not have been payable by Abraxis but for sales of Licensed Products by AADi, its Affiliates or Sublicensees. AADi’s obligation under this Section 7.4 for [***] shall continue for so long as any payment obligations are due under [***]. [***] due by AADi will be calculated as follows:

(a) Abraxis will, promptly after the end of each Net Sales Measuring Period notify AADi of the aggregate “Net Sales” of products or services subject to royalty payments under [***] (such products and services, collectively, the “[***]”) sold by Abraxis, AADi, and all Abraxis’ other licensees under [***] during the applicable reporting period as determined in accordance with [***]. In the event of any conflict between the definition of “Net Sales” in this Agreement and “Net Sales” in [***], the definition in [***] shall apply to determining AADi’s [***].

(b) AADi will pay Abraxis a share of the royalties owed under each royalty tier of [***]. By way of nonlimiting example, if (x) [***], (y) [***], and (z) [***], then, (A) [***].

(c) AADi will make all [***] due with respect to [***] to Abraxis not less than [***] prior to the date on which such amounts must be paid by Abraxis to [***] under [***].

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7.5 Sublicense Fees.

7.5.1 AADi shall pay to Abraxis [***] of any and all Sublicense Fees. Such amounts shall be paid to Abraxis within [***] of AADi's receipt of Sublicense Fees from a Sublicensee.

7.6 Other Charges. Abraxis will invoice AADi for other amounts payable by AADi hereunder (including amounts due pursuant to Sections 6.3 and 6.5) on a periodic basis, but no more frequently than [***]. Such amounts will be due within [***] of the date of the applicable invoice. For the avoidance of doubt, Abraxis may submit invoices to AADi for [***] as such costs are incurred, subject to the foregoing [***] limitation.

7.7 Payments. All sums payable herein to Abraxis pursuant to this Agreement are specified in and shall be paid in United States Dollars without any deductions and are exclusive of any sales, use, transfer, excise, import, value added or other national, federal, state or local taxes (but excluding withholding taxes to the extent provided in Section 7.9), and AADi agrees to pay, and to hold Abraxis harmless from and against, all such taxes. All amounts due to Abraxis shall be remitted by check, electronically or other manner as mutually agreed by the Parties and to the location designated by Abraxis in the applicable invoice. In the event royalties accrue in a currency other than United States Dollars, those royalties shall be converted to United States Dollars at the exchange rate listed in the Wall Street Journal (N.Y. Edition) on the last day of the calendar quarter during which the royalties accrued. AADi's reports, as required by Section 8.12.2, shall contain a statement setting forth any such computation of the number of United States Dollars remitted. Past due payments shall be subject to interest payable at the rate of [***], or the highest rate allowed by applicable law, whichever is lower.

7.8 Taxes. If laws or regulations require withholding by AADi of any taxes imposed upon Abraxis with respect to Abraxis' gross or net income on account of any royalties or other payments paid under this Agreement, such taxes shall be deducted by AADi as required by law from such payment and shall be paid by AADi to the proper taxing authorities. Official receipts of payment of any withholding tax shall be secured and sent to Abraxis as evidence of such payment. At the request of Abraxis, AADi shall give Abraxis such reasonable assistance, which shall include the prompt provision of appropriate certificates of such deductions made together with other supporting documentation as may be required or requested by the relevant tax authority, to enable Abraxis to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and shall upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax. In any event, at Abraxis' reasonable request, AADi shall provide Abraxis reasonable assistance so that Abraxis may ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the applicable tax treaty, and each Party shall reasonably cooperate in filing any forms required for such reduction.

7.9 Records. Each Party will keep accurate books and supporting data showing the amounts payable hereunder and will retain such books and supporting data for [***] following the end of the calendar year to which they pertain.

7.10 Audits.

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7.10.1 Abraxis may request an audit in writing for the sole purpose of verifying payments due from AADi under this Agreement for any period within the preceding [***] that has not previously been audited in accordance with this Section 7.10.1 or such other longer period as required of Abraxis pursuant to [***]; provided, however, that until [***], Abraxis may also audit AADi's compliance with the payment terms of this Agreement during the entire period between [***]; provided further that AADi's records for any particular calendar quarter shall be subject to no more than [***]. Audits may only occur [***] and will be conducted at Abraxis' sole expense during normal business hours by an independent certified public accountant selected by Abraxis that is reasonably acceptable to AADi. AADi shall immediately remit to Abraxis the amount of royalties or other amounts due, including payments arising under the CVR Agreement, found to have been underpaid by AADi. If royalties or other amounts due are found to have been understated by an amount in excess of [***] during the period subject to the audit, AADi shall reimburse Abraxis for the fees, costs and expenses of the independent auditor incurred in having the inspection conducted. AADi shall pay interest for any understated royalty or other amount due at the rate of specified in Section 7.8. Any amounts found to have been overpaid by AADi shall be promptly refunded by Abraxis. AADi agrees that, if an audit is requested under [***], AADi will allow the independent accountant appointed thereunder to review AADi's records in accordance with the terms of this Section 7.10.1.

7.10.2 AADi may request an audit in writing for the sole purpose of verifying payments due from AADi under Sections 6.4 and 7.2 with respect to supplies of Licensed Products for any period within the preceding [***] that has not previously been audited in accordance with this Section 7.10.2; provided, however, that Abraxis' records for any particular calendar quarter shall be subject to no more than [***]. Audits may only occur [***] and will be conducted at AADi's sole expense during normal business hours by an independent certified public accountant selected by AADi that is reasonably acceptable to Abraxis. AADi shall immediately remit to Abraxis any amounts found to have been underpaid by AADi with respect to the Services provided by Abraxis in accordance with Section 6.4 above or supplies of Licensed Products under Section 7.2 above. If amounts due under Section 6.4 and/or 7.2 are found to have been overstated by an amount in excess of [***] during the period subject to the audit, Abraxis shall reimburse AADi for the fees, costs and expenses of the independent auditor incurred in having the inspection conducted. Any amounts found to have been overpaid by AADi under Section 6.4 and/or 7.2 with respect to Services or supplies of Licensed Product, as applicable, shall be promptly refunded by Abraxis.

7.11 Reports.

7.11.1 Until [***] after AADi becomes a publicly traded entity on either the NYSE or NASDAQ, AADi will provide Abraxis with financial statements for the preceding fiscal year [***], on or before the [***] following the close of its fiscal year, but at a minimum AADi must provide Abraxis with an audited balance sheet and an audited operating statement, on or before the [***] following the close of its fiscal year.

7.11.2 Within [***], or as otherwise mutually agreed, after [***] of each year, AADi will deliver to Abraxis any and all payments due to Abraxis under this Article 7 (other [***], which are due as set forth in Section 8.5.1(c)) for the relevant quarter and true and accurate reports, including at least the following with respect to the Territory:

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- (a) quantity of Licensed Products sold;
- (b) total gross invoice price charged by AADi and its Sublicensees for Licensed Products sold;
- (c) an itemized calculation of Net Sales for the Licensed Products showing deductions for such reporting period provided for in accordance with the definition of Net Sales;
- (d) total royalties due under Section 7.3;
- (e) names and addresses of all Sublicensees;
- (f) total of Abraxis' share of Sublicense Fees paid during the relevant quarter or due with the report; and
- (g) to the extent that sales for the Licensed Products for an applicable period is recorded in currencies other than United States dollars, the exchange rates used for conversion of such foreign currency into United States dollars.

7.11.3 To the extent Abraxis needs additional information from AADi to calculate amounts due under [***], AADi will promptly provide such information to Abraxis upon request.

8. REPRESENTATIONS, WARRANTIES AND COVENANTS; LIMITATION OF LIABILITY

8.1 **Mutual Representations and Warranties.** Each Party hereby represents, warrants and covenants to the other Party that:

- (a) such Party is a corporation or entity duly organized, validly existing and in good standing under the laws of its state or country of incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) such Party is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such Party does not require any shareholder action or approval and the Person executing this Agreement on behalf of such Party is duly authorized to do so by all requisite corporate action;
- (c) no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required on the part of such Party in connection with the valid execution, delivery and performance of this Agreement, except where the failure to obtain any of the foregoing would not have a material adverse impact on the ability of such Party to meet its obligations hereunder;
- (d) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms except as enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors' rights and (ii) equitable principles of general applicability; and

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(e) the execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions of this Agreement does not and will not conflict with or result in a breach of any of the terms or provisions of (i) any other contractual or other obligations of such Party, (ii) the provisions of its charter, operating documents or bylaws, or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which it or any of its property is bound except where such breach or conflict would not materially impact the Party's ability to meet its obligations hereunder; and it shall comply in all material respects with all laws, rules and regulations applicable to its performance under this Agreement, including requirements relating to listing clinical trials on clinicaltrials.gov.

8.2 Disclaimer of Warranties.

8.2.1 Nothing in this Agreement shall be construed as a representation, and warranty and Abraxis expressly disclaims any and all representations or warranties (a) regarding the validity or scope of the Licensed IP, (b) that anything made, used, sold, imported or otherwise disposed of under this Agreement is or shall be free from infringement of Third Party Intellectual Property rights; or (c) regarding an obligation to bring or prosecute infringement or other actions or suits against Third Parties. Abraxis makes no representations or warranties, either express or implied, with respect to the use, importation, sale, lease, distribution or other disposal by AADi of Licensed Products.

8.2.2 THE LICENSE AND OTHER RIGHTS GRANTED TO AADI HEREUNDER AND ANY INFORMATION PROVIDED BY OR ON BEHALF OF ABRAXIS HEREUNDER ARE GRANTED AND PROVIDED ON AN "AS IS," "WHERE IS" AND "WITH ALL FAULTS" BASIS. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8.3 Limitation of Liability.

8.3.1 NOTWITHSTANDING THE FOREGOING, EXCEPT FOR (A) [***], OR (B) [***], NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR PUNITIVE, EXEMPLARY, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) ATTRIBUTABLE TO ANY BREACH OR DEFAULT BY SUCH PARTY UNDER THIS AGREEMENT. THIS LIMITATION SHALL SURVIVE ANY FAILURE OF THE ESSENTIAL PURPOSE OF A LIMITED OR EXCLUSIVE REMEDY SET FORTH HEREIN.

8.3.2 [***], IN NO EVENT SHALL ABRAXIS' LIABILITY FOR ANY DAMAGE, LOSS OR CAUSE OF ACTION IN CONNECTION WITH, RELATED TO OR ARISING OUT OF THIS AGREEMENT EXCEED THE GREATER OF (A) [***] OR (B) \$[***]. [***], IN NO EVENT SHALL ABRAXIS' LIABILITY FOR ANY DAMAGE, LOSS OR CAUSE

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OF ACTION IN CONNECTION WITH, RELATED TO OR ARISING OUT OF THIS AGREEMENT EXCEED THE GREATER OF (I) [***] OR (II) \$[***]. THE FOREGOING LIMITATIONS ON ABRAXIS' LIABILITY IN THIS SECTION 8.3.2 DO NOT APPLY TO ABRAXIS' ACTIVITIES OUTSIDE THE FIELD WITH ABI-009 NOR LIMIT ABRAXIS' INDEMNIFICATION OBLIGATIONS UNDER SECTION 11.2(B) OR (C).

9. CONFIDENTIALITY/ABRAXIS PROTECTED INFORMATION, PUBLICATION AND PUBLIC ANNOUNCEMENTS

9.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, Abraxis and AADi agree that each of Abraxis and AADi, upon receiving or learning of any Confidential Information of the other Party, shall keep such Confidential Information confidential and otherwise shall not disclose or use such Confidential Information during and after the Term for any purpose other than as provided for in this Agreement. The Receiving Party shall advise its employees and consultants who might have access to the Disclosing Party's Confidential Information of the confidential nature thereof and agrees that its employees and consultants shall be bound by obligations of confidentiality, nonuse and nondisclosure at least as stringent the terms of this Section 9.1 and Sections 9.2, 9.3, 9.5, 9.9, 9.10 and 9.11. The Receiving Party shall not disclose any Confidential Information of the Disclosing Party to any employee, consultant or other individual who does not have a need for such information.

9.2 Authorized Disclosure. Notwithstanding the foregoing, each of Abraxis and AADi may disclose Confidential Information of the other Party (a) to a Third Party to the extent such disclosure is reasonably necessary to exercise the rights granted to or retained by it under this Agreement; (b) [***] on a need to know basis and subject to obligations of confidentiality, nonuse and nondisclosure at least as stringent as those set forth in Sections 9.1, 9.2, 9.3, 9.5, 9.9, 9.10 and 9.11; and (c) in defending litigation, complying with applicable governmental regulations, or submitting information to tax or other governmental authorities (including Regulatory Authorities), provided that, if a Party is required pursuant to an order of a court of competent jurisdiction or other government order or judicial process to make any such disclosure of the Disclosing Party's Confidential Information, to the extent it may legally do so, it will give reasonable advance written notice to the Disclosing Party of such disclosure and will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). Notwithstanding the foregoing authorized disclosures of the Disclosing Party's Confidential Information or the provisions of Sections 1.17(a) through (f), subject to Section 9.7, AADi is prohibited from disclosing, under any circumstances, any [***], including any information relating to the manufacture of the Licensed Products or processes or know-how relating thereto, except to any Permitted Parties (as defined in Section 9.7.12), without Abraxis' prior written consent; provided that, if AADi is required pursuant to a valid order of a court of competent jurisdiction or other government order or judicial process to make any such disclosure of any [***], AADi may disclose [***] if AADi has first given (i) written notice to Abraxis within [***] of receipt of the document to which AADi is responding or at least [***] prior to any disclosure if such notice is less than [***] in advance of the required production of the applicable [***], (ii) Abraxis an opportunity to review and approve any disclosures AADi intends to make in response to the applicable court or governmental order or judicial process, and (iii) Abraxis a reasonable opportunity to take appropriate

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action and cooperate with Abraxis as necessary and requested by Abraxis to obtain an appropriate protective order; provided further that, in each case, the [***] disclosed in response to such court or governmental order or judicial process will be limited to that information that is legally required to be disclosed in response to such court or governmental order or judicial process, as determined in good faith by counsel to AADi.

9.3 Return of Confidential Information. Upon termination or expiration of this Agreement the Receiving Party shall promptly return all of the Disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the Receiving Party may retain one copy for its legal files; provided that any [***] must be returned by AADi upon request of Abraxis without any copies being retained; provided that, to the extent that the provisions of Section 11.3.2 apply, Abraxis may retain copies of AADi's Confidential Information to use in accordance with such section.

9.4 Destruction of Confidential Information. On Abraxis' request, AADi will destroy, or at Abraxis' option return, and will cause the destruction or return of any [***] in the possession or control of AADi, its Affiliates, Sublicensee or any Designee prior to any such Person entering into any partnering arrangement for nab-rapamycin, or prior to AADi being acquired by a Third Party.

9.5 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

9.6 Use of Abraxis Resources. The Parties acknowledge that [***], a member of AADi, [***], and that his activities and those by AADi, pursuant to the terms of this Agreement, shall not be construed in any way to constitute a violation of [***]. In connection with such employment, [***] may have access to Confidential Information, including [***], and other resources of Abraxis and its Affiliates. AADi represents, warrants and covenants that it will ensure that [***] does not use any such Abraxis' Confidential Information, including [***], or other resources obtained as a result of his employment relationship with Abraxis in connection with the conduct of the business of AADi, including in connection with this Agreement.

9.7 [***], AADi acknowledges and agrees to the following:

9.7.1 AADi has or will have certain access to [***] through this Agreement.

9.7.2 Abraxis reasonably believes that AADi has a need for access to [***] under this Agreement solely for the purposes of developing, commercializing, making and having made ABI-009 or Licensed Product(s) for the Field ("**Authorized Purpose**").

9.7.3 Abraxis may disclose [***] to AADi in order for AADi or any Permitted Parties (as defined in Section 9.7.12) to perform activities under this Agreement for the Authorized Purpose.

9.7.4 AADi's access and use of [***] shall only be in connection with activities under this Agreement for the Authorized Purpose and for no other purpose whatsoever.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

9.7.5 AADi acknowledges that the [***] requires [***].

9.7.6 All [***] received by AADi shall remain property owned by Abraxis or its Affiliates.

9.7.7 AADi shall not disclose the [***] to any other Person other than a Permitted Party, except as expressly permitted pursuant to Sections 3.2.3, 9.2 and 9.7.12, but subject to the provisions of this Section 9.7. The prohibitions and restrictions on disclosure and use of and access to [***] in this Agreement survive the expiration or termination of this Agreement for any reason whatsoever.

9.7.8 The disclosure of [***] to AADi does not give any express or implied right or license to AADi to use the [***] for any purpose other than to perform activities under this Agreement for the Authorized Purpose.

9.7.9 Nothing in this Agreement shall be construed as an obligation on Abraxis to disclose [***] to AADi.

9.7.10 All [***] provided to AADi by Abraxis must be returned to Abraxis as provided in Section 9.3 or 9.4 above, as applicable, or otherwise on Abraxis' request, with all copies and other materials containing any [***] including any such materials generated by or for AADi such as notes, data, results, etc.

9.7.11 Given that it is presumed that any breach by AADi of the covenants and terms contained in this Agreement will cause irreparable harm to Abraxis, the Parties further agree that, in addition to and without limiting the provisions of Section 12.9, Abraxis shall be entitled to injunctive relief in any court of competent jurisdiction to enjoin any such breach or threatened breach by AADi. This shall not limit the recovery of money damages as may be appropriate and awarded by any such court.

9.7.12 AADi acknowledges and agrees that it may not disclose the [***] to any Person (whether a Third Party, Affiliate, or any employee or contractor of AADi or an Affiliate) except to a [***] (collectively, the "**Permitted Parties**"); provided that under no circumstances shall [***] ever be considered to be a Permitted Party. [***]. Furthermore, any other Persons to whom AADi discloses [***] (as approved by Abraxis) will enter into an appropriate written agreement obligating such Persons to be bound by obligations of confidentiality and restrictions on disclosure and use of such Confidential Information that are no less restrictive than the obligations set forth in this Article 9.

9.7.13 To the extent any inspection, audit, or other rights granted by Abraxis to AADi under this Agreement (or any ancillary agreement such as the GMP Agreement or any commercial manufacturing agreement) would result in the disclosure of any [***], such inspection, audit, or other right may only be exercised by AADi through [***], at least to the extent of such disclosure of [***].

9.7.14 AADi certifies that it has read, understood and voluntarily agreed to the obligations set forth in this Section 9.7.

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9.8 Specific Restrictions on Use of Confidential Information. To ensure adequate protection and maintenance of the confidentiality [***], AADi acknowledges and agrees to the following:

9.8.1 Prohibited Activities. As a condition to this Agreement, which provides, inter alia, access to the [***], including [***], and licenses to the Licensed Patents and Licensed Technology on the terms set forth herein, AADi covenants and agrees that, except for Licensed Products in accordance with this Agreement, AADi shall not, directly or indirectly:

(a) make, develop, market or distribute, alone or in concert with others during the Term and [***] in which (i) [***] or (ii) [***]; and

(b) without limiting the foregoing restrictions in Section 9.8.1(a), make, develop, market, or distribute alone or in concert with others anywhere in the world, any pharmaceutical formulation or product manufactured by use of or with reference to any of Abraxis' (or its Affiliates') Confidential Information, [***], or Abraxis' or its Affiliates' Intellectual Property or assist any other Person in doing the same (other than Abraxis or any of its Affiliates).

9.8.2 AADi further expressly agrees that its obligations in subsections 9.8.1(a) and (b) are reasonable and necessary to [***], and that Abraxis would be irreparably harmed if AADi breached its obligations.

9.8.3 AADi covenants and agrees that any proposed Sublicensee, successor, assign, Desai or any other Affiliate shall be advised of these prohibitions and shall agree in a writing in favor of Abraxis and its Affiliates to be bound to the provisions of this Article 9, including this Section 9.8, as a condition of, and prior to seeking, Abraxis' approval for the grant of a Sublicense to such Sublicensee, or the transfer or assignment of any of AADi's rights under this Agreement to a successor or assign or Affiliate.

9.8.4 AADi and Abraxis agree that the contractual period of time set forth herein shall not limit or otherwise affect (a) the duration of trade secret rights under governing trade secret law, which may be substantially longer in time or (b) the duration of AADi's obligations pursuant to this Article 9.

9.9 Publications. AADi will provide Abraxis with a copy of any proposed publication or presentation relating to ABI-009 or relating to the Licensed IP or otherwise mentioning Abraxis or its Affiliates at least [***] prior to submission for publication or presentation. Any such publication or presentation shall be subject to reasonable review by Abraxis. AADi will delete from the proposed disclosure any of Abraxis' Confidential Information upon the request of Abraxis. Abraxis may require AADi to delay such publication or presentation for a period of up to [***] to allow Abraxis to secure adequate Intellectual Property protection of Abraxis' property that would be affected by the publication or presentation. AADi will not include the name of Abraxis, Celgene or any of their Affiliates or the terms "Abraxane" or "nab" in any publication or presentation without Abraxis' prior written consent, which may be withheld in its sole discretion except that Abraxis will not unreasonably withhold its consent to the use of any such names or terms if the use of such names or terms is necessary for compliance with applicable laws. In the event a proposed publication or presentation

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violates the foregoing restriction, Abraxis has the right to require AADi to cancel the proposed publication or presentation or delete the prohibited terms or words. Required submissions on clinicaltrials.gov will be subject to the provisions of this Section 9.9, except that the period for Abraxis' review will be limited to [***]. Abraxis' prior review under this Section 9.9 will not be required with respect to AADi reprinting any publications (a) previously published by Abraxis as of the Effective Date that are solely directed to ABI-009 or ABI-009's use in the Field or (b) previously approved by Abraxis under this Section 9.9, so long as, in either case, such reprint by AADi is in the format previously published by Abraxis or AADi, as applicable, without any modification or the addition of any new content and subject to AADi obtaining permission from any Third Parties having rights with respect to such publications.

9.10 Terms of Agreement. Each of the Parties agrees not to disclose to any Third Party the existence (unless and until a public announcement is made in accordance with Section 9.11) or the terms and conditions of this Agreement without the prior approval of the other Party, except each Party may make such a disclosure: (a) [***], in each case, subject to complying with the provisions of Section 10.2(b); or (b) to the extent necessary to comply with applicable laws, including securities laws, regulations or guidances; provided that, in the case of clause (b), (i) the disclosing Party shall promptly notify the other Party and allow the other Party a reasonable opportunity to oppose with the governmental authority initiating the process and, to the extent allowable by law, to seek limitations on the portion of this Agreement that is required to be disclosed; and (ii) any disclosure will be solely in the form of a redacted version of this Agreement, such redacted version to be reasonably and mutually agreed upon by the Parties.

9.11 Public Announcements. Neither Party may issue press releases or other similar public communications regarding this Agreement without the prior written consent of the other Party. The foregoing notwithstanding, communications required by applicable law or regulation will not require advance approval if (a) any such disclosure is limited to that information that is legally required to be disclosed; (b) a copy of the proposed communication is provided to the other Party at least [***] prior to release or communication thereof (or such lesser period as is necessitated in order to comply with law or by an emergency situation due to unexpected circumstances); provided that, if a Party does not reject or otherwise fails to approve such public announcement within [***] day period (or shorter period as applicable), the proposed communication will be deemed approved (subject, in any event, to a Party's non-disclosure and other obligations with respect to the other Party's Confidential Information under this Article 9); and (c) such Party considers in good faith the comments of the other Party. Further, neither Party shall employ or use the name of the other Party in any promotional materials or advertising without the prior express written permission of the other Party.

10. INDEMNIFICATION; INSURANCE

10.1 By AADi. AADi shall, at AADi's cost and expense, defend, indemnify and hold harmless Abraxis and its Affiliates and their respective directors, officers, employees and agents ("**Abraxis Indemnitees**") from and against any and all claims, actions, liabilities, losses, costs, damages, fees or expenses (including reasonable defense costs and reasonable attorneys' fees and expenses) ("**Losses**") incurred in connection with or arising out of any Third Party claim (a "**Third Party Claim**") to the extent relating to (a) [***], (b) [***], or (c) [***], in each case, provided,

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however, that such indemnity shall not apply to the extent such Loss relates to a matter described in clauses (a) through (d) of Section 10.2.

10.2 By Abraxis. Abraxis shall, at Abraxis' cost and expense, defend, indemnify and hold harmless AADi and its Affiliates and their respective directors, officers, employees and agents ("**AADi Indemnitees**") from and against any and all Losses, incurred in connection with or arising out of any Third Party Claim to the extent relating to (a) [***], (b) [***], (c) [***], or (d) [***]; provided, however, that such indemnity shall not apply to the extent such Loss relates to a matter described in clauses (a) through (c) of Section 10.1.

10.3 Indemnification Procedures.

10.3.1 In the case of a Third Party Claim as to which a Party may be obligated to provide indemnification pursuant to this Agreement, a Party or the applicable Indemnatee shall notify the indemnifying Party in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure.

10.3.2 If a Third Party Claim is made against an Indemnatee, the indemnifying Party will be entitled, within [***] after receipt of written notice from the Indemnatee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof (at the expense of the indemnifying Party) with counsel selected by the indemnifying Party and reasonably satisfactory to the Indemnatee, for so long as the indemnifying Party is conducting a good faith and diligent defense. Should the indemnifying Party so elect to assume the defense of a Third Party Claim, the indemnifying Party will not be liable to the Indemnatee for any legal or other expenses subsequently incurred by the Indemnatee in connection with the defense thereof; provided that, if under applicable standards of professional conduct a conflict of interest exists between the indemnifying Party and the Indemnatee in respect of such claim, such Indemnatee shall have the right to employ separate counsel (which shall be reasonably satisfactory to the indemnifying Party) to represent such Indemnatee with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by the indemnifying Party; provided, further, that the indemnifying Party shall only be responsible for the reasonable fees and expenses of one separate counsel for such Indemnatee; provided further that any conflict of interest will not impair the indemnifying Party's obligation to indemnify and hold harmless the Indemnatee. If the indemnifying Party assumes the defense of any Third Party Claim, (a) the Indemnatee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the indemnifying Party; (b) the indemnifying Party will promptly supply to the Indemnatee copies of all correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnatee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnatee (including, without limitation, providing to the Indemnatee on reasonable request updates and summaries as to the status thereof) and (c) all Indemnitees shall reasonably cooperate with the indemnifying Party in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the indemnifying

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Party). If the indemnifying Party does not elect to assume control of the defense of any Third Party Claim within the [***] set forth above, or if such good faith and diligent defense is not being or ceases to be conducted by the indemnifying Party, the Indemnitee shall have the right, at the expense of the indemnifying Party, after [***] notice to the indemnifying Party of its intent to do so, to undertake the defense of the Third Party Claim for the account of the indemnifying Party (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

10.3.3 The Indemnitee will agree to any settlement, compromise or discharge of such Third Party Claim that the indemnifying Party may recommend that by its terms obligates the indemnifying Party to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all liability in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the indemnifying Party shall not consent to any settlement, compromise or discharge (including the consent to entry of any judgment), and the Indemnitee may refuse in good faith to agree to any such settlement, compromise or discharge, that provides for injunctive or other non-monetary relief affecting the Indemnitee. The Indemnitee shall not (unless required by law) admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the indemnifying Party's prior written consent (which consent shall not be unreasonably withheld).

10.4 Insurance Proceeds. Any indemnification by Abraxis hereunder shall be made net of any insurance proceeds recovered by the AADi Indemnitee (it being understood that an Indemnitee may simultaneously pursue an insurance claim and a claim for indemnification hereunder); provided, however, that, if, following the payment to the AADi Indemnitee of any amount under this Article 10, such AADi Indemnitee recovers any insurance proceeds in respect of the claim for which such indemnification payment was made, the AADi Indemnitee shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to Abraxis.

10.5 Insurance. AADi shall maintain the following insurance, from reputable and financially secure insurance carriers: comprehensive commercial general liability insurance, including products liability insurance, with aggregate and single occurrence limits of not less than [***] and [***], and subject to such deductibles, in each case, as are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities. AADi also agrees that it will be solely responsible for ensuring that its agents (including contractors and subcontractors), its permitted assignees, licensees and Sublicensees maintain such other insurance as is reasonably required by AADi or such other insurance as is customary in such other parties' industries, at levels no less than those required as set forth above. Abraxis will be named as an additional insured in such policies. AADi will cause the liability it assumed under this Agreement to be specifically insured under the contractual liability section of the liability insurance policies. The liability policy will be primary without right of contribution from any insurance by Abraxis. Such policies will require that Abraxis be given not less than [***] prior written notice of any cancellation thereof or material change therein. AADi will provide Abraxis with certificates of insurance evidencing all of the above coverage and will provide Abraxis with certificates of insurance evidencing renewal or substitution of such insurance [***] prior to the effective date of such renewal or substitution. AADi shall bear the cost

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of maintaining such insurance for so long as Licensed Products continue to be sold or otherwise distributed and thereafter for so long as is necessary to cover any and all Third Party Claims which may arise from the development or sale of Licensed Products.

11. TERM AND TERMINATION

11.1 **Term.** This Agreement is effective as of the Effective Date and, unless sooner terminated as provided herein, shall remain in full force and effect until expiration of all milestone and royalty payment obligations under Sections 7.1 and 7.3 unless earlier terminated as set forth herein.

11.2 **Continuing Rights of Sublicensees.** Upon any termination of this Agreement, any Specified Third Party Sublicenses granted by AADi shall remain in effect and shall become a direct license of such rights by Abraxis to such Third Party Sublicensees, subject to such Third Party Sublicensees' agreeing in writing to assume AADi's terms, conditions and obligations to Abraxis under this Agreement as they pertain to the sublicensed rights; provided that, for the avoidance of doubt, Abraxis will not be liable to such Third Party Sublicensee with respect to any obligations of AADi that are not consistent with, or not required by, Abraxis' obligations to AADi under this Agreement. "**Specified Third Party Sublicense**" means any Third Party Sublicense granted by AADi that (a) [***], (b) [***], or (c) [***]. For the avoidance of doubt, upon any termination of this Agreement, any other sublicenses, including any sublicense of any AADi Affiliate Sublicensee, will terminate.

11.3 **Effect of Expiration or Termination.**

11.3.1 Expiration or termination of this Agreement pursuant to this Article 11 shall not (a) relieve a Party hereto of any obligation accruing to such Party prior to such expiration or termination, or (b) result in the waiver of any right or remedy by a Party hereto accruing to such Party prior to such expiration or termination; provided that, in the case of termination pursuant to Section 11.6.2, [***]; provided that AADi must submit a claim for indemnification under such section on or before the [***] anniversary of the Termination Date.

11.3.2 Upon termination of this Agreement by mutual agreement under Section 11.5, termination by AADi under Section 11.6.1 or termination by Abraxis under Section 11.4, 11.6.2, or 11.6.3, AADi agrees to the following:

(a) AADi shall assign to Abraxis all of AADi's Regulatory Approvals, all correspondence with the FDA or equivalent foreign Regulatory Authorities and any and all data, results and information for the Licensed Products and, unless otherwise agreed between Abraxis and any Sublicensees pursuant to Section 11.2, AADi shall cause all of its Sublicensees to assign to Abraxis all of such Regulatory Approvals and correspondence with the FDA or equivalent foreign Regulatory Authorities of the Sublicensees.

(b) AADi shall assign to Abraxis all of AADi's and its Affiliates' right, title and interest in the product trademark(s) (but not any house marks) and, to the extent owned by AADi, the generic name of the Licensed Product at the USAN (United States Adopted Name) Council.

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(c) AADi shall transfer to Abraxis all counsel patent files with respect to the Licensed Patents Prosecuted by AADi pursuant to Section 5.1.

(d) Without limiting Section 11.3.2(a) above, AADi agrees to grant, and does hereby grant (effective upon such termination), Abraxis an exclusive, irrevocable, perpetual, royalty-free, fully paid-up, worldwide, transferable license, including the right to grant sublicenses, under Patents and Technology (with rights of references as applicable) Controlled by AADi as of the effective date of termination that are necessary or useful to use, make, have made, sell, offer for sale, and import Licensed Products.

(e) AADi shall assign or sublicense to Abraxis, to the extent possible and as requested by Abraxis, AADi's rights and obligations under any Third Party licenses entered into with respect to the Licensed Products.

AADi will use reasonable efforts to complete the foregoing activities within [***] of the date of termination.

11.3.3 Upon termination of this Agreement for any reason, as of the effective date of such termination, all licenses (including all rights of reference) granted by Abraxis to AADi under this Agreement will terminate automatically (and Abraxis will thereafter have all rights previously licensed to AADi under this Agreement).

11.3.4 Upon termination of this Agreement for any reason, as of the effective date of such termination, all submitted but unfilled purchase orders of Licensed Product will be cancelled; and Abraxis will [***] discontinue any manufacturing or other services being provided to AADi in the most cost effective manner possible and as promptly as possible; provided that upon, termination of this Agreement by mutual agreement under Section 11.5 (except as otherwise agreed by the Parties), termination by AADi under Section 11.6.1 or termination by Abraxis under Section 11.4, 11.6.2, or 11.6.3, AADi will be responsible to pay for or reimburse Abraxis for such manufacturing and services until they are discontinued, including all non-cancelable obligations and including any costs associated with undelivered inventory of Licensed Product or works-in-process. Such payment will be at the same rate as otherwise provided in this Agreement. AADi will return to Abraxis all Licensed Product then in AADi's, its Affiliates, or Sublicensees' possession or control.

11.4 License Termination Events. If any one of the following events shall occur, each Party shall have the right to terminate this Agreement:

(a) to the extent permitted by law immediately upon written notice if any Party shall be adjudicated bankrupt, or shall make a transfer of all or substantially all of its assets for the benefit of creditors, or if a receiver shall be appointed to manage its business or assets, or if a petition shall be filed by such Party or by a creditor seeking adjudication of such Party as a bankrupt and such petition shall not have been dismissed within [***] of its filing;

(b) if any Party shall fail to perform its material obligations under this Agreement within [***] after a written default notice from the non-breaching Party; provided, however, that, if the purportedly breaching Party provides written notice to the non-breaching Party

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within [***] of the default notice disputing the alleged breach, the Parties agree to use good faith efforts to resolve the dispute amicably for up to [***], during which period the default notice will not become effective. [***] that this Agreement was materially breached and the breaching Party fails to cure such breach within [***] after such determination; or

(c) [***] after the FDA or EMA puts a clinical hold on all then-current Licensed Products or withdraws approval of the manufacture or marketing of all then-current Licensed Products, or if the FDA or any other Regulatory Authority that regulates all then-current Licensed Products takes any action the result of which is to prohibit the manufacture, sale, marketing or use of all then-current Licensed Products or takes any similar action concerning Licensed Product or any raw material contained therein or otherwise imposes any significant restriction with respect to the manufacture, sale, marketing or use all then-current Licensed Products.

11.5 Mutual Termination. The Parties may at any time terminate this Agreement through mutual agreement.

11.6 Unilateral Termination.

11.6.1 AADi may terminate this Agreement at any time upon written notice to Abraxis.

11.6.2 Abraxis has the right to terminate this Agreement as set forth in Section 4.5.

11.6.3 Abraxis has the right to immediately terminate this Agreement in the event that AADi, any Affiliate of AADi, or any Third Party assigned or designated by AADi, takes any action, directly or indirectly, [***] in connection with a challenge to the validity, enforceability, scope, inventorship or ownership of any of the Licensed IP in any court or tribunal or before the United States Patent and Trademark Office or, any other patent office or in any arbitration proceeding, including in connection with an opposition proceeding or re-examination.

12. MISCELLANEOUS

12.1 Designated Representative. The Parties each designate the following as their principal representatives to address questions and issues related to the following subject areas:

	<u>Abraxis</u>	<u>AADi</u>
•Manufacture and Supply of Licensed Products	[***]	[***]
•Regulatory Affairs	[***]	[***]
•Regulatory CMC	[***]	[***]
•Patent Prosecution	[***]	[***]
•Other matters related to this Agreement	[***]	[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

AADi may inquire with Abraxis as to its designated representatives from time-to-time. Neither Party will contact any employees, agents or representatives of the other Party, other than the individuals set forth above, except, on an issue-by-issue basis, with the express written consent of such other Party, the first Party may contact another person specifically designated as the point of contact for that issue, provided that, notwithstanding the foregoing, AADi may contact the designated Alliance Management person at Abraxis regarding any of the foregoing subject areas.

12.2 Assignment. This Agreement may be assigned or otherwise transferred (in whole or in part, whether voluntarily, by operation of law or otherwise) by AADi without the prior written consent of Abraxis *solely* [***]; provided, however, in no event will AADi be permitted to assign or otherwise transfer or delegate [***] this Agreement to [***]. Abraxis has the right to assign this Agreement without AADi's consent. If Abraxis assigns any of the Licensed Patents or Licensed Technology to a person or entity to whom this Agreement is not also assigned in its entirety, Abraxis shall obtain a written acknowledgement agreement from such person or entity that the relevant Licensed Patents and/or Licensed Technology are subject to the rights granted to AADi under this Agreement. Any attempted assignment in violation of this provision shall be null and void. This Agreement shall be binding upon the permitted successors and assigns of the Parties.

12.3 Further Actions and Obligations. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement. AADi acknowledges and agrees that at all times during the term of this Agreement, AADi will be responsible and liable for the activities of its Affiliates and Subsidiaries that have any rights or obligations under this Agreement, including as a Sublicensee.

12.4 Force Majeure. Neither Party shall be liable to the other Party for loss or damages, or shall have any right to terminate this Agreement for any default or delay directly attributable to any Force Majeure, provided that the Party affected gives prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder for so long as it is thereby disabled from performing such obligations; provided, however, that such affected Party promptly commences and continues to use its [***] to cure such disablement as soon as practicable.

12.5 Notices. Notices, payments, statements, reports, and other communications under this Agreement shall be in writing and shall be deemed to have been received as of the date received if sent by public courier (e.g. Federal Express), by Express Mail, return receipt requested, or by facsimile (with a copy of such facsimile also sent by one of the other methods of delivery) and addressed as follows:

If to Abraxis:

[***]

with a copy to:

[***]

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If to AADi:
[***]

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

12.6 Interpretation. The captions to the several Articles, Sections and Paragraphs of this Restated Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Restated Agreement. In this Restated Agreement, unless the context requires otherwise, (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine, and neuter pronouns and expressions shall be interchangeable; (d) the words “herein” or “hereunder” relate to this Restated Agreement; (e) “or” is disjunctive but not necessarily exclusive; (f) the word “will” shall be construed to have the same meaning and effect as the word “shall”; (g) all references to “dollars” or “\$” herein shall mean U.S. Dollars; (h) unless otherwise provided, all reference to Sections, Paragraphs, and exhibits in this Agreement are to Sections, Paragraphs and exhibits of and in this Agreement; and (i) whenever this Restated Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified. Business days shall mean a day on which banking institutions in New Jersey and New York are open for business. Each Party represents that it has been represented by legal counsel in connection with this Restated Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Restated Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

12.7 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

12.8 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

12.9 Equitable Relief. AADi acknowledges that a breach by it of the provisions of this Agreement (including Article 9 generally and AADi’s breach of Section 9.7 specifically) and Abraxis acknowledges that a breach by it of the provisions of Article 9, in each case, may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party is entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any such breach of this Agreement by such Party; provided, however, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach.

12.10 Counterparts, Facsimile Signatures. This Restated Agreement may be executed in 2 counterparts and such counterparts taken together shall constitute one and the same agreement. This

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Restated Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

12.11 Descriptive Headings. The descriptive headings of this Restated Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Restated Agreement.

12.12 Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to any choice of law provisions thereof that would result in the application of the law of any jurisdiction other than New York and excluding the United Nations Convention on Contracts for the International Sale of Goods.

Each Party hereby submits itself for the purpose of this Agreement and any controversy arising hereunder to the exclusive jurisdiction of the state and federal courts located in the State of New York, and any courts of appeal therefrom, and waives any objection on the grounds of lack of jurisdiction (including, without limitation, venue) to the exercise of such jurisdiction over it by any such courts.

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

12.14 Effect of Restatement; Entire Agreement of the Parties. The Parties agree that this Restated Agreement supersedes and replaces the Original Agreement, as amended, from and after the Restatement Effective Date. Notwithstanding the foregoing, the Parties agree and acknowledge that the Original Agreement shall govern the Parties' rights and obligations regarding the subject matter thereof from the Effective Date to the Restatement Effective Date, unless expressly modified herein. Subject to the foregoing sentence, this Restated Agreement hereby, together with the Exhibits attached hereto, constitutes and contain the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements whether oral or written, between the Parties respecting the subject matter hereof and thereof, including the Original Agreement.

12.15 Independent Contractors. The relationship between the Parties created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other except as expressly set forth in this Agreement.

12.16 Accrued Rights; Surviving Obligations. Upon the expiration or termination of this Agreement for any reason, all rights and obligations of the Parties under this Agreement shall

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terminate, except as provided in [***] or those rights or obligations described in the following Sections and Articles: [***].

12.17 Compliance with Export Regulations. AADi shall not export any technology licensed to it under this Agreement, except in compliance with United States export laws and regulations.

12.18 Expenses. Unless otherwise provided herein, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party which shall have incurred the same and the other Party shall have no liability relating thereto.

12.19 Third Party Beneficiaries. For the avoidance of doubt, Celgene and its Affiliates (other than Abraxis) are third party beneficiaries of this Agreement with the right to enforce any obligations of AADi hereunder. Except for Celgene and its Affiliates, no Person other than the Parties hereto and their respective successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

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

12.21 Dispute Resolution.

12.21.1 Resolution by Executive Officers. Except as otherwise provided in this Restated Agreement, in the event of any dispute, claim, or controversy arising under, out of, or in connection with this Agreement (a “**Dispute**”), including as to the breach, performance, or interpretation of this Agreement or the rights, duties, or liabilities of either Party hereunder, the Parties will first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. If such Dispute is not resolved on an informal basis within [***], either Party may, by written notice to the other Party, refer the Dispute to the Executive Officers for attempted resolution by good faith negotiation within [***] after such notice is received. Such Executive Officers will attempt in good faith to promptly resolve such Dispute. If any matter is not resolved, or both Parties believe that it will not be resolved, under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such matter in accordance with Section 12.21.2.

12.21.2 Arbitration. Except as otherwise expressly provided in this Section, if the Parties do not reach a mutually acceptable resolution pursuant to Section 12.21.1 as to a Dispute, the Dispute shall be referred for resolution by final, binding arbitration in accordance with the provisions of this Section. The arbitration shall be conducted by the American Arbitration Association (or any successor entity thereto) (“AAA”) under its rules of commercial arbitration then in effect, except as modified in this Restated Agreement. The arbitration shall be conducted in the English language, by a single arbitrator knowledgeable in the subject matter at issue in the Dispute and acceptable to both Parties; provided, however, that the Parties may by mutual agreement elect to have the arbitration conducted by a panel of three arbitrators (such single arbitrator or panel, the “**Arbitrator**”). The Arbitrator shall, if appropriate, engage an independent expert with experience in the subject matter of the Dispute to advise the Arbitrator.

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(a) With respect to any Dispute referred to arbitration pursuant to Section 12.21.2, the Parties and the Arbitrator shall use all reasonable efforts to complete any such arbitration within [***] from the issuance of notice of a referral of any such Dispute to arbitration except that for Disputes under Section 11.4(b), the Parties and the Arbitrator shall use all reasonable efforts to complete the arbitration within [***] from the issuance of notice of a referral of the Dispute to arbitration. The Arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery; provided that the Arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the Dispute.

(b) The decision of the Arbitrator shall be the sole, exclusive, and binding remedy between them regarding the Dispute presented to the Arbitrator. Any decision of the Arbitrator may be entered in a court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the Arbitrator shall not be made public without the joint consent of the Parties, and each Party shall maintain the confidentiality of such proceedings and decision.

(c) Unless otherwise agreed by the Parties, the arbitration proceedings shall be conducted in New York, New York. The Parties shall share equally the cost of the arbitration filing and hearing fees, the cost of the independent expert retained by the Arbitrator, and the cost of the Arbitrator and administrative fees of AAA. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses.

12.21.3 Temporary Relief. Pending the selection of the Arbitrator or pending the Arbitrator's determination of the merits of any Dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that Party.

[Signature Page Immediately Follows.]

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

ABRAXIS BIOSCIENCE, LLC

Pinto

By: /s/ Alexis M.

Name: Alexis M. Pinto
Title: Corporate Secretary

AADI BIOSCIENCE INC

Desai

By: /s/ Neil

Name: Neil Desai
Title: President and CEO

Desai acknowledges and agrees to
comply with the obligations set forth in
Article 9:

By: /s/ Neil Desai
NEIL DESAI

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Exhibit 1.40
Licensed Patents

[***]

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Exhibit 1.42: Licensed Technology

The following constitutes “Licensed Technology” to the extent otherwise included within the definition of “Licensed Technology” in Section 1.42(a) and, to the extent available in electronic form, shall be made available to AADi electronically on a secure server site or on DVD.

1. Regulatory Documents

[***]

2. Non-Clinical Study Documentation

[***]

3. Clinical Study Documentation

[***]

4. Manufacturing Documentation

[***]

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Exhibit 1.43: Listed Entities

[***]

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Exhibit 6.1: Supply Terms

1. Definitions

“**API**” means the Active Pharmaceutical Ingredient [***], also known as [***] with the Molecular Formula: [***] and Molecular Weight: [***].

“**Certificate of Analysis**” means the certificate for each batch of Licensed Product delivered hereunder in the form contemplated by the Specifications.

“**GMP Agreement**” means that certain Quality Agreement by and between the Parties dated as of October 26, 2015.

“**Specification**” means the specifications for Licensed Product agreed to by the Parties from time to time during the Term (and which, as of the Restatement Effective Date, are set forth in Appendix 1 to Exhibit 6.1). The Specifications may be modified upon the agreement by the Parties. Abraxis will not unreasonably withhold its consent to an amendment by AADi if such amendment is necessary to meet ongoing or new regulatory requirements or as required by Regulatory Authorities worldwide; and AADi will not unreasonably withhold its consent to an amendment by Abraxis if such amendment is necessary to address changes in the manufacturing process for the Licensed Products. The Parties will agree upon new specifications for any [***] of the Licensed Product developed in accordance with this Agreement.

2. Order and Supply of Licensed Product

2.1 AADi shall place purchase orders for Licensed Product electronically, by facsimile or by other means as established by Abraxis. All orders shall indicate the quantity and requested delivery date of each Licensed Product. Purchase orders must comply with the provisions of Section 3 of this Exhibit 6.1 below.

2.2 Abraxis shall manufacture all clinical supplies of Licensed Products in accordance with the Specifications for the Licensed Product. Abraxis’ manufacturing obligations will pertain to activities from API ordering through release testing of the Licensed Product in unlabeled vials, including sourcing and testing of raw materials, quality assurance and quality control, release testing, and validation batches and stability batches (including storage of such validation batches and stability batches). Unless otherwise agreed by the Parties or as set forth in Section 2.2 below, AADi will be responsible for all activities following such manufacturing, including all labeling and packaging, storage, distribution, shipping and logistics activities related to Licensed Product. Notwithstanding the foregoing, Abraxis has packaged and labeled the Existing Supply; provided that all costs incurred by Abraxis for such packaging and labeling will be included in the calculation of “Fully Loaded Costs” and will be subject to AADi’s

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payment obligations under this Agreement (including under Sections 6.1.1 and 7.2, as applicable). The Parties shall at all times comply with their obligations as set out in the GMP Agreement.

- 2.3 Abraxis shall make the Licensed Product (including the Existing Supply available to AADi or, if requested by AADi, directly to AADi's investigator sites on [***] at Abraxis' manufacturing facilities. Title and all risk of loss shall pass from Abraxis to AADi when such Licensed Product is made available to the common carrier designated by AADi.
- 2.4 Abraxis may subcontract any of its obligations with respect to manufacture or testing of Licensed Product, subject to obtaining any necessary approval from, or the provision of any required notice to, all appropriate Regulatory Authorities with respect thereto.
- 2.5 Abraxis shall provide reasonable advance notice to AADi of any changes to the manufacturing processes for a Licensed Product or the facilities at which such Licensed Product is manufactured to the extent the same may require an amendment to any regulatory filings or Regulatory Approvals for Licensed Products in the Territory, or otherwise require the provision of notice to, or the approval of, an applicable Regulatory Authority.
- 2.6 For the avoidance of doubt, AADi will be responsible for all storage, distribution and logistics activities associated with the supply of Licensed Product; provided that, upon AADi's request, Abraxis will provide reasonable assistance in such storage, distribution and logistics activities with respect to the Existing Supply for not more than [***] following the Restatement Effective Date. All costs incurred by Abraxis for such storage, distribution and logistics activities will be included in the calculation of "Fully Loaded Costs" and will be subject to AADi's payment obligations under this Agreement (including under Section 7.2, as applicable).

3. **Purchase Orders and Forecasts**

- 3.1 Within [***] after the Restatement Effective Date and on the [***], AADi shall provide Abraxis a [***] forecast, based on actual and planned enrollment for applicable clinical trials, showing AADi's estimated requirement for clinical supply of Licensed Product for [***] in which each such forecast is submitted. [***] of such forecast will be non-binding on AADi, and the delivery dates for [***] are binding on AADi. Given the lead times required for manufacturing Licensed Product and Abraxis' inability to modify the lead times, AADi acknowledges that in determining its requirements for clinical supply, AADi should consider including a [***] overage to account for any unexpected increase in the enrollment of clinical trials being conducted by AADi.
-

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- 3.2 Purchase orders for clinical supply of Licensed Product shall provide a minimum lead time prior to the desired delivery date, unless otherwise mutually agreed and must be consistent with the [***] forecast. The Parties will agree upon a minimum lead time for delivery, but AADi acknowledges that such lead time may be at least [***], depending on whether API or other materials must be ordered and on the then-current scheduling requirements of the facility being used to manufacture the Licensed Product. If necessary, the forecasting time periods will be modified to be consistent with the agreed upon lead time.
- 3.3 Each purchase order must be for the batch size quantity specified in Section 7 below (or integer multiple thereof), unless otherwise mutually agreed. Purchase orders shall be binding on the Parties as and when such orders are accepted by Abraxis; provided that Abraxis will use [***] to accept any purchase orders that do not exceed the applicable forecasted amount and are otherwise in accordance with this Agreement. With respect to any purchase order in excess of forecasted amounts or containing terms different than or in addition to those set forth in this Agreement, Abraxis shall use [***] to accommodate AADi's requests, but the Parties shall have no obligation with respect thereto until Abraxis specifically accepts such purchase order or the Parties mutually agree to a modification of the terms of such purchase order.

4. **Samples and Testing**

- 4.1 Final release testing shall be conducted according to the Specifications. Release testing shall be conducted per the required regulations in different regulatory jurisdictions. For product designated for use in the US, [***] on behalf of Abraxis shall complete all the release testing followed by a paper verification by AADi. For product designated for the EU, the [***] on behalf of Abraxis or Celgene 'Qualified Person' (QP) shall perform the product release on behalf of AADi, or alternatively, if mutually agreed by the Parties, product release shall be performed under subcontract.
 - 4.2 Abraxis' product development personnel (or those Third Party contract manufacturing organizations or contract laboratories that are specifically authorized by Abraxis) shall obtain a representative sample from each batch of Licensed Product produced by Abraxis. Abraxis shall perform release testing of such samples in strict accordance with the procedures set forth in the Specifications and shall provide a Certificate of Analysis for each batch. Abraxis shall provide AADi with a copy of the Certificate of Analysis in the format agreed upon by the Parties. All such activities shall be conducted in accordance with the terms of the GMP Agreement.
 - 4.3 **Rejection and Replacement of Licensed Products**
-

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- 4.3.1 AADi and/or its designee shall have [***] following Abraxis making the Licensed Product available to AADi to reject such Licensed Product on the grounds that all or part of the Licensed Product fails to conform to the Specifications or cGMP (as set forth in the GMP Agreement), which rejection shall be accomplished by giving written notice to Abraxis summarizing the manner in which all or part of such Licensed Product fails to meet the foregoing requirements.
- 4.3.2 Abraxis shall respond in writing to a rejection notice from AADi within [***] from the date of receipt of such rejection notice in accordance with Section 4.3.1 above. If Abraxis does not agree with AADi's determination that such Licensed Product fails to conform to the Specifications or cGMP (as set forth in the GMP Agreement), then Abraxis and AADi shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, Abraxis and AADi shall discuss in good faith mutually acceptable testing procedures pursuant to which both Abraxis and AADi will re-test a sample of the disputed Licensed Product to determine whether such Licensed Product so conforms. Notwithstanding the foregoing, in the event Abraxis and AADi are unable to resolve such disagreement within [***] of the date of the applicable rejection notice, either Party may submit a sample of the allegedly non-conforming Licensed Product for tests and a determination as to whether or not such Licensed Product so conforms to an independent testing organization mutually agreed upon by the Parties (the "**Laboratory**"), the appointment of which shall not be unreasonably withheld or delayed by either Party. The determination of the Laboratory with respect to all or part of any Licensed Product shall be final and binding upon the Parties. The fees and expenses of the Laboratory making such determination shall be borne equally by AADi and Abraxis.
- 4.3.3 Licensed Product accepted by Abraxis as not meeting the Specifications or cGMP (as set forth in the GMP Agreement), or which is determined by the Laboratory not to so conform, shall be returned by AADi to Abraxis, or disposed of, as directed by Abraxis. Abraxis shall replace all such rejected Licensed Product within the shortest possible time, but in any event, within [***] after its receipt of notice of such rejection (or, if applicable, the Laboratory's determination that such Licensed Product was non-conforming). If AADi rejects Licensed Product before the date on which payment therefor is due, AADi may withhold payment for such Licensed Product or the rejected portion thereof until replacement product is made available to AADi.
-

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5. **Product Complaints and Recalls.** AADi shall manage and resolve all Third Party complaints, grievances, product quality and any and all matters relating to any product recalls with respect to any Licensed Product in the Territory. To the extent such Third Party complaints are a result of product quality, Abraxis will reasonably collaborate with AADi in a timely fashion to resolve such issues.
6. **Cost of Licensed Products.** Abraxis shall supply Licensed Products to AADi pursuant to the terms of Section 7.2 of this Agreement.
7. **Batch Size of Licensed Products.** Abraxis shall produce the Licensed Products for clinical and non-clinical use in the batch sizes specified herein or as otherwise mutually agreed.

For clinical lots [***], a batch size of [***].

The Parties shall discuss in good faith and mutually agree upon appropriate batch sizes for any [***] developed under this Agreement.

8. **EMA and FDA compliant facilities.** Licensed Product for clinical use shall be manufactured in a facility that is fully qualified, and is simultaneously compliant under the GMP and regulatory requirements of the EMA and FDA.
-

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Appendix 1 to Exhibit 6.1

[***]

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Exhibit 6.3
Transition Assistance

[***]

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Exhibit 9.7: Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

This Confidentiality Agreement (“Agreement”) is entered into between _____ (“Recipient”) and Abraxis BioScience, LLC (“Abraxis”) as of _____ (“Effective Date”).

WHEREAS, “Abraxis Confidential Information” means Abraxis’ or its affiliates’ proprietary or confidential information, trade secret information, and know-how, including [***], manufacturing processes, business processes, and other technical information proprietary to Abraxis or its affiliates;

WHEREAS, “[***]” means Abraxis’ or its [***] that constitute [***];

WHEREAS, [***];

WHEREAS, Abraxis is a wholly-owned subsidiary of Celgene Corporation;

WHEREAS, Abraxis and AADi, LLC (“AADi”) have entered into a License Agreement dated as of April 9, 2014 (the “License Agreement”); and

WHEREAS, Abraxis, AADi, and Recipient would like for Recipient to have access to Abraxis Confidential Information and other confidential information in connection with Recipient’s relationship with AADi;

NOW, THEREFORE, in consideration of the mutual covenants and promises hereinafter set forth and other good and valuable consideration, Recipient agrees as follows:

[Note: Agreement may be narrowed as needed to comply with applicable law of the jurisdiction in which Recipient resides, as reasonably determined by Abraxis.]

1. Recipient is a Permitted Party pursuant to the License Agreement.
 2. AADi may disclose Abraxis Confidential Information to Permitted Parties under the License Agreement.
 3. Recipient acknowledges that the Abraxis Confidential Information requires the highest level of confidentiality and protection against improper disclosure or use. Recipient acknowledges that the Abraxis Confidential Information constitutes [***]. To ensure adequate protection and maintenance of the confidentiality and economic value of the Abraxis Confidential Information, as a condition to being provided access to the Abraxis Confidential Information, Recipient acknowledges and agrees to the terms of this Agreement.
 4. Recipient shall use the Abraxis Confidential Information exclusively for the purposes for which such information is provided to Recipient. As between the parties, all Abraxis Confidential Information received by Recipient shall remain the property of Abraxis.
-

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

5. Recipient shall not disclose the Abraxis Confidential Information to any other person, except to any employee or consultant of AADi (or, if such Abraxis Confidential Information constitutes [***] (as defined in the License Agreement) who has signed a confidentiality agreement) who has a need for such information in connection with such employee's or consultant's (or Desai's or such Designee's) work for AADi for the purposes provided under the License Agreement or to a Regulatory Authority (as defined in the License Agreement) for the purposes contemplated in Article 3 of the License Agreement.
 6. The disclosure of Abraxis Confidential Information to Recipient does not give any express or implied right or license to Recipient to use the Abraxis Confidential Information for any purpose other than the purposes for which such information was provided to Recipient by AADi or to obtain or maintain Regulatory Approval for the Licensed Products (each as defined in the License Agreement).
 7. Recipient shall not, directly or indirectly, disclose or use (except as permitted under Section 4 and 6 above) the Abraxis Confidential Information for any purpose, including making, developing, marketing, or distributing alone or in concert with others anywhere in the world, any pharmaceutical formulation or product manufactured by use of or with reference to any Abraxis Confidential Information or assist any other person or entity (other than AADi, Abraxis or any of their affiliates) in such activities.
 8. Recipient further expressly agrees that his/her obligations in Sections 8 and 14 are reasonable and necessary to protect [***], including Abraxis Confidential Information, and that Abraxis would be irreparably harmed if Recipient breached his/her obligations under this Agreement.
 9. Recipient agrees that the contractual period of time set forth in this Agreement will not limit or otherwise affect (a) the duration of trade secret rights under governing trade secret law, which may be substantially longer in time, or (b) the duration of his/her obligations pursuant to other obligations, including obligations of confidentiality, he/she owes to AADi or Abraxis or their affiliates.
 10. Nothing in this Agreement shall be construed as an obligation on Abraxis to disclose Abraxis Confidential Information to Recipient.
 11. All Abraxis Confidential Information provided to Recipient must be returned to Abraxis upon request, with all copies and other materials containing any Abraxis Confidential Information such as notes.
 12. As a condition to this Agreement, which provides, inter alia, access to the Abraxis Confidential Information, Recipient covenants and agrees that Recipient shall not, directly or indirectly, [***].
 13. Inasmuch as a breach of the covenants and terms contained in this Agreement are not fully measurable in money damages, the parties further agree that Abraxis shall be entitled to injunctive relief in any court of competent jurisdiction to enjoin any such breach or
-

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threatened breach by Recipient, together with such provable money damages as may be awarded by any such court.

14. This Agreement shall be construed in accordance with the laws of the State of New York, without regard to the conflicts of law principles that would provide for application of the law of a jurisdiction other than New York. Any disputes arising hereunder shall be resolved exclusively in a court of competent jurisdiction located in the Southern District of New York. Both parties submit to the personal jurisdiction and venue of such courts.
15. The parties desire and intend that the provisions of this Agreement be enforced to the fullest extent permissible under the law applied in each jurisdiction in which enforcement is sought. Accordingly, if any court of competent authority holds any provision of this Agreement to be invalid, prohibited, or unenforceable for any reason in any jurisdiction, including a determination that the character, duration, geographical area, or subject matter scope of any provision of this Agreement exceeds that permitted by applicable law in a particular jurisdiction, then the parties agree the offending provision will be deemed severed from this Agreement and will be ineffective within that jurisdiction, without invalidating the remaining provisions of this Agreement within that jurisdiction or affecting the validity or enforceability of any provisions of this Agreement in any other jurisdiction. Notwithstanding the foregoing, if an offending provision as described above could be more narrowly drawn or otherwise "blue-penciled," modified, or reformed so as not to be invalid, prohibited, or unenforceable in the jurisdiction where it was held to be offending, then it will, as to such jurisdiction, be deemed more narrowly drawn, blue-penciled, modified, or reformed, by the minimum necessary to render it valid and enforceable in that jurisdiction, (i) with the nature and extent of such redrawing, blue-penciling, modification, or reformation to be determined by a court of competent authority in accordance with applicable procedural and substantive law, and (ii) without invalidating the remaining provisions of this Agreement within that jurisdiction or affecting the validity or enforceability of any provisions of this Agreement in any other jurisdiction.
16. Recipient certifies that he/she has read, understood, and voluntarily agreed to the obligations set forth in this agreement.

IN WITNESS WHEREOF, the parties have caused this Confidentiality Agreement to be effective as of the Effective Date.

Abraxis Bioscience, LLC

Recipient

By:
Name:
Title:

Name:

AMENDMENT NO. 1 TO AMENDED AND RESTATED LICENSE AGREEMENT

This AMENDMENT NO. 1 TO AMENDED AND RESTATED LICENSE AGREEMENT (the “First Amendment”) is effective this 30th day of August, 2021 (the “**Amendment Effective Date**”) by and between Abraxis Bioscience, LLC, a Delaware limited liability company (“**Abraxis**”), and AADi Bioscience, Inc., a Delaware corporation (“**AADi**”).

WHEREAS, the Parties first entered into that certain Amended and Restated License Agreement (the “**Restated Agreement**”) dated as of November 15, 2019, whereby AADi obtained a license to certain intellectual property rights of Abraxis pertaining to the compound known as ABI-009.

WHEREAS, the Parties now desire to amend the Restated Agreement as set forth below to, among other matters, modify certain payment and royalty obligations of AADi.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I.

DEFINITIONS

Unless otherwise defined in this Second Amendment, initially capitalized terms used herein shall have the meanings given to such terms in the Restated Agreement.

ARTICLE II.

LICENSES AND EXCLUSIVITY

2.1 **Section 7.2.** The following is to be added to the end of Section 7.2 of the Restated Agreement (and immediately prior to Section 7.2.1 of the Restated Agreement):

As of the Amendment Effective Date, AADi has outstanding payment obligations under this Section 7.2 equal to \$11,514,473 (the “**Payment Obligations**”). The Payment Obligations will be due and paid as follows: (i) [***] of the closing of AADi’s \$155 million private investment in public equity financing (the “**PIPE Closing Date**”), \$5,757,237 (which represents 50% of the Payment Obligations) will be paid by AADi to Abraxis; and (ii) on the day of the third (3rd) anniversary of the PIPE Closing Date, the remaining

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amount of the Payment Obligations not paid pursuant to clause (i) plus any accrued and unpaid interest thereon (together, the “**Balloon Payment**”) will be paid by AADi to Abraxis. All payments by AADi to Abraxis pursuant to this Section 7.2 will be made by electronic fund transfer of immediately available funds to a bank account of Abraxis or one of its Affiliates as designated by Abraxis to AADi. The Balloon Payment shall accrue interest, beginning on the PIPE Closing Date until paid in full, at a rate equal to 4% per annum based on the weighted average amount outstanding during the applicable calendar quarter, and interest shall be payable quarterly in arrears by AADi within 30 days of the end of each calendar quarter. Failure to make such payment shall constitute a material breach and default under the Restated Agreement. Quarterly interest shall be calculated on a 90/360 basis. The Balloon Payment may be prepaid, in whole or in part, at any time, in AADi’s sole discretion. The Parties acknowledge that Abraxis is no longer supplying AADi with Licensed Products pursuant to Section 6.1 of this Agreement and, following payment of the Payment Obligations (and the interest thereon), all outstanding payment obligations of AADi pursuant to this Section 7.2 shall be satisfied.

2.2 **Section 7.2.1.** Section 7.2.1 of the Restated Agreement is hereby amended and restated by deleting the existing Section 7.2.1 in its entirety and replacing it with the following:

7.2.1. **Royalties.** In consideration of the rights granted to AADi hereunder, AADi shall pay to Abraxis a royalty on Net Sales of Licensed Products in the percentages set forth below, as set forth in this Section during the applicable Royalty Term, in addition to the [***] in accordance with Section 7.5 below. AADi will pay to Abraxis the royalties due hereunder simultaneously with each such report submitted under Section 8.12.2. AADi will pay a royalty of [***] on the portion of Annual Net Sales of [***]. AADi will pay a royalty of [***] on the portion of Annual Net Sales [***]. For such purposes, “Annual Net Sales” means the total Net Sales of Licensed Products in a particular calendar year by AADi, its Affiliates and Sublicenses.

ARTICLE III.

GENERAL

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

3.1 **No Other Modifications.** Except as specifically set forth in this First Amendment, the terms and conditions of the Restated Agreement shall remain in full force and effect. No waiver, alteration or modification of any of the provisions of this First Amendment shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized. The waiver by either Party of a breach or a default of any provision of this First Amendment by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

3.2 **Effectiveness.** This First Amendment shall become effective on the Amendment Effective Date; provided, however, that if the PIPE Closing Date has not occurred on or prior to December 31, 2021, this First Amendment shall terminate and shall be of no force or effect. In such event, the Parties will discuss in good faith the repayment of the Payment Obligations.

3.3 **Miscellaneous.** This First Amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This First Amendment once executed by a Party may be delivered via electronic means of transmission and shall have the same force and effect as if it were executed and delivered by the Parties in the presence of one another. This First Amendment shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law principles thereof.

[Signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this First Amendment to be executed as of the Amendment Effective Date by their duly authorized representatives.

ABRAXIS BIOSCIENCE, LLC

By: /s/ Daniel O'Connell

Name: Daniel O'Connell

Title: Authorized Signatory

AADI BIOCIENCE, INC.

By: /s/ Neil Desai

Name: Neil Desai

Title: CEO

FIRST AMENDMENT TO OFFICE LEASE

This FIRST AMENDMENT TO OFFICE LEASE (“**First Amendment**”) is made and entered into as of August 30, 2021, by and between BRE SUNSET COAST, LLC, a Delaware limited liability company (“**Landlord**”), and AADI BIOSCIENCE, INC., a Delaware corporation (“**Tenant**”).

R E C I T A L S :

A. Landlord and Tenant entered are parties to that certain Office Lease dated April 19, 2019 (the “**Lease**”), pursuant to which Tenant leases Suite A250, containing approximately 2,760 rentable square feet of space (the “**Premises**”) on the 2nd floor of the building (the “**Building**”) located at 17383 Sunset Boulevard, Los Angeles, California.

B. The parties desire to extend the Lease Term and otherwise amend the Lease on the terms and conditions set forth in this First Amendment.

A G R E E M E N T :

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Terms.** All capitalized terms when used herein shall have the same respective meanings as are given such terms in the Lease unless expressly provided otherwise in this First Amendment.

2. **Condition of the Premises.** Landlord and Tenant acknowledge that Tenant has been occupying the Premises pursuant to the Lease, and therefore Tenant continues to accept the Premises in its presently existing, “as is” condition. Except as specifically set forth herein, Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises, other than Landlord’s ongoing maintenance, repair, restoration and replacement obligations as expressly set forth in the Lease. Notwithstanding the foregoing, Landlord hereby agrees, at Landlord’s sole cost and expense, to apply one (1) coat of paint to the surface of one (1) kitchen wall of the Premises (the “**Tenant Improvement**”), at a time that Landlord and Tenant mutually agree to. Such Tenant Improvement shall be completed to Landlord’s “Building standard” condition, using Building standard methods, materials, and procedures, in Building standard color or colors (if applicable).

3. **Extended Lease Term.** Pursuant to the Lease, the Lease Term is scheduled to expire on August 31, 2021. Landlord and Tenant hereby agree to extend the Lease Term for a period of three (3) years and six (6) months, from September 1, 2021, until February 28, 2025 (the “**Extended Term**”), on the terms and conditions set forth in the Lease, as hereby amended by this First Amendment, unless sooner terminated as provided in the Lease.

3.1 **Option to Extend Lease Term.** Landlord and Tenant acknowledge and agree that notwithstanding the extension of the Lease for the Extended Term provided herein, Tenant shall continue to have one (1) option to extend the Lease Term for a period of three (3) years in accordance with, and pursuant to the terms of, Section 2.2 of the Lease, provided that references therein to the expiration of the Lease Term shall be deemed to refer to the expiration of the Extended Term.

4. **Rent.**

4.1 **Base Rent.** Prior to September 1, 2021, Tenant shall continue to pay monthly installments of Base Rent for the Premises in accordance with the terms of the Lease. Commencing on September 1, 2021, and continuing through the Extended Term, Tenant shall pay to Landlord monthly installments of Base Rent for the Premises as follows:

<u>Period During Extended Term</u>	<u>Annual Base Rent</u>	<u>Monthly Installment of Base Rent</u>	<u>Monthly Rental Rate per Square Foot</u>
9/1/21 – 8/31/22	\$221,738.40	\$18,478.20	\$6.695
9/1/22 – 8/31/23	\$228,390.55	\$19,032.55	\$6.896
9/1/23 – 8/31/24	\$235,242.27	\$19,603.52	\$7.103
9/1/24 – 2/28/25	\$242,299.54	\$20,191.63	\$7.316

4.2 **Abated Base Rent.** Subject to the terms of this Section 4.2, during the (a) three (3) month period commencing on September 1, 2021, and ending on November 30, 2021 (the “**Full Base Rent Abatement Period**”), Tenant shall not be obligated to pay any Base Rent otherwise attributable to the Premises (the “**Full Base Rent Abatement**”), and (b) during the six (6) month period commencing on December 1, 2021, and ending on May 31, 2022 (the “**Partial Rent Abatement Period**,” and referred to collectively with the Full Base Rent Abatement Period as the “**Base Rent Abatement Period**”), Tenant shall be obligated to pay only fifty percent (50%) of Base Rent attributable to Premises (the “**Partial Base Rent Abatement**,” and referred to collectively with the Full Base Rent Abatement as the “**Base Rent Abatement**”). In no event shall the aggregate amount of all Base Rent Abatement exceed One Hundred Ten Thousand Eight Hundred Sixty Nine and 20/100 Dollars (\$110,869.20).

4.3 **Direct Expenses.** Prior to September 1, 2021, Tenant shall continue to be obligated to pay Tenant’s Share of the Direct Expenses in accordance with the terms of the Lease. Effective as of September 1, 2021, and continuing throughout the Extended Term, Tenant shall pay Tenant’s Share of the Direct Expenses in accordance with the terms of the Lease; provided that for purposes of calculating the amount of Tenant’s Share of the Direct Expenses, the Base Year shall be calendar year 2021.

5. **Right of First Offer.** Landlord hereby grants to AADI BIOSCIENCE, INC., a Delaware corporation (the “Original Tenant”) a right of first offer with respect to Suite A-210 containing approximately 3,176 RSF on the 2nd floor of the Building (the “First Offer Space”), which First Offer Space is vacant and unleased as of the date of this First Amendment. Such right of first offer shall expire as of August 31, 2023. Tenant’s right of first offer shall be on the terms and conditions set forth in this Section 1.2.

5.1 **Procedure for Offer.** Prior to Landlord entering into any new lease of the First Offer Space Landlord shall offer to lease to Tenant such First Offer Space (the “First Offer Notice”).

5.2 **Procedure for Acceptance.** If Tenant wishes to exercise Tenant’s right of first offer with respect to the space described in the First Offer Notice, then within five (5) business days after delivery of the First Offer Notice to Tenant, Tenant shall deliver notice to Landlord of Tenant’s election to exercise its right of first offer with respect to the entire space described in the First Offer Notice (the “First Offer Exercise Notice”). If Tenant does not so notify Landlord within the five (5) business day period, then Landlord shall be free to lease the space described in the First Offer Notice to anyone to whom Landlord desires on any terms Landlord desires. Notwithstanding anything to the contrary contained herein, Tenant must elect to exercise its right of first offer, if at all, with respect to all of the space offered by Landlord to Tenant at any particular time, and Tenant may not elect to lease only a portion thereof.

5.3 **First Offer Rent and Lease Term.** The Rent for the First Offer Space (the “First Offer Rent”) shall be at the same Base Rent per RSF as is payable with respect to the Premises, with the same annual adjustments, and subject to applicable Base Rent Abatement or Partial Base Rent Abatement during the same period as applicable to the Premises under Section 4.2, above, and Tenant shall pay Direct Expenses for the First Offer Space over a 2021 Base Year (with Tenant’s Share for the First Offer Space based on the RSF of the First Offer Space).

5.4 **Construction In First Offer Space.** Tenant shall take the First Offer Space in its “as is” condition, subject to any improvement allowance granted as a component of the First Offer Rent, and the construction of improvements in the First Offer Space shall comply with the terms of Article 8 of this Lease.

5.5 **Amendment to Lease.** If Tenant timely exercises Tenant’s right to lease the First Offer Space as set forth herein, Landlord and Tenant shall within fifteen (15) days thereafter execute an amendment to this Lease adding such First Offer Space (and any additional space) to the Premises upon the terms and conditions as set forth in the First Offer Notice and this Section 5. Tenant shall commence payment of Rent for the First Offer Space, and the term of the First Offer Space shall commence upon the date that is sixty (60) days after Tenant’s delivery of the First Offer Exercise Notice (the “First Offer Commencement Date”) and terminate on the date that is the later of (i) the end of the Extended Term, and (ii) 46 months after the First Offer Commencement Date (the “New Expiration Date”). If the New Expiration Date is after the end of the Extended Term, then (i) Tenant’s lease of the initial Premises shall be extended through the New Expiration Date, and (ii) as of each of March 1, 2025, and March 1, 2026 (if applicable), the Base Rent payable for the Premises and First Offer Space shall be increased to equal 103% of the Base Rent payable immediately prior to such date.

5.6 **Termination of Right of First Offer.** The rights contained in this Section 5 shall be personal to the Original Tenant and any transferee pursuant to Section 14.7 of the Lease (a “**Permitted Transferee**”), and may only be exercised by the Original Tenant or any Permitted Transferee (and not any other assignee, sublessee or other transferee of the Original Tenant’s interest in this Lease) if the Original Tenant or such Permitted Transferee occupies the entire Premises. The right of first offer granted herein shall terminate on August 31, 2023, or upon any earlier failure by Tenant to exercise its right of first offer with respect to First Offer Space as offered by Landlord. Tenant shall not have the right to lease First Offer Space, as provided in this Section 1.2, if, as of the date of the attempted exercise of any right of first offer by Tenant, or as of the scheduled date of delivery of such First Offer Space to Tenant, Tenant is in default under the Lease beyond applicable notice and cure periods, or Tenant has previously been in default beyond applicable notice and cure periods under this Lease more than once.

6. **Brokers.** Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this First Amendment other than NAI Capital and Cushman & Wakefield of California, Inc. (collectively, the “**Brokers**”), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this First Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, costs and expenses (including without limitation reasonable attorneys’ fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of any dealings with any real estate broker or agent, other than the Brokers, occurring by, through, or under the indemnifying party. The terms of this Section shall survive the expiration or earlier termination of the term of the Lease, as hereby amended.

7. **California Accessibility Disclosure.** For purposes of Section 1938 of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges that the Common Areas and the Premises have not undergone inspection by a Certified Access Specialist (CASP).

8. **Miscellaneous.** This First Amendment, together with the Lease, constitutes the entire agreement between Landlord and Tenant regarding the Lease and the subject matter contained herein and supersedes any and all prior and/or contemporaneous oral or written negotiations, agreements or understandings. This First Amendment shall be binding upon and inure to the benefit of Landlord and Tenant and their respective heirs, legal representatives, successors and assigns. No subsequent change or addition to this First Amendment shall be binding unless in writing and duly executed by both Landlord and Tenant. This First Amendment may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of such counterparts shall constitute one document. To facilitate execution of this First Amendment, the parties may execute and exchange, by electronic mail PDF, counterparts of the signature pages. Signature pages may be detached from the counterparts and attached to a single copy of this First Amendment to physically form one document. In addition, the parties hereto consent and agree that this First Amendment may be signed using electronic signature technology (e.g., via DocuSign or similar electronic signature technology), and that such signed electronic record shall be valid and as effective to bind the party so signing as a paper copy bearing such party’s handwritten signature.

9. **No Further Modification.** Except as specifically set forth in this First Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect and are hereby ratified and confirmed.

IN WITNESS WHEREOF, this First Amendment has been executed as of the day and year first above written.

“Landlord”:

BRE SUNSET COAST, LLC,
a Delaware limited liability company

By: /s/ Michael Esquenazi
Name: Michael Esquenazi
Its: Treasurer

“Tenant”:

AADI BIOSCIENCE INC.,
a Delaware limited liability company

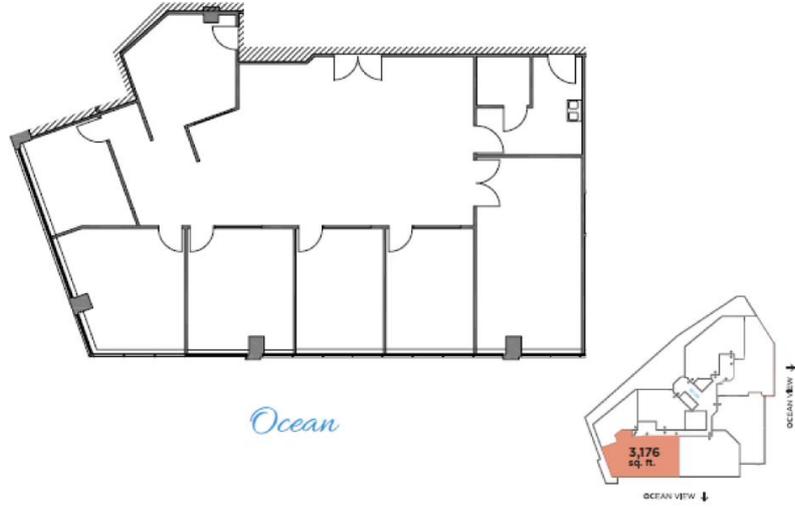
By: /s/ Neil Desai
Name: Neil Desai
Its: CEO

Exhibit A

First Offer Space

FLOOR PLAN

Suite A210
3,176 RSF



AADI BIOSCIENCE, INC.

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the “**Agreement**”) is entered into as of October 19, 2021 by and between Aadi Bioscience, Inc. (“**Aadi**”), and Loretta Itri, M.D. (“**Executive**”). This Agreement will be effective October 21, 2021 (the “**Effective Date**”). As you know, Aadi recently consummated a merger (with the parent company of the merger being formerly known as Aerpio Pharmaceuticals, Inc. (“**Aerpio**”)) and Aerpio changed its name to Aadi Bioscience, Inc. as part of the merger. Aadi, together with any other subsidiaries, including the entity employing you, shall be referred to in this letter as the “**Company**”.

1. Duties and Scope of Employment.

(a) Positions and Duties. Effective as of the Effective Date, Executive will serve as the Company’s Chief Medical Officer. Executive will render such business and professional services in the performance of Executive’s duties, consistent with Executive’s position within the Company, as will reasonably be assigned to Executive by the Company’s Board of Directors (the “**Board**”) and the Chief Executive Officer. The period of Executive’s employment under this Agreement is referred to herein as the “**Employment Term.**”

(b) Obligations. During the Employment Term, Executive will perform Executive’s duties faithfully and to the best of Executive’s ability and will devote Executive’s full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board, except as provided in Schedule 1; provided, however, that Executive may manage personal investments, participate in civic, charitable, educational and professional activities. In the event of any conflict between any policy of the Company and the terms of this Agreement, the terms of this Agreement shall govern and control.

(c) Principal Location of Services. Executive shall perform his duties during the Employment Term principally out of offices located in the New Jersey or New York Metropolitan area and shall undertake such travel within or outside of the United States as is necessary or advisable for the efficient operations of the Company.

2. At-Will Employment. The parties agree that Executive’s employment with the Company will be “at-will” employment and may be terminated at any time with or without Cause or notice. Executive understands and agrees that neither Executive’s job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of Executive’s employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive’s termination of employment with the Company.

3. Compensation.

(a) Base Salary. Effective as of the Effective Date and for the remainder of the Employment Term, the Company will pay Executive an annual salary of \$500,000 as compensation for Executive's employment services to the Company (the "**Base Salary**"). The Base Salary will be paid periodically in accordance with the Company's normal payroll practices and be subject to the usual, required withholdings. Executive's salary will be subject to review at least annually and adjustments will be made based upon the Company's normal performance review practices.

(b) Target Bonus. Effective as of the Effective Date and for the remainder of the Employment Term, Executive will be eligible to receive an annual bonus of up to 45% of Executive's Base Salary upon achievement of performance objectives to be determined by the Board or its authorized committee (the "**Committee**") in its sole discretion, with reasonable input from Executive (the "**Target Bonus**"). For calendar year 2021, the achieved Target Bonus will be pro-rated for the portion of the calendar year that Executive is actually employed by the Company under the terms of this Agreement. The achieved portion of Executive's Target Bonus will be paid, less applicable withholdings, as soon as practicable after the Board or Committee determines that the Target Bonus has been earned, but in no event shall the Target Bonus be paid after the later of (i) the fifteenth (15th) day of the third (3rd) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned.

(c) Stock Option. Executive will be granted a nonstatutory stock option to purchase 185,000 shares of the Company's common stock at an exercise price per share equal to the fair market value of the Company's common stock on the date of grant, which will be the closing price of the Company's common stock as reported by the Nasdaq Stock Market on the Effective Date (the "**Option**"). Subject to the accelerated vesting provisions set forth herein, the Option will vest as to twenty-five percent (25%) of the shares subject to the Option one (1) year after the Effective Date, and as to 1/48th of the shares subject to the Option monthly thereafter on the same day of the month as the Effective Date (and if there is no corresponding day, the last day of the month), so that the Option will be fully vested and exercisable four (4) years from the Effective Date, subject to Executive continuing to provide services to the Company through the relevant vesting dates. Except as provided herein, the Option will be subject to the terms and conditions of an equity incentive plan and related stock option agreement approved by the Board or Committee, including vesting requirements (collectively, the "**Equity Documents**") and will be granted in accordance with the Company's equity grant policy.

(d) Equity. During the Employment Term, Executive will be eligible to receive equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or Committee will determine in its discretion whether Executive will be granted any equity awards and the terms of any equity award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

4. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time. Executive shall also be entitled to four weeks of vacation, accruing annually, and participation in any 401(k) or

employee benefit plan established by the Company, each as subject to the terms and conditions of such plans or programs adopted by the Company.

5. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. Severance.

(a) Termination for other than Cause, Death or Disability Apart from a Change of Control. If, outside of the Change of Control Period, (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability, or (ii) the Executive resigns from such employment for Good Reason, then, subject to Section 7, Executive will be entitled to receive:

(i) continuing payments of severance pay for a period of 12 months at a rate equal to the sum of (A) (x) one hundred percent (100%) of Executive's Base Salary rate, as then in effect, *plus* (y) Executive's Target Bonus for the fiscal year in which Executive's termination occurs, prorated based on the number of days Executive is employed by the Company during such fiscal year and subject to satisfaction of the applicable performance conditions as reasonably determined by the Company, *divided by* (B) 12. The severance will be paid, less applicable withholdings, in installments over the severance period described herein with the first payment to commence on the sixty-first (61st) day following Executive's termination of employment (and include any severance payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date), with any remaining payments paid in accordance with the Company's normal payroll practices for the remainder of the severance period following Executive's termination of employment (subject to any delay as may be required by Section 7(b)).

(ii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**") within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of twelve (12) months from the date of termination or (B) the date upon which Executive and/or Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be made by the Company to Executive consistent with the Company's normal expense reimbursement policy. Notwithstanding the first sentence of this Section 6(a)(ii), if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage for Executive and/or Executive's eligible dependents in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive and/or Executive's eligible dependents elect COBRA continuation coverage and will commence on the month following

Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment with comparable health insurance coverage as that provided by Employer to Executive, or (y) the date the Company has paid an amount equal to twelve (12) payments. Any such taxable monthly payments that otherwise would have been paid to Executive within the sixty (60) days following Executive's termination date instead will be paid on the sixty-first (61st) day following Executive's termination of employment, with any remaining payments paid as provided in the prior sentence (subject to any delay as may be required by Section 7(b)). For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

(iii) If, following the termination of Executive's employment with the Company other than for Cause, death or Disability, or the Executive's resignation from such employment for Good Reason, the sale of any shares received on exercise of a Company stock option would violate the Company's insider trading policy or Rule 10b5-1(a) under the Exchange Act (as defined in the Plan), then such Company stock option will remain exercisable until the earlier of (a) the later of (i) three (3) months following the date of your termination of employment or (ii) thirty (30) days following the earliest date the sale of the shares received upon exercise of such Company stock option would not be in violation of the Company's insider trading policy or Rule 10b5-1(a) under the Exchange Act, or (b) the expiration of the term of such Company stock option as set forth in the applicable Company stock option.

(b) Termination for other than Cause, Death or Disability or Resignation by Executive for Good Reason Related to a Change of Control. If, within the Change of Control Period (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment with the Company other than for Cause, death or Disability, or (ii) the Executive resigns from such employment for Good Reason, then, subject to Section 8, Executive will be entitled to receive:

(i) a lump sum payment equal to one hundred percent (100%) of the sum of: (A) Executive's Base Salary, as then in effect, or if greater, at the level in effect immediately prior to the Change of Control, *plus* (B) Executive's Target Bonus in effect for the fiscal year in which Executive's termination of employment occurs. The severance will be paid, less applicable withholdings, on the sixty-first (61st) day following Executive's termination of employment in accordance with the Company's normal payroll practices (subject to any delay as may be required by Section 7(b)). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for severance payments under Section 6(a)(i); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the superior benefits under this Section 6(b)(i), then Executive shall be entitled to a lump-sum payment of the amount calculated under this Section 6(b)(i), less amounts already paid under Section 6(a)(i).

(ii) if Executive elects continuation coverage pursuant to COBRA within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) a period of twelve (12) months from the date of termination or (B) the date upon which Executive and/or

Executive's eligible dependents are no longer eligible for COBRA continuation coverage. The reimbursements will be subject to the same conditions, limitations, and restrictions as the COBRA benefits described in Section 6(a)(ii). For the avoidance of doubt, if (x) Executive incurred a termination of employment prior to a Change of Control that qualifies Executive for COBRA benefits under Section 6(a)(ii); and (y) a Change of Control occurs within the three (3)-month period following Executive's termination of employment that qualifies Executive for the benefits under this Section 6(b)(ii), then Executive's benefits under this Section 6(b)(ii) shall be offset by the benefits already provided to Executive under Section 6(b)(i); and

(iii) accelerated vesting as to one hundred percent (100%) of Executive's then-outstanding and unvested equity awards to acquire Company common stock.

(c) Termination for Cause, Death or Disability; Resignation without Good Reason. If Executive's employment with the Company (or any parent or subsidiary or successor of the Company) terminates voluntarily by Executive (except upon resignation for Good Reason), for Cause by the Company or due to Executive's death or Disability, then (i) all vesting will terminate immediately with respect to Executive's outstanding equity awards, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (iii) Executive will only be eligible for severance benefits in accordance with the Company's established policies, if any, as then in effect.

(d) Termination for Any Reason. Upon termination of Executive's employment for any reason, Executive (or his estate) shall be entitled to receive (i) his Base Salary accrued through the date of termination, (ii) earned but unused vacation and paid time off as of the date of termination, (iii) reimbursement of expenses properly incurred prior to termination and properly documented in accordance with the Company's policy, (iv) all benefits, including continuation and conversion rights, provided upon termination of employment under the Company's employee benefit plans and policies in accordance with the terms of such plans and policies, and (v) except in the case of termination for Cause or resignation without Good Reason, Executive's Target Bonus actually earned for the fiscal year ending prior to the date of termination to the extent not yet paid on the date of termination (collectively the "**Accrued Obligations**"). For avoidance of doubt, upon termination for Cause or resignation without Good Reason, Executive shall not be entitled to any payments or benefits other than the Accrued Obligation.

(e) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement, including any prior employment agreements entered into between the Company and Executive. Executive will be entitled to no severance or other benefits upon termination of employment with respect to acceleration of award vesting or severance pay other than those benefits expressly set forth in this Section 7.

7. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Section 6(a) or (b) will be subject to Executive signing and not revoking a separation

agreement and release of claims in a form reasonably satisfactory to the Company (the “**Release**”) and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the “**Release Deadline**”). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable.

(b) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Code Section 409A, and the final regulations and any guidance promulgated thereunder (“**Section 409A**”) (together, the “**Deferred Payments**”) will be paid or otherwise provided until Executive has a “separation from service” within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a “separation from service” within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a “specified employee” within the meaning of Section 409A at the time of Executive’s termination (other than due to death), then the Deferred Payments that are payable within the first six (6) months following Executive’s separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive’s separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive’s separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive’s death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any amount paid under this Agreement that satisfies the requirements of the “short-term deferral” rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(v) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and Executive agree to work together in good faith to consider

amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. Executive agrees and acknowledges that the Company makes no representations or warranties with respect to the application of Section 409A and other tax consequences to any payments hereunder and, by the acceptance of any such payments, Executive agrees to accept the potential application of Section 409A and the other tax consequences of any payments made hereunder.

(c) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 6 will be subject to Executive continuing to comply with the terms of Confidential Information Agreement (as defined in Section 10). In the event Executive breaches any material provision of the Confidential Information Agreement, all continuing payments and benefits to which Executive may otherwise be entitled pursuant to Section 6(a) or (b) will immediately cease.

(d) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

8. Definitions.

(a) Cause. For purposes of this Agreement, "**Cause**" is defined as (i) the willful failure, disregard, or refusal by Executive to perform the services hereunder or follow the reasonable instructions of the Board; *provided, however*, that any willful failure, disregard, or refusal by Executive to perform the services hereunder shall not constitute Cause unless cure is not effected within thirty (30) days after notice thereof is received by the Executive from the Company; (ii) any willful or grossly negligent act by the Executive having the effect of injuring, in a material way (whether financial or otherwise), the business or reputation of the Company or any of its subsidiaries or affiliates; (iii) Executive's conviction of, guilty plea, or plea of nolo contendere to any felony or a misdemeanor involving moral turpitude; (iv) engagement by Executive in some form of harassment prohibited by law (including, without limitation, age, sex, disability, or race discrimination) unless Executive's actions were specifically directed by the Board; or (v) material breach by the Executive of any material provision of this Agreement or any Confidential Information Agreement; *provided, however*, that any such breach by Executive to perform the services hereunder shall not constitute Cause unless cure is not effected within thirty (30) days after notice thereof is received by the Executive from the Company.

(b) Change of Control. For purposes of this Agreement, "**Change of Control**" means the occurrence of any of the following events:

(i) a change in the ownership of the Company which occurs on the date that any one person (as defined in Section 13(d) and Section 14(d) of the Exchange Act), or more than one person acting as a group ("**Person**"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change in Control; provided, further, that any change in the ownership of the stock of the Company as a result of a private financing

of the Company that is approved by the Board also will not be considered a Change of Control. Further, if the stockholders of the Company immediately before such change in ownership continue to retain immediately after the change in ownership, in substantially the same proportions as their ownership of shares of the Company's voting stock immediately prior to the change in ownership, direct or indirect beneficial ownership of fifty percent (50%) or more of the total voting power of the stock of the Company or of the ultimate parent entity of the Company, such event shall not be considered a Change of Control under this subsection (i). For this purpose, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company, as the case may be, either directly or through one or more subsidiary corporations or other business entities;

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board of Directors of the Company is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same person will not be considered a Change in Control; or

(iii) a change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions; provided, however, that for purposes of this subsection (iii), the following will not constitute a change in the ownership of a substantial portion of the Company's assets: (A) a transfer to an entity that is controlled by the Company's stockholders immediately after the transfer, or (B) a transfer of assets by the Company to: (1) a stockholder of the Company (immediately before the asset transfer) in exchange for or with respect to the Company's stock, (2) an entity, fifty percent (50%) or more of the total value or voting power of which is owned, directly or indirectly, by the Company, (3) a Person, that owns, directly or indirectly, fifty percent (50%) or more of the total value or voting power of all the outstanding stock of the Company, or (4) an entity, at least fifty percent (50%) of the total value or voting power of which is owned, directly or indirectly, by a Person described in this subsection (8)(b)(ii). For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

Notwithstanding the foregoing, a transaction will not be deemed a Change in Control unless the transaction qualifies as a change in control event within the meaning of Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and Internal Revenue Service guidance that has been promulgated or may be promulgated thereunder from time to time.

Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the state of the Company's incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

(c) Change of Control Period. For purposes of this Agreement, "**Change of Control Period**" means the period that begins three (3) months prior to a Change of Control and ends twelve (12) months following a Change of Control.

(d) Code. For purposes of this Agreement, "**Code**" means the Internal Revenue Code of 1986, as amended.

(e) Disability. For purposes of this Agreement, "**Disability**" means that Executive has been unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment for a period of ninety (90) consecutive days or more, or more than one hundred and eighty (180) days within any twelve (12)-month period, in each case, determined by the Board. This provision shall be subject to compliance with all federal, state and local disability laws.

(f) Good Reason. For the purposes of this Agreement, "**Good Reason**" means Executive's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive's express written consent: (i) a material breach of any provision of this Agreement by the Company; (ii) any material reduction by the Company of Executive's duties, responsibilities, or authority which causes Executive's position to become materially of less responsibility or authority than Executive's position as of immediately following the Effective Date; (iii) a material relocation of the Company's principal place of business of Executive more than 35 miles from Executive's residence in Manhattan; or (iv) a material diminution in Executive's base salary (other than in the context of salary or consideration reductions applied in identical percentages to all executive officers of the Company). Executive will not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason" and a reasonable cure period of not less than thirty (30) days following the date the Company receives such notice during which such condition must not have been cured.

(g) Section 409A Limit. For purposes of this Agreement, "**Section 409A Limit**" will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during the Executive's taxable year preceding the Executive's taxable year of Executive's separation from service as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

9. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting “parachute payments” is necessary so that no portion of such severance benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (1) reduction of the cash severance payments; (2) cancellation of accelerated vesting of equity awards; and (3) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive’s equity awards.

A nationally recognized certified professional services firm selected by the Company, the Company’s legal counsel or such other person or entity to which the parties mutually agree (the “**Firm**”) shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Code Sections 280G and 4999. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section. The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive’s right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

10. Confidential Information. Executive agrees to execute the Company’s Confidential Information and Invention Assignment Agreement (the “**Confidential Information Agreement**”) concurrently with the execution of this Agreement.

11. Indemnification Agreement. The Company and Executive shall enter into an Indemnification Agreement (the “**Indemnification Agreement**”) in substantially the form attached as Exhibit 10.11 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 27, 2021. In the event that the Company adopts a more favorable form of Indemnification Agreement, or amendments to the form of Indemnification Agreement, for other executives or Board members in the future, Executive shall be given the opportunity to enter into a new or amended Indemnification Agreement on the same terms

12. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive’s death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company

under the terms of this Agreement for all purposes. For this purpose, “**successor**” means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive’s right to compensation or other benefits will be null and void.

13. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Aadi Bioscience, Inc.
17383 Sunset Boulevard, Suite A250
Pacific Palisades, CA 90272
Attn: Chief Executive Officer

If to Executive:

at the last residential address known by the Company.

14. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

15. Arbitration. Executive agrees that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive’s service to the Company, shall be subject to arbitration in accordance with the provisions of the Confidential Information Agreement.

16. Integration. This Agreement, along with the Confidential Information Agreement, Equity Documents and Indemnification Agreement, represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. With respect to equity awards granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such equity awards except to the extent the applicable equity award agreement expressly supersedes this Agreement. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

17. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

18. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

19. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes.

20. Governing Law. This Agreement will be governed by the laws of the State of New Jersey (with the exception of its conflict of laws provisions).

21. Acknowledgment. Executive acknowledges that Executive has had the opportunity to discuss this matter with and obtain advice from Executive's private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

22. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

AADI BIOSCIENCE, INC.

By: /s/ Neil Desai Date: October 19, 2021

Name: Neil Desai, Ph.D.

Title: President and Chief Executive Officer

EXECUTIVE:

/s/ Loretta Itri Date: October 20, 2021
Loretta Itri, M.D.

[SIGNATURE PAGE TO EXECUTIVE EMPLOYMENT AGREEMENT]

None

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Exhibit 10.18

LICENSE AGREEMENT

BY AND BETWEEN

AADI BIOSCIENCE, INC

AND

EOC PHARMA (HONG KONG) LIMITED

December 8, 2020

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

LICENSE AGREEMENT

This License Agreement (the “**Agreement**”) is entered into as of December 8, 2020 (the “**Effective Date**”) by and between Aadi Bioscience, Inc., a Delaware corporation with a place of business at 17383 Sunset Blvd, Suite A250, Pacific Palisades, CA 90272 USA (“**Aadi**”) and EOC Pharma (Hong Kong) Limited, a Hong Kong corporation with a place of business at Unit B, 12/F., Chinaweal Centre, 414-424 Jaffe Road, Wanchai, Hong Kong (“**EOC**”). Aadi and EOC are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, Aadi is a biotechnology company developing the pharmaceutical product, nanoparticle albumin-bound sirolimus, described as nab-sirolimus or ABI-009 (“**ABI-009**”), for treatment of various human diseases;

WHEREAS, EOC is a pharmaceutical company engaged in the research, development and commercialization of products for human use;

WHEREAS, Aadi is party to that certain Amended and Restated License Agreement signed by and between Abraxis Bioscience, LLC (“**Abraxis**”) and Aadi on November 15, 2019 and any amendments, supplemental agreement, [***] (the “**Abraxis License**”), pursuant to which Aadi is licensed with certain intellectual property;

WHEREAS, Aadi and EOC desire to establish a license agreement for the further development and commercialization of ABI-009 in the Territory.

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

ARTICLE I. DEFINITIONS AND CONSTRUCTION

The following terms shall have the following meanings as used in this Agreement:

Section 1.01 “**Aadi**” shall have the meaning set forth in the preamble.

Section 1.02 “**Aadi Know-How**” means any and all Know-How, [***], which exists as of the Effective Date or during the Term, [***].

Section 1.03 “**Aadi Manufacturing Information**” means any and all confidential documents and information relating to the manufacture of Product Controlled by Aadi and/or its Affiliates or its designated Manufacturer.

Section 1.04 “**Aadi Patents**” means Patents generically or specifically claiming or covering [***], to the extent such Patents are Controlled by Aadi or its Affiliates as of the Effective Date or during the Term in the Territory, including without limitation the Patents set forth in Exhibit A. Notwithstanding anything to the contrary, [***].

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Section 1.05 "Aadi Technology" shall mean, for purposes of this Agreement, the Aadi Know-How and Aadi Patents.

Section 1.06 "Aadi Trademarks" means any trademarks, applications to register trademarks, intent-to-use applications, or other registrations or applications related to trademarks, common-law trademarks and rights, service marks, trade dress, logos, trade names, corporate names, all rights arising from the use of or existing in connection with domain names, and all goodwill associated with the foregoing and all registrations and applications for registration of any of the foregoing, currently pending or will be applied for in the future by Aadi, all to the extent Controlled by Aadi or its Affiliates in the Territory as of the Effective Date or during the Term.

Section 1.07 "Abraxis License" shall have the meaning as set forth in the second WHEREAS clause of the RECITALS.

Section 1.08 "ABI-009" shall have the meaning as set forth in the first WHEREAS clause of the RECITALS.

Section 1.09 "Acquiring Entity" means a Third Party that merges or consolidates with or acquires a Party, or to which a Party transfers all or substantially all of its assets to which this Agreement pertains.

Section 1.10 "Affiliate" means with respect to either Party, any Person controlling, controlled by or under common control with such Party, from time to time and for so long as such control exists. For purposes of this definition of Affiliate, "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of a Person or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

Section 1.11 "Alliance Manager" shall have the meaning assigned in Section 3.01.

Section 1.12 "ANDA" means an abbreviated new drug application (or any successor application or procedure) as defined in 21 U.S.C. § 355(j) or any successor application for Regulatory Approval having substantially the same function, or its foreign equivalent for approval to market or sell a pharmaceutical product.

Section 1.13 "Annual Net Sales" means the aggregate Net Sales in the Territory made during any given Calendar Year.

Section 1.14 "Annual Gross Profit" means the aggregate Gross Profit in the Territory made during any given Calendar Year.

Section 1.15 "Anti-Corruption Laws" means the U.S. Foreign Corrupt Practices Act, as amended, the PRC Anti-Unfair Competition Law, the PRC Criminal Law, and any other applicable anti-corruption laws and laws for the prevention of fraud, bribery, racketeering, money laundering or terrorism applicable to the business activities of the Parties.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Section 1.16 “**Applicable Laws**” means all applicable statutes, ordinances, codes, executive or governmental orders, laws, rules and regulations, including without limitation, any rules, regulations, guidelines or other requirements of Regulatory Health Authorities that may be in effect from time to time.

Section 1.17 “**Approved Indication**” has the meaning set forth in Section 3.03(f).

Section 1.18 “**Bankruptcy Code**” means Title 11, United States Code, as amended, or analogous provisions of Applicable Laws outside the United States.

Section 1.19 “**BPCI Act**” means the Biologics Price Competition and Innovation Act of 2009 within the Patient Protection and Affordable Care Act, as set forth in Section 351(k) of the United States Public Health Services Act (42 U.S.C. 262), which was signed into law in the United States in March 2010, as may be subsequently amended.

Section 1.20 “**Breaching Party**” shall have the meaning assigned in Section 11.02(4).

Section 1.21 “**Business Day**” means any day other than (a) a Saturday or a Sunday or (b) a day on which commercial banking institutions are authorized or required by Applicable Laws to be closed in New York City, New York, the U.S., or in Shanghai, People's Republic of China.

Section 1.22 “**Calendar Quarter**” means each successive period of three (3) consecutive calendar months commencing on 1st January, 1st April, 1st July and 1st October.

Section 1.23 “**Calendar Year**” means each successive period of twelve (12) consecutive calendar months commencing on 1st January.

Section 1.24 “**Change of Control**” means, with respect to a Party, (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of such Party's assets; or (b) a merger or consolidation in which, the shareholders of such Party immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the Party's outstanding stock and other securities or the power to elect a majority of the members of such Party's board of directors; or (c) the acquisition of beneficial ownership, directly or indirectly, by any Person (other than such Party or an Affiliate of such Party, and other than by virtue of obtaining irrevocable proxies) of securities or other voting interests of such Party representing a majority or more of the combined voting power of such Party's then outstanding securities or other voting interests.

Section 1.25 “**Co-Chair**” shall have the meaning assigned in Section 3.04.

Section 1.26 “**Commercialization**” means, with respect to the Product, all activities undertaken relating to the use, sale, offer to sale, import, advertising, education, planning, marketing, promotion, distribution, market and product support, [***]. “**Commercialize**” shall have a corresponding meaning. For clarity, [***].

Section 1.27 “**Commercialization Plan**” shall have the meaning assigned in Section 4.09.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Section 1.28 “**Commercially Reasonable Efforts**” shall mean, with respect to a Party’s obligations under this Agreement, the efforts and resources typically used by pharmaceutical companies similar in size and scope to perform the obligations at issue in good faith, which efforts shall not be less than those efforts made by the performing Party with respect to [***], taking into account [***]. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party apply efforts [***]. It is anticipated that the level of effort will change over time, reflecting changes in the status of the Product and the market involved.

Section 1.29 “**Competitive Product**” shall have the meaning set forth in Section 2.05.

Section 1.30 “**Confidential Information**” means, subject to the exceptions listed at Section 7.02, any and all (a) Know-How relating to the Exploitation of the Product or relating to other aspects of this Agreement, and (b) information and Materials, whether oral or in writing or in any other form, disclosed before, on or after the date of this Agreement by one Party to the other Party, including the terms of this Agreement.

Section 1.31 “**Control**” means, with respect to an item of Know-How, Patent or other Intellectual Property Rights, the ability and authority of a Party or its Affiliates, whether arising by ownership, or pursuant to a license or sublicense, to grant licenses, sublicenses, or other rights to the other Party under or to such item of Know-How, Patent or Intellectual Property Rights as provided for in this Agreement without breaching the terms of any agreement between such Party and any Third Party. Notwithstanding anything to the contrary in this Agreement, the following shall not be deemed to be Controlled by Aadi: [***].

Section 1.32 “**Cost of Goods**” or “**COGs**” shall mean, with respect to Product manufactured by Aadi, the costs to manufacture the Product including the following elements which shall be calculated in accordance with U.S. GAAP or any applicable GAAP otherwise agreed by the Parties: (a) [***], (b) [***], (c) [***], and (d) [***]. Notwithstanding the foregoing, to the extent that the Product is sourced from a Third Party Manufacturer designated by Aadi, the COGs of such Products means (i) [***] and (ii) [***].

Section 1.33 “**CRO**” means a contract research organization, as defined in 21 C.F.R. 312 or in any Applicable Laws, that assumes, as an independent contractor with the sponsor of a clinical trial, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation or reports, and preparation of materials to be submitted to the applicable Regulatory Health Authority.

Section 1.34 “**Development**” means all activities relating to obtaining Regulatory Approval of the Product and Indications therefor, [***]. Development activities includes, for example, [***]. “**Develop**” and “**Developing**” shall have a corresponding meaning.

Section 1.35 “**Drug Approval Application**” means an application for Regulatory Approval required before commercial sale or use of the Product as a drug in a regulatory jurisdiction, such as an NDA or BLA.

Section 1.36 “**Effective Date**” shall have the meaning assigned in the first paragraph of this Agreement.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

Section 1.37 “**Exploit**” means to import, use, sell or offer for sale, including to Develop and Commercialize, the Product in the Territory. “**Exploitation**” shall have a corresponding meaning. For clarity, Exploitation does not include activities related to Manufacture of Product.

Section 1.38 “**FDA**” means the United States Food and Drug Administration or any successor thereto.

Section 1.39 “**FFDCA**” means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq., as amended from time to time.

Section 1.40 “**Field**” means any and all therapeutic uses of Product for the treatment of an Approved Indication in humans.

Section 1.41 “**Filing**” means, with respect to a submission to a Regulatory Health Authority, the date that such submission is confirmed to have been received by the relevant Regulatory Health Authority.

Section 1.42 “**First Commercial Sale**” means, with respect to the Product, the first [***] after all needed Regulatory Approvals have been obtained in the Territory with respect to the Product.

Section 1.43 “**EOC Technology**” means all Patents and Know-How (i) Controlled by EOC as of the Effective Date, or (ii) that thereafter comes into EOC’s Control independent of this Agreement. For clarity, EOC Technology may include inventions that are broadly applicable to the Development or Commercialization of pharmaceutical products generally.

Section 1.44 “**EOC Triggered Termination**” shall have the meaning assigned in Section 11.03.

Section 1.45 “**GAAP**” means Generally Accepted Accounting Principles.

Section 1.46 “**GCP**” or “**Good Clinical Practices**” means the current standards for clinical trials for pharmaceuticals, as set forth in the Territory as well as in the United States Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto and applicable regulations, laws or rules as promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by other organizations and Governmental Bodies in the Territory.

Section 1.47 “**Generic Product**” means, with respect to a Product being sold in any country, a product that is (a) identical to such Product, and (b) approved in such country for sale in reliance on a prior approval of a Product by the applicable Regulatory Health Authority, under Section 505(j) of the Federal Food, Drug and Cosmetic Act or 42 U.S.C. §§ 262(i)(2) and (k), or in each case, any successor or foreign equivalent Applicable Law, by way of an abbreviated or expedited approval process, pursuant to which such product is determined to be equivalent to the applicable Product by the applicable Regulatory Health Authority (including a determination that the product

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is "therapeutic equivalent", "interchangeable", "substitutable", or other term of similar meaning, with respect to such Product). A product shall not be considered to be a Generic Product [***].

Section 1.48 "GLP" or "Good Laboratory Practices" means all applicable good laboratory practices including, as required under the regulations set forth in 21 C.F.R. Part 58, as in effect during the Term, and the requirements thereunder imposed by the FDA and the NMPA, and the equivalent thereof in any jurisdiction.

Section 1.49 "Government Official" means any Person employed by or acting on behalf of a Governmental Body, government-controlled entity or public international organization or candidate for government or political office.

Section 1.50 "Governmental Body" means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; or (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, instrumentality, official, ministry, fund, political party, foundation, center, organization, unit, body or entity and any court or other tribunal).

Section 1.51 "Gross Profit" equals [***], in each case, during the corresponding Net Sales Measuring Period.

Section 1.52 "IFRS" means the International Financial Reporting Standards, the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.

Section 1.53 "IND" means an Investigational New Drug application or the equivalent filed with or submitted to the relevant Regulatory Health Authority, including, for example, the FDA, for authorization to commence human clinical trials.

Section 1.54 "Indication" means any disease, disorder, medical condition, patient population or mutation status.

Section 1.55 "Indirect Taxes" means value added taxes, sales taxes, consumption taxes and other similar taxes.

Section 1.56 "Initial Indication" means the following Indications: (a) [***], (b) [***], and (c) [***].

Section 1.57 "Intellectual Property Rights" or "IPR" means Patents, Trademarks, service marks, Know-How, Trade Secrets (including patentable inventions), trade names, registered designs, design rights, copyrights (including rights in computer software), domain names, database rights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

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Section 1.58 “**Know-How**” means all inventions, discoveries, data, information (including scientific, technical or regulatory information), Trade Secrets, processes, means, methods, practices, formulae, instructions, procedures, techniques, materials, technology, results, analyses, designs, drawings, computer programs, apparatuses, specifications, technical assistance, laboratory, pre-clinical and clinical data (including laboratory notes and notebooks), and other material or know-how, in written, electronic or any other form, whether or not confidential, proprietary or patentable, including without limitation: development technology; biology, chemistry, pharmacology, toxicology, drug stability, Manufacturing and formulation, test procedures, synthesis, purification and isolation techniques, quality control data and information, methodologies and techniques; information regarding clinical and non-clinical safety and efficacy studies, including study designs and protocols, marketing studies, absorption, distribution, metabolism and excretion studies; assays and biological methodology.

Section 1.59 “**Knowledge**” means the good faith actual knowledge of the officers of the Party associated with the representation.

Section 1.60 “**Listed Entity**” means [***].

Section 1.61 “**Losses**” means any and all direct and indirect liabilities, claims, actions, damages, losses or expenses, including interest, penalties, and reasonable lawyers' fees and disbursements. In calculating Losses, the legal duty to mitigate on the part of the Party suffering the Loss shall be taken into account.

Section 1.62 “**Manufacture**” or “**Manufacturing**” means activities in connection with the manufacture, processing, formulating, testing (including, without limitation quality control, quality assurance, lot release testing and activities related to chemistry, manufacturing and controls (i.e. CMC) for the Product), bulk packaging or storage and delivery of Product.

Section 1.63 “**Manufacturer**” means Aadi or such other Third Party manufacturer as may be selected by Aadi to Manufacture Product.

Section 1.64 “**Materials**” means information, data or assays necessary or useful for the Development or Commercialization of Product in the Territory.

Section 1.65 “**NDA**” means a New Drug Application (as defined by the NMPA or FDA), or any successor application for regulatory approval having substantially the same function, or its foreign equivalent for approval to market or sell a pharmaceutical product.

Section 1.66 “**Net Sales**” means, for each Net Sales Measuring Period, the sum of, without any duplication, [***] so as to arrive at "net sales" reported by EOC, its Affiliate or its Sublicensee, as applicable, in such Person's financial statements, [***]. For the avoidance of doubt, Net Sales shall exclude any Indirect Taxes received or imposed on the receipt of such gross amounts.

Any and all set-offs against gross invoice prices shall be calculated in accordance with IFRS. [***]. Notwithstanding the foregoing, if Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be [***]. Such

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amount that would have been invoiced shall be determined, wherever possible, by reference to [***].

Notwithstanding the foregoing, in the event that the JSC approves the sale of Product in conjunction with another active component (whether packaged together or in the same therapeutic formulation or otherwise) (a “**Combination Product**”), Net Sales shall be calculated [***]. If no such separate sales are made by EOC, its Affiliates or Sublicensees in a country, Net Sales of the Combination Product shall be calculated [***].

Section 1.67 “**Net Sales Measuring Period**” means the one-year period beginning January 1st of each year during the Term and ending December 31st of each year during the Term; provided that the first Net Sales Measuring Period will begin on the Effective Date and end on December 31, 2020.

Section 1.68 “**NMPA**” means the National Medical Products Administration under the People's Republic of China's State Administration for Market Regulation, or any successor thereto. For the avoidance of doubt, the NMPA shall refer to the agency formerly known as the People's Republic of China's Food and Drug Administration (CFDA).

Section 1.69 “**Non-Breaching Party**” shall have the meaning assigned in Section 11.02(a).

Section 1.70 “**P.R.C. GAAP**” means Generally Accepted Accounting Principles of the People's Republic of China, consistently applied.

Section 1.71 “**Patent**” means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

Section 1.72 “**Payments**” shall have the meaning assigned in Section 6.07(a).

Section 1.73 [***].

Section 1.74 “**Person**” means any individual, sole proprietorship, corporation, partnership, association, joint-stock company, trust, unincorporated organization, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

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Section 1.75 “**Pharmacovigilance Agreement**” shall have the meaning assigned in Section 4.07(a).

Section 1.76 “**Product**” means the [***] ABI-009 described in [***].

Section 1.77 “**Product-related Assigned IPR**” means all Product-related IPR made, conceived, formed, reduced to practice or discovered in the performance of this Agreement that relates to [***].

Section 1.78 “**Product-related Licensed IPR**” means all Product-related IPR other than Product-related Assigned IPR.

Section 1.79 “**Product-related IPR**” means all Know-How and Intellectual Property Rights therein, including but not limited to rights to Patents and clinical data, not otherwise licensed by Aadi to EOC under this Agreement, that is [***], which are specifically [***] to the Manufacture or Exploitation of the Product anywhere in the world.

Section 1.80 “**Regulatory Approval**” means any and all approvals, product or establishment licenses, registrations, or authorizations of any regional, federal, state, or local Regulatory Health Authority, department, bureau, or other governmental entity, necessary to commercially distribute, sell or market the Product in a regulatory jurisdiction, including, where applicable, (a) pricing or reimbursement approval in such jurisdiction, (b) pre- and post-approval marketing authorizations, (c) labeling approval and (d) technical, medical and scientific licenses.

Section 1.81 “**Regulatory Documentation**” means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Health Authorities (including minutes and official contact reports relating to any communications with any Regulatory Health Authority) and all supporting documents, including documentation arising in the course of all clinical studies and tests, in each case relating to the Product, including all INDs, NDAs, Regulatory Approvals, regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

Section 1.82 “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Health Authority with respect to Product other than issued and unexpired Patents, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), orphan drug exclusivity, or rights similar thereto outside the U.S.

Section 1.83 “**Regulatory Health Authority**” or “**Regulatory Health Authorities**” means any applicable national (for example, FDA or NMPA), supranational, regional, state, provincial or local regulatory health authority, department, bureau, commission, council, or other government entity regulating or otherwise exercising authority with respect to the Exploitation of Product, including any such entity involved in the granting of Regulatory Approval for pharmaceutical products.

Section 1.84 “**Review Period**” shall have the meaning assigned in Section 7.07.

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Section 1.85 “**Senior Executives**” means [***]. A Party shall be entitled, effective upon written notice thereof to the other Party, to designate one of its other representatives having equivalent seniority and experience to replace such foregoing representative as that Party’s Senior Executive for the purpose of this Agreement.

Section 1.86 “**Separate**” means, with respect to a pharmaceutical product, to ensure that no personnel involved in performing the research, development or commercialization of such product has access to or use of (i) Aadi’s Confidential Information, any Inventions owned in whole or in part by Aadi, or (ii) non-public plans or non-public information or data related to the Product.

Section 1.87 “**Sublicense**” shall mean an agreement into which EOC enters with a Third Party for the purpose of (i) granting certain rights, (ii) granting an option to certain rights, or (iii) forbearing exercise of any rights, in each case, granted to EOC under this Agreement. For clarity, a contract for services to be performed solely for EOC or its Affiliate and under which the contractor obtains no independent right to conduct any activity with Aadi Patents or Aadi Know-How or with the Product shall not be considered a “Sublicense”.

Section 1.88 “**Sublicensee(s)**” means any Third Party or Affiliate of EOC with whom EOC enters a Sublicense.

Section 1.89 “**Supply Agreement**” means the agreement for the manufacture and supply of Product by Aadi to EOC or its designated agent for the purposes of this Agreement, which shall be executed by EOC and Aadi in accordance with Section 5.01 of this Agreement.

Section 1.90 “**Tax**” means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

Section 1.91 “**Tax Authority**” means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax.

Section 1.92 “**Term**” shall have the meaning assigned in Section 11.01.

Section 1.93 “**Territory**” means the [***].

Section 1.94 “**Third Party**” means any Person other than Aadi, EOC, or their respective Affiliates.

Section 1.95 “**Third Party Claims**” shall have the meaning assigned in Section 12.01(a).

Section 1.96 “**Third Party Compensation**” shall have the meaning assigned in Section 6.04(c).

Section 1.97 “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

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Section 1.98 “**Trade Secret**” means information, including but not limited to formulae, techniques, conditions, reagents, processes, or methods, that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Section 1.99 “**Transfer Price**” means with respect to the Product supplied by Aadi, the [***], subject to the terms and conditions set forth in the Supply Agreement.

Section 1.100 “**U.S. GAAP**” means United States Generally Accepted Accounting Principles, consistently applied.

Section 1.101 “**Valid Claim**” means (a) a claim of an issued and unexpired Patent within the Aadi Patents that has not been held permanently revoked, invalid, or unenforceable by a court or other Governmental Body, which decision is unappealable or has not been appealed within the time allowed for appeal, and has not been admitted to be invalid or unenforceable through disclaimer, or otherwise or (b) a claim of a pending patent application within the Aadi Patents that has not been abandoned, finally rejected or expired without the possibility of appeal or re-filing.

Section 1.102 “**Withholding Income Tax**” shall mean the aggregate withholding of income tax required by the Peoples Republic of China and any province or municipal subdivision, agency or department thereof.

Section 1.103 “**Written Disclosure**” shall have the meaning assigned in Section 10.02.

Section 1.104 Construction. Except where the context requires otherwise, whenever used in this Agreement, the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The term “**including**” or “**includes**” as used in this Agreement means including, without limiting the generality of any description preceding such term. The article, section, and subsection headings contained in this Agreement are for the purposes of convenience only and are not intended to define or limit the contents of such articles, sections, and subsections. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

ARTICLE II. GRANT OF RIGHTS AND LICENSES; EXCLUSIVITY

Section 2.01 License to EOC.

(a) Subject to the terms, conditions and limitations set forth in this Agreement, including without limitation the provisions in Section 2.03 below, Aadi hereby grants to EOC an exclusive (exclusive even with regard to Aadi, Abraxis and their respective Affiliates), royalty-bearing license during the Term to Develop, and Commercialize, including without limitation repackage and have repackaged the Product in the Field in the Territory, [***], under Aadi Know-

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How and Aadi Patents (but specifically excluding [***]. For the avoidance of doubt, the license granted in this Section 2.01 does not include [***].

(b) EOC shall have the right to engage and appoint service providers, at its own discretion for the sole purpose of conducting clinical development, obtaining marketing authorization or import authorization, importing, distribution, marketing and/or promotion services in relation to the Product on behalf of EOC in the Territory. For avoidance of doubt, the Affiliates and the Sublicensees (as defined in Section 2.02) of EOC shall also have the right to engage and appoint service providers at their own discretion for the aforementioned purposes (together with service providers engaged by EOC, “**Third Party Subcontractors**”). Third Party Subcontractors shall be bound by obligations of confidentiality no less restrictive than those contained in this Agreement. EOC shall remain liable for any action or failure to act by any Third Party Subcontractor if such action or failure to act by such Third Party Subcontractor would have constituted a breach of this Agreement if such action or failure were committed by EOC. Without limiting the foregoing, (a) any Third Party Subcontractor to whom EOC or its Affiliate or Sublicensee discloses Confidential Information will enter into an appropriate written agreement obligating such Third Party Subcontractor to be bound by obligations of confidentiality and restrictions on disclosure and use of Confidential Information that are no less restrictive than the obligations set forth in Exhibit C, (b) unless otherwise approved in advance by Aadi in writing, EOC will obligate each Third Party Subcontractor who might generate Product-related IPR to agree in writing [***], and (c) [***] of such Third Party Subcontractors during the Term and shall provide [***].

Section 2.02 Sublicenses. Subject to the terms and conditions of this Agreement, EOC [***], through multiple tiers of sublicenses, under the license granted to EOC under Section 2.01, [***]. Without limiting the foregoing, before granting any such Sublicense, EOC shall give written notice to Aadi of EOC's intent to grant such a Sublicense. Such written notice shall identify the prospective Sublicensee. Aadi shall have a period of [***] to [***], the prospective Sublicensee and EOC shall [***] provided during such [***] period. Notwithstanding anything else in this Section 2.02 or otherwise in this Agreement, in no event will EOC be permitted to enter into a Sublicense or other agreement [***]. In the event [***], Aadi will promptly notify EOC thereof. Aadi will consider any comments provided within a reasonable period of time by EOC regarding such proposed addition in good faith, [***]. EOC, its Affiliates and its Sublicensees shall ensure that all Persons to which they grant Sublicenses comply with all applicable terms and conditions of this Agreement. EOC acknowledges and agrees that the grant of any Sublicense shall not relieve EOC from its obligations under this Agreement and EOC shall, under each Sublicense agreement, obligate the Sublicensee to be bound by all of the applicable terms and conditions of this Agreement. Each Sublicense agreement must be in the English language and must (i) provide that the Sublicensee's rights are not further sublicensable without Aadi's prior written consent, which may be withheld by Aadi in its sole discretion, (ii) provide that Abraxis is a third party beneficiary, (iii) provide that the Sublicensee expressly acknowledge and agree in writing to Abraxis that it shall comply with the provisions of [***], and (iv) include terms and conditions substantially identical to those of [***]. EOC shall remain liable for any action or failure to act by any Sublicensee, or any other Party that is granted a sublicense under the licenses granted in Section 2.01 by EOC, its Affiliates or its Sublicensees, if such action or failure to act by the Sublicensee would have constituted a breach of this Agreement if such action or failure were committed by

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EOC. In the event of a revocation or expiration of the license granted hereunder, all Sublicenses granted to Sublicensees in accordance with the terms hereof shall [***] without any further action on the part of Aadi.

Section 2.03 Rights Retained by Aadi. Notwithstanding the foregoing, Aadi hereby expressly retains all rights to, and excludes from the license grant in Section 2.01, [***], provided that to the extent necessary for the approval of an IND or NDA for the Product in the Territory, Aadi shall either provide such [***] to EOC or [***], in Aadi's sole discretion. Aadi retains the exclusive right to practice, license and otherwise exploit the [***] outside the scope of the license set forth in Section 2.01, including the rights to use, import and export Product in the Territory for Development and Commercialization outside of the Territory and the rights to use the [***] in the Field in the Territory in order to exercise its rights and perform its obligations under this Agreement and the Global Development Plan.

Section 2.04 No Implied Rights. This Agreement confers no right, license, or interest by implication, estoppel, or otherwise under any Patents, Know-How, or other Intellectual Property Rights of either Party except as expressly set forth in this Agreement. Each Party hereby expressly retains and reserves all rights and interests with respect to Patents, Know-How, or other Intellectual Property Rights not expressly granted to the other Party hereunder. Without limiting the generality of the foregoing, no license or other rights are granted to EOC under this Agreement to any pharmaceutical compositions claimed or disclosed in any Aadi Patents other than the Product.

Section 2.05 Non-Compete. Upon the Effective Date and throughout the Term, EOC shall not, and shall ensure that its Affiliates do not (a) engage in, independently or for or with any Third Party, any research, development, manufacture or commercialization of 1) [***]; or 2) [***] as the only primary mechanism of action of the drug for any indication for which Aadi has been developing the Product outside the Territory as of the Effective Date or during the Term or for the indications that EOC agrees to develop in the Territory with the Product during the Term of this Agreement; or (b) market or promote [***] as the only primary mechanism for any indication during the Term or for the indications that EOC agrees to develop in the Territory or has received Regulatory Approval by NMPA for the Product (the foregoing products in this Section 2.05 defined hereunder as the "**Competitive Product**"); provided, in the event EOC terminates this Agreement under Section 11.02 (d) (Termination for Convenience), the restrictions of this Section 2.05 shall extend for [***] following such termination by EOC. Nevertheless, if [***], EOC shall be relieved from this Non-Compete obligation with respect to [***]. In the event EOC and/or any of its Affiliates directly or indirectly acquires or merges with a Third Party, which will become an Affiliate of EOC immediately after closing of such acquisition or merger transaction, and such Third Party is engaging in the commercialization of any Competitive Products as of the date of such acquisition or merger, EOC will notify Aadi immediately after the closing of such acquisition or merger transaction [***]. Notwithstanding the above, in the event that an Affiliate of EOC is (a) [***], such activities of such Affiliate shall not be a violation of this Section 2.05; provided, however, that such Affiliate does not [***]; or (b) [***], such activities of such Affiliate shall not be a violation of this Section 2.05. Aadi shall not, either itself or through any Affiliate or Third Party, directly or indirectly [***].

Section 2.06 Trademark Rights.

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(a) **Product Trademarks.** Aadi hereby grants to EOC a royalty-free, [***] license to use Aadi Trademarks, including Aadi Product trademarks and Aadi corporate trademarks, solely in connection with the Commercialization in accordance with Section 3.03(a), including but not limited to use, sale, offering for sale, and import of Product in the Territory. EOC shall have the right to select its own Trademarks and/or apply for new Trademarks in its own name, at its own discretion, to be used for the Commercialization of the Product in the Territory (the “**Product Trademarks**”) provided, however, that EOC shall provide Aadi with a reasonable opportunity to review and provide comments on each proposed Product Trademark and shall [***]. [***] shall [***] bear the full costs and expense of and be responsible for filing, prosecuting and maintaining all the Product Trademarks. [***] shall, at its sole discretion, protect, defend, and maintain each Product Trademark for use with Product in the Territory, and all registrations therefor. To the extent permitted by Applicable Laws, EOC shall indicate on the product packaging, advertisement and promotional materials that [***].

(b) EOC shall be responsible for the design and procurement of all packaging (non-commercial and commercial) and labeling of the Product.

Section 2.07 Cooperation. Aadi shall use, or shall cause its Affiliates to use its [***] to provide within [***] of the Effective Date, the Aadi Know-How that exists on the Effective Date and was not previously provided to EOC (the “**Initial Technology Transfer**”), which shall be completed in a reasonable amount of time. Thereafter, during the Term, Aadi shall (a) [***] at a meeting of the JSC (and, in any event, at least on [***] if any JSC meeting is not held in a particular [***]), [***], (b) transfer any such Aadi Know-How to EOC promptly following EOC's reasonable request and (c) [***] (the “**Continuing Technology Transfer**,” and together with the Initial Technology Transfer, the “**Technology Transfer**”). [***], and Aadi's transfer obligations under this Section 2.07 shall apply solely to the extent the [***] in accordance with this Agreement. Notwithstanding the foregoing, Aadi's Technology Transfer obligations hereunder shall not include the obligation to transfer [***], except as expressly set forth in [***] or unless otherwise mutually agreed by the Parties in writing. Aadi shall [***] provide documents necessary for the Development and Commercialization of the Product within Aadi's possession and control, participate in the communication with the government authority when requested by EOC, and accommodate other reasonable requests of EOC [***].

Section 2.08 New Technology. If, after the Effective Date, Aadi acquires [***] (“**New Technology**”) that is subject to royalty, milestone or other payment obligations to such Third Party, then Aadi shall so notify EOC and with EOC's approval, the following shall apply: The rights and licenses granted to EOC under this Agreement with respect to such New Technology shall be subject to [***]. Upon request by EOC, Aadi shall disclose to EOC a true, complete and correct written description of such [***]. In the event EOC does not provide the foregoing approval or does not agree in writing to [***], then such New Technology shall thereafter be deemed excluded from [***], hereunder.

ARTICLE III. GOVERNANCE

Section 3.01 Alliance Manager. Within [***], of the Effective Date, each Party will identify (and notify the other Party of the identity of) an personnel of such Party as a representative to act as its informal liaison under this Agreement (the “**Alliance Manager**”). The Alliance Managers

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will serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers may facilitate the flow of information and otherwise promote communication, coordination and collaboration between the parties, providing single point communication for seeking consensus both internally within each Party's organization, including facilitating review of external corporate communications, and raising cross-Party and/or cross-functional disputes in a timely manner. Each Party may change its Alliance Manager by written notice to the other Party.

Section 3.02 Joint Steering Committee. Within [***] of the Effective Date, the Parties shall establish a Joint Steering Committee (the "JSC"). Each Party shall designate [***] as the members to the JSC, and the initial members nominated by the Parties are listed at Exhibit D herein. Such representatives shall be individuals suitable in seniority, having direct knowledge, expertise and experience in the development, manufacture and commercialization of [***] and having been delegated authority to make decisions of the JSC with respect to matters within the scope of the JSC's responsibilities. At least one JSC member of each Party shall be fluent in English and all communications of the JSC (written and oral) shall be in English. The JSC shall operate in accordance with the provisions of Sections 3.03 to 3.07, and shall have no authority to alter, amend or waive the terms and conditions of this Agreement, the Supply Agreement, the Quality Agreement or the Pharmacovigilance Agreement, including any payment conditions or terms, periods of performance, or obligations of the Parties or determine any issue in a manner that would conflict with the express terms and conditions of this Agreement. A Party may change one or more of its representatives serving on the JSC at any time upon written notice to the other Party; provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. At its meetings, the JSC shall discuss the matters described below and such other matters as are reasonably requested by either Party's Alliance Manager. The JSC shall remain in effect as from its establishment through the Term.

Section 3.03 Responsibilities of JSC. Subject to Section 3.07, the JSC shall plan, coordinate, integrate and monitor activities of the Parties in the Territory including safety reporting to Regulatory Health Authorities and supply chain, including performing the following functions:

- (a) review and approve the Development and Commercialization strategy for the Product in the Territory, including amendments to the Development Plan and the initial Commercialization Plan and any amendments thereto (defined below) [***];
- (b) ensure harmonization of the Product Development and regulatory strategy in the Territory with the Global Development Plan, and approve any activities to be conducted by EOC thereunder, provided that the JSC will not have authority with respect to [***];
- (c) review and approve all pre-clinical and/or clinical Development activities proposed to be conducted with respect to the Product in the Territory;
- (d) review and approve the protocols for each clinical trial of Product proposed to be conducted in the Territory;
- (e) review and approve the Development and Commercialization of any Combination Product in the Territory;

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- (f) review and approve the Development and Commercialization of the Product for [***];
- (g) facilitate and approve the exchange of Product-related data and information between the Parties;
- (h) facilitate and approve the clinical trial data publication strategy in the Territory;
- (i) ensure that EOC's Development and Commercialization activities are in compliance with the Development Plan, Pharmacovigilance Agreement, Commercialization Plan, Quality Agreement and other relevant obligations under this Agreement, including but not limited to, obligations to keep Aadi reasonably informed and updated regarding (i) the status of such Development and Commercialization activities, (ii) results from any clinical trials, (iii) any adverse events, and (iv) material correspondence with a Regulatory Health Authority; and
- (j) perform such other functions as are specifically designated for the JSC in this Agreement.

Section 3.04 Co-Chairs. Each Party shall designate one of its representatives on the JSC to co-chair the meetings for the JSC (each, a “**Co-Chair**”). The Co-Chairs shall, through and with the assistance of the Alliance Managers, coordinate and prepare the agenda for, and ensure the orderly conduct of, the meetings of the JSC. The Co-Chairs shall, through and with the assistance of the Alliance Managers, solicit agenda items from the JSC members and provide an agenda, along with appropriate information for such agenda, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. In the event the Co-Chairs or another JSC member from either Party is unable to attend or participate in a meeting of the JSC, the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for the meeting.

Section 3.05 Meetings. The JSC shall meet at least [***], or more or less frequently if determined by the JSC, during the period in which EOC is Developing the Product in the Territory, and JSC meetings can be called at other times by agreement between the Parties for any reason. JSC meetings may be conducted by telephone, videoconference or in person. Any in-person JSC meetings shall be held on an alternating basis between Aadi's and EOC' s facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for the cost of such Party's own personnel and for its own expenses in attending such meetings and carrying out the other activities contemplated under this Article III. As appropriate, the JSC may invite a reasonable number of non-voting employees, consultants and scientific advisors to attend its meetings as non-voting observers; provided, that such invitees are bound by confidentiality obligations at least as stringent as the provisions set forth herein. Each Party may also call for special meetings of the JSC to discuss particular matters within the JSC's authority as reasonably requested by such Party. The Alliance Managers shall provide the members of the JSC with no less than [***] notice of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than [***] notice of any special meetings called by either Party.

Section 3.06 Minutes. Minutes will be kept of all JSC meetings, with the minutes for each JSC meeting to be the responsibility of the Co-Chair (or his or her designees) of the Party that is hosting

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such meeting, unless otherwise agreed by the Parties. Draft meeting minutes shall be sent to all members of the JSC by e-mail for review and approval within [***] after each such meeting. The JSC shall formally accept the minutes of the previous meeting at or before the next meeting of the JSC. Minutes will be deemed approved unless any member of the JSC objects to the accuracy of such minutes by providing written notice to the other members of the JSC prior to the next meeting. Minutes shall list action items and shall designate any issues that need to be resolved by the JSC or applicable resolution process. In the event of any objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

Section 3.07 Decision Making of JSC. Decisions of the JSC shall be made by unanimous vote, with each Party's representatives on the JSC collectively having one vote. In the event that the JSC is unable to reach a decision, the matter shall be first referred to the Senior Executives of each Party for resolution by agreement of the two Senior Executives. In the event that the two Senior Executives are unable to reach agreement, then final decision-making authority shall be determined as follows:

- (i) [***] shall have final decision-making authority for matters within the JSC's decision-making authority with respect to (A) [***]; (B) [***]; (C) [***] and (D) [***];
- (ii) [***] shall have final-decision making authority for matters within the JSC's decision-making authority with respect to (A) [***]; and (B) [***].

In no event shall either Party be permitted to use its decision making authority under this Section 3.07 to supersede its obligations under this Agreement, and each Party's final decision shall comply with the Applicable Law and common practice and shall not be reasonably likely to adversely impact the other Party's development or registration or commercialization of the Product in or outside the Territory.

ARTICLE IV. GENERAL PROVISIONS ON DEVELOPMENT AND COMMERCIALIZATION

Section 4.01 Record Keeping. EOC shall maintain, or cause to be maintained, records of its activities under this Agreement in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes related to the Product in the Territory, which shall be complete and accurate and shall fully and properly reflect all work done and all data and other results achieved in or resulting from the performance of its activities hereunder, which shall record only such activities and shall not include or be commingled with records of activities outside the scope of this Agreement. EOC shall also document all non-clinical studies and clinical trials of the Product in formal written study reports in accordance with Applicable Laws and national and international guidelines (e.g., GCP, GLP and GMP). All such records shall be retained by EOC for at least [***] after the termination of this Agreement, or for such longer period as may be required by Applicable Laws. Upon Aadi's request, EOC shall, and shall cause its Affiliates and Sublicensees to, provide Aadi with copies of such records. Aadi shall also have the right, during normal business hours and upon reasonable prior notice to EOC, to inspect and copy any such records of such other party,

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provided however, such inspection shall require a [***] prior written notice and shall not interfere with EOC's regular operation.

Section 4.02 Development Plan. All Development of the Product in the Field in the Territory to be conducted by EOC shall be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 4.02, the “**Development Plan**”). The initial Development Plan will be agreed by the Parties within [***] of the Effective Date. Such initial Development Plan may be adjusted in accordance with this Section 4.02 and Section 3.03 according to liaisons with the Regulatory Health Authorities in the United States and/or in the Territory and according to the approval (or consent in case of no formal approval) to the pivotal clinical trial design by the Regulatory Health Authorities in the United States and/or in the Territory. [***]. From time to time, but at least [***], EOC shall propose updates or amendments to the Development Plan in consultation with Aadi to reflect changes in the plans, including timelines for activities therein. Thereafter, EOC shall submit the proposed updated or amended Development Plan to the JSC for review and approval, and once approved by the JSC, any amended Development Plan shall become effective. For clarity, the Development Plan and any amendments thereto shall be consistent with the Global Development Plan in material aspects and the Global Development Plan shall take precedence in case of any conflict or inconsistency between the Development Plan and the Global Development Plan

Section 4.03 Conduct of Certain Development Activities. Except for the activities allocated to EOC under the Global Development Plan pursuant to this Section 4.03, any clinical trial(s) and other Development studies that are commenced in the Territory after the Effective Date to support Regulatory Approval of the Product in the Territory shall be set forth in the Development Plan and will be conducted solely by EOC at its sole expense; provided, however, in its sole discretion but to the extent practicable, Aadi may [***] pursuant to the Applicable Law of the Regulatory Health Authority of the Territory, in which case Aadi shall [***] cooperate with EOC to conduct such clinical trials in the Territory. The Parties' collaborative work to support the global Development of the Product by conducting certain Development activities in the Territory will be conducted pursuant to a global development plan (as amended from time to time in accordance with this Section 4.03, the “**Global Development Plan**”). The Global Development Plan shall include (i) an outline of major Development activities (including clinical trials) planned by Aadi for the Product, (ii) details and timelines of the Development activities in the Territory assigned to EOC to support any multi-regional clinical study, and (iii) the details and timelines of any other Development activities (including clinical trials) in the Territory assigned to EOC to support the global Development of the Product. Aadi shall prepare an initial Global Development Plan within [***] of the Effective Date and shall provide such plan and any amendments thereto to the JSC. The JSC shall [***] the Global Development Plan and any amendments thereto solely with respect to Development activities to be conducted by EOC thereunder. EOC shall be solely responsible for the costs and expenses incurred by EOC in the Development of the Product in the Territory, including in the performance by or on behalf of EOC, its Affiliates or Sublicensees of Development activities under the Development Plan and any Development activities assigned to EOC under the Global Development Plan. For clarity, Aadi may conduct global Development activities with respect to the Product outside of the Global Development Plan and timely inform EOC of such Development activities through JSC.

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Section 4.04 Diligence Obligations.

(a) EOC shall use [***] in accordance with the Development Plan and the Global Development Plan at its own cost and expense to carry out its activities under this Agreement and to Develop, Commercialize, and obtain Regulatory Approval for the Product in the Field in the Territory. EOC shall conduct such tasks in a timely, professional manner and in compliance with the Development Plan, Global Development Plan in all material aspects, and all Applicable Laws. Without limiting the foregoing, as of the Effective Date, EOC shall be responsible for preparing, conducting, and bearing the cost and expense of all Development, regulatory, and Commercialization activities with respect to the Product in the Field in the Territory, including but not limited to:

- (i) preparing amendments to the Development Plan as contemplated by Section 4.02 above;
- (ii) preparing the Commercialization Plan contemplated by Section 4.09 hereunder no later than [***] prior to the anticipated date of filing of the first NDA or Drug Approval Application for the Product in the Territory;
- (iii) conducting any clinical trials set forth in the Development Plan in the Territory;
- (iv) timely making all regulatory submissions and filings in the Territory in accordance with the Development Plan and as is customary with industrial practices in the Field in the Territory; and
- (v) marketing, pre-launch and launch activities by no later than [***] prior to [***] after marketing approval and necessary custom clearance in the Territory.

Section 4.05 Reports of Development Activities. EOC shall prepare and provide reports in English on the Development activities of the Product undertaken by it at each meeting of the JSC (and, in any event, at least on [***] if the JSC does not meet in a particular [***]). The Development reports shall include a reasonably detailed summary of [***]. In addition, EOC shall, at its own expense, make appropriate scientific and regulatory personnel available to Aadi, either by telephone or in person as the Parties may mutually agree, as reasonably required to keep Aadi informed of Development activities conducted by EOC.

Section 4.06 Regulatory Matters.

(a) To the extent required under Applicable Laws in the Territory to enable [***] to manufacture and supply Product [***] for Development and Commercialization in the Territory and to obtain Regulatory Approvals for the Product in the Territory, Aadi shall be the marketing authorization or drug license holder of the Product in the Field in the Territory. Except as expressly set forth in this Agreement, Aadi shall not have any right, whether directly or indirectly, to Develop and/or Commercialize or otherwise distribute the Product in the Field in the Territory during the Term, which rights have been granted to EOC under Section 2.01. [***]. EOC shall promptly reimburse Aadi for any and all reasonable expenses (internal and external) that Aadi may incur in being the holder of, or transferring to EOC, the marketing authorization or drug license in the

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Territory. [***]. For so long as Aadi is the marketing authorization or drug license holder of the Product in the Field in the Territory, EOC shall [***]. EOC or its Affiliate incorporated within the Territory and appointed as a subcontractor in accordance with Section 2.01(b), as Aadi's agent shall have the right to make regulatory submission on Aadi's behalf while Aadi is the marketing authorization or drug license holder of the Product in the Field in the Territory, provided that to the extent necessary for the approval of an IND or NDA for the Product in the Territory, [***]. EOC shall not access such [***] unless necessary. For clarity, Aadi shall not be prohibited under this Agreement from assigning or transferring its marketing authorization in the United States to any Third Party, including any partner or licensee of Aadi (“**Marketing Authorization Transferee**”), provided that Aadi shall [***] ensure that any such transfer shall not adversely affect EOC's interests. Notwithstanding anything to the contrary, Aadi shall [***] ensure that the Marketing Authorization Transferee will provide the same level of collaboration and support and undertake Aadi's obligations and responsibilities as committed hereunder.

(b) EOC shall [***] pursue the Regulatory Approval for the Product in the Territory for all Indications specified in the Development Plan and approved by the JSC. EOC shall be responsible for preparing, translating, filing and submitting all Regulatory Documents related to the Product with the Regulatory Health Authority in the Territory, including all applications for Regulatory Approval, at its own cost. Aadi acknowledges that any and all applications for Regulatory Approvals, the Regulatory Approvals, and other regulatory filings related to the Product shall be submitted and held, to the extent set forth in Section 4.06(a), in the name of Aadi. EOC shall also be responsible for providing, in the format required by the applicable Regulatory Health Authorities, the data and information required to be submitted to such Regulatory Health Authorities for Regulatory Approval of the Product in the Territory, including without limitation data from all clinical trials. To the extent set forth in Section 2.07, Aadi shall transfer the original or provide a copy of the Regulatory Approvals and other necessary Regulatory Documents to EOC for Regulatory Approval in the Territory.

(c) Aadi shall cooperate with EOC, [***], to enable EOC to obtain any or all Regulatory Approvals for the Products in the Field in the Territory and make all regulatory submissions in accordance with the Development Plan. Aadi shall provide, upon reasonable request by EOC, all data and other clinical development information Controlled by Aadi and reasonably necessary for EOC to Develop the Product or seek Regulatory Approval in the Field in the Territory, and all necessary certification documents for any IND (including a proposed multinational clinical trial) application or NDA equivalent application or Drug Approval Application in the Territory which shall include data or information related to the manufacture of the Product to the extent Aadi elects to provide such information to EOC or is not able to directly submit such information to the applicable Regulatory Health Authority. [***]. Upon request by EOC (and at EOC's expense), Aadi shall also provide specification validation samples and reference standards and will provide EOC with information necessary for EOC to purchase any special equipment for specification validation and local CoA testing. Aadi shall provide the above mentioned data, information, documents, samples, materials and equipment within the timeframe agreed by both Parties. Aadi shall request the suppliers of excipient and package material to register and obtain DMF (Drug Master File) code to the Regulatory Health Authorities in the Territory before the NDA equivalent application or Drug Approval Application, provided that EOC will bear any reasonable costs Aadi incurs as a result of such requests. To the extent set forth

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in the Supply Agreement, Aadi shall support, and [***] ensure that the Manufacturer support, on-site inspection to the Manufacturer's facility to be conducted by the Regulatory Health Authorities of the Territory. For clarity, if any Regulatory Health Authority in the Territory requires, in connection with EOC's IND or NDA equivalent application or Drug Approval Application in the Territory, any data other than the data required to be transferred by Aadi pursuant to this Section 4.06(c), EOC shall be responsible at its sole cost for generating such data.

(d) Each Party shall provide the other Party with written notice no later than [***] after receiving notice of any meeting or discussion with any Regulatory Health Authority in the Territory related to the Product in the Field. Without limiting Aadi's obligations pursuant to Section 4.06(a), Aadi shall have the right, but not the obligation to attend all meetings or hearings (i) accomplished by telecommunications or other electronic means, and/or (ii) physically, as permitted by Regulatory Health Authorities. Except as set forth in Section 4.06(a), [***] shall bear the cost of physical attendance at such meetings or hearings.

(e) Aadi shall inform EOC any [***] and provide EOC related documents and data within [***], and support EOC to file and submit the [***] application in the Territory.

(f) Aadi shall timely report to EOC through the JSC the status of each IND application and Drug Approval Application covering the Product outside the Territory during the Tenn.

(g) EOC shall report to Aadi regarding the status of each pending or proposed IND application, NDA equivalent application or Drug Approval Application covering a Product in the Territory. EOC shall provide to Aadi, for Aadi's review and comment, all regulatory submissions (including summaries in English thereof) prepared by or on behalf of EOC at least [***] prior to submission and shall consider in good faith any comments received from Aadi within [***] after delivering such documents to Aadi with respect thereto and, in EOC's discretion, incorporate such comments prior to submission. EOC shall promptly notify Aadi of any request for information by any Regulatory Health Authority, and EOC shall reasonably cooperate with Aadi in providing such information. EOC shall as soon as reasonably practicable furnish Aadi with copies (and summaries in English) of all substantive correspondence EOC has had with any Regulatory Health Authority, and contact reports concerning substantive conversations or substantive meetings with any Regulatory Health Authority, in each case relating to any such IND, NDA equivalent or Drug Approval Application.

(h) In case Aadi needs any translation with respect to the documents and correspondence submitted the Regulatory Health Authority under Section 4.06, EOC may, at Aadi's expense, provide such English translation.

(i) Each Party hereby grants to the other Party the right of reference to all regulatory submissions pertaining to Product in the Field submitted by or on behalf of such Party or its Affiliates, solely to the extent set forth in this Section 4.06(i). EOC may use such right of reference to Aadi's regulatory submissions solely for the purpose of seeking, obtaining and maintaining Regulatory Approval for the Product in the Field in the Territory. Aadi may use such right of reference to EOC's regulatory submissions and Regulatory Approvals solely for the purpose of seeking, obtaining and maintaining regulatory approval of products outside the Territory or, to the extent permitted pursuant to this Agreement, in the Territory. Each Party shall bear its own costs

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and expenses associated with providing the other Party with the right of reference and sharing of data and information pursuant to this Section 4.06(i). Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 4.06(i) and to give the other Party the benefit of the rights of reference to the granting Party's regulatory submissions in the other Party's territory as provided herein.

(j) If either Party believes that the other Party is taking or intends to take any action with respect to a Product in such other Party's territory that could have a material adverse impact upon the regulatory status of the Product in the Field in its respective territory, then such Party shall have the right to bring the matter to the attention of the JSC, and the Parties shall discuss in good faith a resolution to such concern. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth herein or in the Development Plan): (i) neither Party shall communicate with any Regulatory Health Authority having jurisdiction outside of its respective territory with respect to any Product, unless required by such Regulatory Health Authority, in which case such Party shall notify the other Party of such order as promptly as possible, but in no event later than [***] following such communication; and (ii) neither Party shall submit any regulatory submissions or seek regulatory approvals for any Product in the other Party's respective territory

Section 4.07 Adverse Event Reporting and Product Recall.

(a) Each Party agrees to provide the other Party with the necessary safety information required by Regulatory Health Authorities to comply with Applicable Laws. EOC will maintain an adverse event database for clinical trials conducted in the Territory ("**Territory Safety Database**") at its sole cost and expense. EOC shall be responsible for (i) reporting to the applicable Regulatory Health Authorities in the Territory, all quality complaints, adverse events and safety data related to the Product for clinical trials conducted in the Territory under the Development Plan and (ii) responding to safety issues and to all requests of Regulatory Health Authorities related to such safety issues with respect to the Product in the Field in the Territory, in each case ((i) and (ii)), in accordance with Applicable Law, the Pharmacovigilance Agreement and in consultation with Aadi. Aadi shall report to EOC, in accordance with the procedures set forth in the Pharmacovigilance Agreement, all adverse events occurring in the conduct of the activities by or on behalf of Aadi in the Territory for inclusion in the Territory Safety Database. EOC shall, to the extent permitted by applicable laws, at all times provide to Aadi access to the Territory Safety Database, and shall transfer the data included therein to Aadi for inclusion in the global adverse event database for the Product in accordance with the Pharmacovigilance Agreement and as reasonably requested by Aadi. As between the Parties, Aadi shall maintain a global adverse event database for the Product, at Aadi's cost and expense, except that within [***] of receipt of an invoice therefor, EOC shall reimburse Aadi for that portion of such costs and expenses resulting from EOC's Development and Commercialization of Products in the Territory. As promptly as possible following the Effective Date, but no later than [***] after the Effective Date or otherwise agreed by both Parties, the Parties will enter into a detailed pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"), governing, among other things, appropriate adverse event reporting procedures and pharmacovigilance responsibilities of the Parties relating to Product and reflecting the provisions set forth above in this Section 4.07(a).

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(b) In the event that any Governmental Body issues or requests a recall or takes similar action in connection with the Product, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the Party notified of or desiring such recall or market withdrawal shall promptly advise the other Party thereof. Aadi shall have the right to review, and comment on any response to any Regulatory Health Authority that relates to a Product. EOC shall consider Aadi's comments in good faith. Aadi shall be responsible for any costs associated with a recall or similar action in connection with any Product which is defective or fails to meet specifications or conform to the requirements of this Agreement, Supply Agreement or the Quality Agreement (the “**Defective Product**”), to the extent set forth in the Supply Agreement. In addition, Aadi shall promptly notify EOC of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party, or any recall or withdrawal, that would reasonably be expected to materially affect the Development or Commercialization of the Product in the Field in the Territory, and EOC shall promptly notify Aadi of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party that would reasonably be expected to materially affect the Development or Commercialization of the Product.

Section 4.08 General Provisions Regarding Commercialization. EOC will control and perform for, itself or through its Affiliates or Sublicensees, the Commercialization of the Product in the Field and throughout the Territory and shall be obligated and responsible for [***] carry out such Commercialization in accordance with the Commercialization Plan (as defined below). EOC will be solely responsible for, and will bear all costs relating to, the Commercialization of the Products in the Territory.

Section 4.09 Commercialization Plan. EOC shall be responsible for providing to the JSC for approval a reasonably detailed plan specifying the major Commercialization activities, including revenue targets and regional price strategy, planned for the Product in the Territory with respect to each Indication for which it is seeking Regulatory Approval, and the timelines for achieving such activities (to the extent approved by the JSC, and as amended from time to time in accordance with this Section 4.09, the “**Commercialization Plan**”). EOC shall deliver an initial draft of its proposed commercialization plan to Aadi for Aadi's review no later than [***] prior to the anticipated date of Approval of the first NDA or Drug Approval Application for the Product in the Territory. Aadi shall have the right to comment prior to the submission of the proposed commercialization plan to the JSC for approval and EOC shall consider such comments in good faith. Following approval of the Commercialization Plan by the JSC, from time to time, but at least every [***], EOC shall propose updates or amendments to the Commercialization Plan in consultation with Aadi to reflect changes in the plans, including those in response to changes in the marketplace, relative commercial success of the Product, and other relevant factors that may influence such plan and activities. EOC shall submit the proposed updated or amended Commercialization Plan to the JSC for review and approval before implementing such update or amendment.

Section 4.10 Reports of Commercialization Activities. For each Calendar Year following the first Regulatory Approval of the Product in the Territory, EOC shall provide to Aadi [***] a written report that summarizes the Commercialization activities performed by or on behalf of EOC, its Affiliates and Sublicensees in the Territory since the prior report by EOC. Such report shall contain

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sufficient detail to enable Aadi to assess EOC's compliance with its Commercialization obligations in Section 4.08 and the Commercialization Plan. Such reports shall be Confidential Information to EOC pursuant to Article VII. EOC shall provide updates to any such reports at JSC meetings, as necessary.

Section 4.11 Clinical Trial Audit Rights. Upon reasonable notification by Aadi and at Aadi's cost and expense, Aadi or its representatives shall be entitled to conduct an audit of any clinical trial sites engaged, or other facilities used, by EOC or its Affiliates or Sublicensees to conduct EOC's obligations under the Development Plan, to ensure that such clinical trials and obligations are conducted in compliance with the Development Plan and all Applicable Laws and meet Aadi's global clinical trial standards, provided that such audit shall require a [***] prior written notice and shall not interfere with the regular operation of the clinical trial. No later than [***] following the completion of any such audit, Aadi will provide EOC with a written summary of Aadi's findings in English, including any deficiencies or other areas of remediation that Aadi identifies during such audit and the Parties shall promptly meet to discuss any such deficiencies or other areas of remediation identified by Aadi. EOC will [***] remediate such deficiencies within [***] following EOC's receipt of such report, at EOC's cost and expense. If EOC is unable to remediate such deficiencies within a reasonable period and EOC reasonably determines, based on such deficiencies, that a clinical trial site engaged to conduct activities pursuant to the Development Plan is inadequate to continue performing in the applicable clinical trial of a Product in the Territory, then without limiting any other remedies under the Agreement, EOC will work with Aadi in good faith to wind-down such clinical trial at such site as promptly as practicable. EOC will provide Aadi with copies of all quality oversight or audit reports, with summaries in English, prepared in connection with any audit that EOC or any of its Affiliates or Sublicensees conducts of a clinical trial site that EOC or any of its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill EOC's obligations under the Development Plan no later than [***] after receiving or preparing, as applicable, any such report.

Section 4.12 Subcontractors. Subject to section 2.01(b), EOC shall obtain Aadi's written approval, such approval not to be unreasonably withheld, conditioned or delayed, prior to engaging any contract research organization to perform services under the Global Development Plan, including with respect to any Clinical Trial for which Aadi may seek global registration for the Product in the Territory. For non-Global Development Plan related clinical trials, EOC shall be able to pick any contract research organization without Aadi's approval.

Section 4.13 Diversion. Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and Sublicensees shall not, either directly or indirectly, Commercialize any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory; provided that each Party shall have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market any Product to Third Party attendees at such conferences and meetings, subject to this Section 4.13. Neither Party shall engage, nor permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliate or Sublicensee receives any order for a Product

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from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, or shall permit its Affiliates or Sublicensees to, deliver or tender (or cause or allow to be delivered or tendered) any Product for use in the other Party's territory.

ARTICLE V. SUPPLY

Section 5.01 **Supply.**

(a) Aadi shall use [***], either itself or through one or more Third Party Manufacturers, the supply of the Product to EOC solely for EOC's Development and Commercialization activities in the Territory under this Agreement. The Parties shall [***] enter into a separate supply agreement (“**Supply Agreement**”) consistent with the terms attached hereto as Exhibit E and the terms and conditions of any agreement between Aadi and its Third Party Manufacturer. The Parties shall use good faith efforts to ensure that the Supply Agreement shall be finalized and entered into between the Parties within [***] of the Effective Date or otherwise agreed by both Parties. The Supply Agreement shall provide specific terms and obligations concerning, among other things, forecasts, purchase orders, and supply of Product for the Territory, in accordance with Sections 5.01(b)-(d) below. The Parties shall also use good faith efforts to enter into a separate Quality Assurance Agreement (“**Quality Agreement**”) within [***] after the Effective Date or otherwise agreed by both Parties. Such Quality Agreement shall define the manufacturing and supply quality responsibilities negotiated in good faith between the Parties.

(b) Development Supply. For supply of Product for Development (including all clinical or regulatory supplies necessary to obtain Regulatory Approval in the Territory) in the Territory, Aadi shall supply sufficient Products to EOC for each Indication, to the extent set forth in the Development Plan or Global Development Plan, at [***], and subject to the terms and conditions of the Supply Agreement.

(c) Commercial Supply. For supply of Product for Commercialization purposes, Aadi shall be responsible for supplying such Product to EOC at [***], subject to the terms and conditions of the Supply Agreement.

(d) The Supply Agreement shall specify, among other things: [***].

Section 5.02 **Restrictions on Manufacture and Supply.**

(a) Notwithstanding anything to the contrary herein, without Aadi's written consent, EOC shall not (i) Manufacture or have Manufactured, itself or through an Affiliate or Sublicensee, or authorize or license any Third Party to Manufacture or have Manufactured the Product; (ii) supply any Product it receives from the Manufacturer under this Agreement to any Third Party for any use, other than Development, compassionate use or patient assistance program (subject to Transfer Price) and Commercialization of the Product in the Territory in compliance with this Agreement; or (iii) purchase any Product from any party other than Aadi pursuant to the Supply Agreement.

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(b) In the event Aadi fails to supply sufficient Products to EOC in any [***] as required pursuant to purchase orders submitted in accordance with the binding forecast pursuant to the Supply Agreement (which failure is not caused by a breach of EOC of its obligations hereunder or under the Supply Agreement), Aadi shall [***]. For purposes hereof, Aadi's failure to supply sufficient Products to EOC aforesaid shall mean a cumulative shortfall of Product equal to or greater than [***]. In the event of Aadi's failure to supply sufficient Products to EOC aforesaid, [***]. From and after NDA approval of the [***] for the Product in the Territory, Aadi shall keep the availability of such [***] and ensure, in the event of [***] failure in supply, [***] shall be able to supply the Product within [***].

(c) In the event the failure to supply sufficient Product in accordance with Section 5.02(b) above remains uncured within [***] of EOC's notice of such failure, [***]. Aadi shall use [***] to promptly implement such agreed measures.

(d) [***].

(e) Any breach of this Agreement or inability to perform hereunder by EOC caused due to Aadi's failure of supply shall not be deemed as a breach of EOC to the obligations hereunder.

ARTICLE VI. CONSIDERATION

Section 6.01 Upfront Payment. As partial payment for the rights and licenses granted to EOC by Aadi under this Agreement, EOC shall pay to Aadi a non-refundable payment of [***] after the Effective Date. This upfront payment shall [***] against any other payments EOC is obligated to make to Aadi under this Agreement.

Section 6.02 Development Milestone.

(a) EOC shall make the following one-time, non-refundable milestone payments to Aadi within [***] of (i) the first achievement of each of the following milestone events for a Product and (ii) the issuance of the invoice by Aadi to EOC, subject to the limitations and additional provisions set forth below in this Section 6.02:

Milestone Event for Product	Milestone Payment (USD)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Each of the milestones set forth in Section 6.02(a) is eligible to be earned individually. Each Party shall provide the other Party with notice of each achievement of the foregoing milestones which such Party is responsible for achieving (EOC for milestones in the Territory and Aadi for milestones in the United States) within [***] thereafter.

(c) **Generic Product:** In the event there is no Regulatory Exclusivity in the Territory and a Generic Product receives approval of an ANDA Application and is launched in the Territory, any unpaid development milestone payments will be reduced to [***] of its original amount. In such event, upon EOC's request both Parties will negotiate in good faith to decide whether to continue the Development of unfinished Development Plan for any Indications.

(d) No payments pursuant to Section 6.02(a) shall [***] against any other payments EOC is obligated to make to Aadi under this Agreement.

Section 6.03 Sales Milestones.

No.	Milestone Event First time Annual Net Sales (USD) in Territory exceeds the following amounts	Milestone Payment (USD)
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(a) Subject to Section 6.03(b)(ii), upon the first achievement of each milestone event set forth in the table above, EOC shall make the corresponding milestone payment to Aadi.

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(b) EOC will deliver to Aadi a final report within [***] following the fourth Calendar Quarter as set forth under Section 6.06. Any sales milestone payable to Aadi or its designee under this Agreement shall be paid within [***] following the date (i) the report disclosing the achievement of such sale milestone is delivered to Aadi as set forth under Section 6.06 and (ii) Aadi issued an invoice for such sales milestone payment.

(c) The Parties agree that (i) each sales milestone payment under Section 6.03 shall only be paid once during the Term (i.e. once one sales milestone payment for item from 1 to 5 has been made pursuant to Section 6.03(b), no additional payment shall be made for such sales milestone); and (ii) [***]. In the event that more than one sales milestone is achieved in a given Calendar Year, EOC shall pay Aadi the sale milestone payment associated with each such sales milestone achieved during such Calendar Year.

(d) [***] against any other payments EOC is obligated to make to Aadi under this Agreement.

Section 6.04 Royalties.

(a) Subject to the provisions set forth below in Section 6.04(c) through Section 6.04(d), and Section 6.05, EOC shall pay to Aadi royalties in the Territory at the following rates:

Range of Annual Net Sales (USD)	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, royalties shall be calculated on a tiered structure where each royalty rate set forth in the table above shall apply only to that portion of the Annual Net Sales in the Territory during a given Calendar Year that falls within the indicated range of Annual Net Sales. As an illustrative example, if the Annual Net Sales in the Territory for a given Calendar Year is [***]. Notwithstanding the above, after the Product is covered by medical insurance in mainland

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China through negotiation with the related Governmental Body, the royalty to be paid by EOC to Aadi will not exceed [***] of the Gross Profit in any given Calendar Year, provided that, in no event shall the royalty to be paid by EOC to Aadi be [***] in any given Calendar Year.

(b) Royalty Term. The royalty payments payable under this Section 6.04 shall be payable from the First Commercial Sale of Product in the Territory until the later of: [***] (the “**Royalty Tenn**”). Upon the expiration of the Royalty Term or upon expiration of this Agreement, the licenses granted pursuant to Section 2.01 and 2.02 to EOC for the Product in the Territory shall continue and become irrevocable and perpetual. The Parties will negotiate the terms for continued supply of the Product to EOC and royalties payable following such expiration, which rate in no case will be higher than the rates set forth under Section 6.04(d) hereunder.

(c) Third Party Compensation. If (i) EOC reasonably determines that it is necessary to obtain a license from any Third Party in order to avoid infringement of such Third Party's Patent in the Territory with respect to the license contemplated hereunder, and (ii) EOC is required to pay to such Third Party any royalty, milestone payments, or other monetary compensation in consideration for the grant of such license or maintenance of the right to Commercialization (“**Third Party Compensation**”), then, provided that [***], for the period during which EOC owes royalties to Aadi hereunder, the royalties that would otherwise be payable on Net Sales of the Product in the Territory under Section 6.04(a) shall be reduced by an amount of [***] of all Third Party Compensation payable by or on behalf of EOC to such Third Party during the same period, provided that such royalty payments owed to Aadi shall not be reduced by more than forty percent (40%) of the amount that would otherwise be payable to Aadi under Section 6.04(a). [***].

(d) Generic Product. If during the Royalty Term, a Third Party receives marketing authorization for and commences commercial sale of a Generic Product in the Territory, then EOC shall have the right to reduce any royalties payable in the Territory for such Product pursuant to Section 6.04(a) to [***] of the rates set forth in Section 6.04(a) beginning on the date of first sale of the Generic Product and for each subsequent Calendar Quarter thereafter unless and until such Generic Product is removed from the market.

Section 6.05 Sales by Sublicensees. In the event that EOC grants sublicenses to one or more Sublicensees to sell Product to the extent permitted hereunder, such sublicenses shall include without limitation an obligation for the Sublicensee to account for and report its Net Sales of such Product on the same basis as if such sales were Net Sales by EOC, and EOC shall pay royalties and sales milestones to Aadi as if the Net Sales of the Sublicensee were Net Sales of EOC.

Section 6.06 Royalty Payments and Reports. The royalties payable under Section 6.04 shall be calculated quarterly as of the last day of March, June, September and December respectively for the Calendar Quarter ending on that date. For each Calendar Quarter following the First Commercial Sale of Product in the Territory, within [***] following the end of such Calendar Quarter, EOC shall deliver to Aadi a report summarizing the calculation of Net Sales of Product in the Territory. Within [***] of receipt of such report, Aadi shall notify EOC of the amount of royalties that Aadi will be responsible to pay under the Abraxis License based on such net sales (the “**Actual Licensor Royalty**”) and the royalty rate to be adopted so as to calculate such Actual Licensor Royalty thereunder (“**Actual Licensor Royalty Rate**”). The royalty rate set forth in the Abraxis License is set forth in Exhibit F. In addition, for each Calendar Quarter following the First

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Commercial Sale of Product in the Territory, EOC shall deliver to Aadi a report summarizing (a) the gross sales of the Product in the Territory, (b) calculation of Net Sales and Gross Profit of Product, (c) calculation of royalties due to Aadi, (d) exchange rate used to calculate Net Sales, (e) aggregate Annual Net Sales as of the end of such Calendar Quarter and (f) whether any sales milestone pursuant to Section 6.03 was achieved during such Calendar Quarter. Such report shall be certified under IFRS and shall be delivered within [***] following the end of such Calendar Quarter. Any royalty payable to Aadi or its designee under this Agreement shall be paid on the date that such report for the Calendar Quarter is delivered to Aadi under this Section 6.06. For the purpose of clearing of the royalty payment in a given Calendar Year, the report for the fourth Calendar Quarter shall summarize the Annual Net Sales and Annual Gross Profit of Product in such given Calendar Year and shall calculate all the royalties payable to Aadi or its designee for such given Calendar Year pursuant to Section 6.04(4). The royalties to be paid on the date of final report for the fourth Calendar Quarter under this Section 6.06 shall be the difference between the royalties payable for such given Calendar Year and the royalties having been paid.

Section 6.07 Taxes.

(a) The royalties, milestones and other amounts payable by EOC to Aadi pursuant to this Agreement (“**Payments**”), shall not be reduced on account of Taxes unless required by Applicable Laws. [***]. To the extent any Payments made by EOC pursuant to this Agreement become subject to Withholding Income Tax under Applicable Laws, EOC shall deduct and withhold the amount of such Taxes from the Payments due Aadi, but only to the extent that Aadi is required to bear such Taxes under this Agreement or Applicable Laws. EOC shall remit the amounts of Withholding Income Tax, whether paid by Aadi or EOC, to the proper Governmental Bodies in a timely manner and transmit to Aadi an official tax certificate or other evidence of payment of such tax obligations from the relevant Governmental Bodies. Except as provided in this Section 6.07(a), all taxes or duties in connection with payments made by EOC for Indirect Taxes, including any value added or similar tax or local tax or surcharge on value added taxes and any import duty or fees, shall be paid by EOC. Notwithstanding the foregoing, if Aadi is entitled (whether under any applicable tax treaty or otherwise under Applicable Laws) to a reduction in the rate of, or the elimination of, Withholding Income Tax, it may deliver to EOC or the appropriate Governmental Body (with the assistance of EOC to the extent that this is reasonably required and is expressly requested in writing), the prescribed forms necessary to reduce or eliminate the applicable rate of Withholding Income Tax, and EOC shall apply the reduced rate of withholding, or dispense with withholding, as applicable. EOC agrees to take all other reasonable and lawful efforts to minimize such Withholding Income Tax, and EOC shall cooperate with Aadi as reasonably requested in any claim for refund or application to any Tax Authority. If any refund of Withholding Income Tax is made to Aadi, such refund shall be allocated to the Parties consistent with the allocation of liability of Withholding Income Tax provided in this Section 6.07(a). If EOC intends to withhold income Tax from any Payments, EOC shall inform Aadi reasonably in advance of making such Payments to permit Aadi an opportunity to provide any forms or information or obtain any Tax Authority approval as may be available to reduce or eliminate such withholding.

(b) Tax Gross-up. Notwithstanding anything to the contrary herein, if (i) EOC redomiciles, designates an Affiliate as payer or assigns its rights or obligations under this Agreement, (ii) as a result of such redomiciliation, designation or assignment, EOC (or its

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assignee) is required by Applicable Law to withhold taxes, or such redomiciliation, designation or assignment results in the imposition of Indirect Taxes that were not otherwise applicable, from or in respect of any amount payable under this Agreement, and (iii) such withholding taxes (which would include Withholding Income Tax) or Indirect Taxes exceed the amount of withholding taxes or Indirect Taxes that would have been applicable but for such redomiciliation or assignment, then any such amount payable to Aadi pursuant to this Agreement shall be increased to take into account such withholding taxes or Indirect Taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable) and/or paying such Indirect Taxes, as the case may be, Aadi receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect Taxes had been imposed. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax or Indirect Taxes would not have been imposed but for the assignment by Aadi of its rights or obligations under this Agreement or the redomiciliation of Aadi outside of the United States, to the extent such assignment or redomiciliation occurs after the redomiciliation or assignment by EOC described in the first sentence of this Section 6.07(b). Solely for purposes of this Section 6.07(b), a Party's "**domicile**" shall include its jurisdiction of incorporation or tax residence and a "**redomiciliation**" shall include a reincorporation or other action resulting in a change in tax residence of the applicable Party or its assignee.

(c) Notwithstanding anything to the contrary contained in this Section 6.07 or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. If any Indirect Taxes imposed by relevant Governmental Bodies in the Territory are chargeable in respect of any Payments, EOC shall be responsible for such Indirect Taxes and shall not reduce any Payments due Aadi hereunder as a result of such Indirect Taxes. The sum of the net amount received by Aadi and the Withholding Income Tax levied by China Tax Authority discussed in Section 6.07(a) above for each payment shall not be less than the amount of the Upfront and Milestone Payments set forth in Section 6.01, 6.02 and 6.03. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, EOC shall promptly inform Aadi and shall cooperate with Aadi to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements.

Section 6.08 **Payments or Reports by Affiliates.** Any Payment required under any provision of this Agreement to be made to Aadi or any report required to be made by EOC shall be made by an Affiliate of EOC if such Affiliate is designated by EOC as the appropriate payer or reporting entity.

Section 6.09 **Mode of Payment.** All payments set forth in this Article VI shall be remitted by wire transfer to the bank account of Aadi as designated in writing to EOC which account may be updated from time to time (unless otherwise specified herein).

Section 6.10 **Payment Currency.** All amounts payable and calculations under this Agreement shall be in United States dollars. As applicable, Net Sales and any adjustments to payments under this Agreement shall be translated into United States dollars at an exchange rate determined by using the 30-day trailing average of the daily middle exchange rate for the renminbi of People's Bank of China (the central bank of the government of China) as published daily at <http://www.safe.gov.cn/wps/portal/english/Home>, as of the date of the applicable invoice.

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Section 6.11 Imports. For the avoidance of doubt, the Parties acknowledge and agree that none of the milestones or royalties payable under this Agreement are related to the license (or right) to import or any import of Products. EOC shall, with the reasonable assistance of Aadi, be responsible for any import clearance, including payment of any import duties and similar charges, in connection with the Product transferred to EOC under this Agreement. The Parties shall co-operate in accordance with Applicable Laws to ensure where permissible that no import duties are paid on imported materials. Where import duties are payable, the Parties shall co-operate to ensure that the Party responsible for shipping values the materials in accordance with Applicable Laws and minimizes where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities.

Section 6.12 Late Payments. Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. In the event that any payment due under this Agreement is not made when due, the amount due [***]. Notwithstanding the foregoing, a Party shall have recourse to any other remedy available at law or in equity with respect to any delinquent payment, subject to the terms of this Agreement.

ARTICLE VII. CONFIDENTIALITY

Section 7.01 Confidentiality. The Parties agree that the Party receiving Confidential Information disclosed by or on behalf of the other Party pursuant to this Agreement is entitled to disclose such Confidential Information only to its and its Affiliates' respective officers, directors, employees, agents, contractors, consultants, advisors, Affiliates and Sublicensees (collectively, "**Permitted Recipients**"), only to exercise its rights or perform its obligations hereunder and only on a need-to-know basis, and shall advise the Permitted Recipients of the confidential nature of such Confidential Information and shall cause the Permitted Recipients to be bound by obligations of confidentiality, non-use and non-disclosure at least as stringent as the terms of this Article VII. Each Party shall keep any Confidential Information of the other Party confidential and shall not publish nor otherwise disclose nor use for any purpose such Confidential Information other than to conduct its activities under this Agreement or otherwise as expressly authorized by this Agreement. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

Section 7.02 Exceptions. Notwithstanding the foregoing, the obligations set forth in Section 7.01 shall not apply in respect of Confidential Information to the extent that it can be established by the receiving Party that such Confidential Information:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by or on behalf of the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

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(c) was independently developed without use of the disclosing Party's information, as evidenced by contemporaneous written records;

(d) became generally available to the public or otherwise part of the public domain after its disclosure to the receiving Party and other than through any act or omission of the receiving Party in breach of this Agreement; or

(e) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

Section 7.03 Authorized Disclosure. The receiving Party may disclose Confidential Information of the disclosing Party to a Third Party only to the extent that such disclosure is:

(a) required by law, order, or regulation of a government agency or a court of competent jurisdiction, or by the rules of a securities exchange, provided that the receiving Party required to make such disclosure shall, after providing reasonable advanced notice to the disclosing Party before the disclosure, (i) give the disclosing Party an opportunity to comment on any such required disclosure, (ii) if requested by the disclosing Party, [***] obtain protective orders or any available limitations on or exemptions from such disclosure requirement where applicable and practicable;

(b) made to a patent office for the purposes of filing or enforcing a Patent as permitted in this Agreement;

(c) made by a Party or its Affiliates, or Sublicensees to the Regulatory Health Authority for the purposes of any filing, application or request for Regulatory Approval for the Product as permitted in this Agreement;

(d) made to advisors, actual or potential Third Party partners, investors, licensees, Sublicensees or acquirers of all or substantially all of the assets to which this Agreement relates; provided, however, in each case, that any such potential or actual partner, investor, licensee, sublicensee or acquirer agrees to be bound by confidentiality and non-use obligations with respect to such Confidential Information at least as protective of the disclosing Party and such Confidential Information as the terms of this Article VII;

(e) made by EOC or its Affiliates, or Sublicensees to Third Parties as may be necessary or useful in connection with the Exploitation of Product as contemplated by this Agreement, including subcontracting or sublicensing transactions in connection therewith; provided that the Party making such disclosures shall ensure that each Third Party recipient is bound by obligations of confidentiality no less restrictive than those contained in this Agreement and shall be liable to the other Party for any breach of such confidentiality obligations by the relevant recipient.

Section 7.04 Survival. This Article VII (other than Sections 7.08) shall survive for a period of [***] following the termination or expiration of the Agreement provided however that all Trade Secret information shall be safeguarded by the receiving Party as required in perpetuity or for so long as such information remains a Trade Secret under Applicable Law.

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Section 7.05 Termination of Prior Agreements. This Agreement supersedes the Confidentiality Agreement between Aadi and EOC dated as of August 6, 2020 (the “CDA”). All information and Materials exchanged between the Parties under the CDA shall be deemed Confidential Information and shall be subject to the terms of this Article VII.

Section 7.06 Publications. Except as required by law, each of the Parties agrees that it shall not publish or publicly present any scientific, technical, or academic information relating to the Product (a) without the prior written consent of the other, and (b) other than in compliance with this Section 7.06. Without limiting the foregoing, EOC may publish clinical or non-clinical data or any associated results or conclusions generated by or on behalf of EOC pursuant to this Agreement solely to the extent that such data, results or conclusions are specific to the Territory and the Field. For the avoidance of doubt, advertising information shall be subject to this Section 7.06 if it is not in accordance with the approved label or published academic papers. Each of the Parties shall provide to the other the opportunity to review any proposed publications, presentations, meeting abstracts, talks or other publicity (including without limitation information to be presented verbally) that relate to the Product as early as reasonably practical, but at least thirty (30) days prior to their intended submission for publication or presentation, and such Party agrees, upon written request from the other, within the Review Period (as defined below), not to submit such abstract, manuscript, or other publicity materials for publication or to make such presentation until the other Party agrees, which agreement by such other Party shall not be unreasonably withheld. For the avoidance of doubt, to the extent practicable, Aadi shall be permitted to withhold such agreement if such publication is not in accordance with Aadi's global publication strategy with respect to the Product or for any reason with respect to the publication of results of any clinical trial of the Product including sites outside of the Territory. Such Party shall have [***] after its receipt of any such publication or presentation (the “Review Period”) to notify the other Party in writing of any specific objections to the intended publication or presentation. Each of the Parties shall, in any such publication or presentation, delete from the proposed disclosure any Confidential Information of the other. Additionally, if a Party notifies the other within the Review Period that it objects to such disclosure on the basis that a patent application claiming information contained in such disclosure should be filed prior to such disclosure, such Party agrees to delay disclosure of the relevant information, for up to [***] after the other Party's timely notification of its objection as per the above, or until such application has been filed, if earlier. Once any such abstract or manuscript is accepted for publication, the publishing Party will provide the other with a copy of the final version of the manuscript or abstract. Notwithstanding the foregoing, Aadi's obligations under this Section 7.06 shall apply only to publications in the Territory or containing the Confidential Information of EOC.

[***]

ARTICLE VIII. OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

Section 8.01 Ownership. Except as expressly provided in this Agreement, Aadi shall retain sole and exclusive Control of the Aadi Trademarks and Aadi Technology, including Aadi Know-How, Aadi Patents,. Except as expressly provided herein, no right, title, or interest is granted by Aadi to EOC in, to, or under any Aadi Technology, and, except as expressly provided herein, EOC shall have no right to assign to any Third Party any right or interest received under Aadi Technology

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under the terms of this Agreement. [***]. EOC shall, at Aadi's cost, take (and cause its Affiliates, Sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by Aadi to evidence such assignment and to reasonably assist Aadi in obtaining Patent and other Intellectual Property Rights protection for Product-related Assigned IPR. Each Party shall promptly disclose to the other all Product-related IPR and Joint Inventions, including all Invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from such other Party for additional information relating thereto. Except as otherwise provided in this Section 8.01, Know-How, including all compositions of matter, method of use or other subject matter, whether patentable or not, that is conceived or reduced to practice as a result of the Development or Commercialization of the Product under this Agreement (“**Inventions**”) that are made solely by or on behalf of Aadi or any of its Affiliates (and all Intellectual Property Rights therein, including any Patents) shall be owned [***]; Inventions that are made solely by or on behalf of EOC or any of its Affiliates (and all Intellectual Property Rights therein, including any Patents) excluding, for clarity, Product-related Assigned IPR, shall be owned [***]; and Inventions that are made jointly by or on behalf of the Parties (and all intellectual property rights therein, including any Patent Rights) [***] (each, a “**Joint Invention**”) shall be owned [***]. Inventorship under this Agreement will be determined in accordance with the laws of the United States relating to patents. Subject to the rights granted under and the restrictions set forth in this Agreement, it is understood that neither Party shall have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit any Joint Invention (or any Patents claiming the same, “**Joint Patents**”), by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting.

Section 8.02 Licenses to Aadi. EOC hereby grants to Aadi: (a) a royalty-free, fully-paid up, perpetual, irrevocable and sublicensable (through multiple tiers), exclusive license (but shall not exclude EOC's use during the Term) under the Product-related Licensed IPR to Develop, make, have made, use, import, export, offer for sale, sell and otherwise Commercialize Products outside the Territory (including to research Develop, make, have made, use, import and export Products in the Territory to support Development and Commercialization outside the Territory), (b) a nonexclusive, fully paid-up royalty-free, perpetual, irrevocable, sublicensable (through multiple tiers) license under the Product-Related Licensed IPR to Develop, make, have made, use, import, export, offer for sale, sell and otherwise Commercialize Products for any purpose, subject to the rights and licenses granted to EOC hereunder, and upon expiration or termination of this Agreement for any reason, in all fields, and (c) a non-exclusive, fully paid-up, royalty-free, perpetual, irrevocable and sublicensable (through multiple tiers) license under the EOC Technology that is necessary for or used or applied by or on behalf of EOC or its Affiliates or Sublicensees in the Development, manufacture or Commercialization of Products, to Develop, make, have made, use, import, export, offer for sale, sell and otherwise Commercialize Products (i) outside the Territory and (ii) in the Territory solely as necessary for Aadi to exercise its rights and perform its obligations under this Agreement (including with respect to Development and Manufacture of the Products) and to conduct global Development activities in accordance with the Global Development Plan. EOC shall be responsible for ensuring its employees, Affiliates, and Sublicensees are obligated to license and execute appropriate documents consistent with EOC's obligations under this Section 8.02. Notwithstanding the above, all clinical data generated by or on behalf of EOC, its Affiliates

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or Sublicensees in the Territory for the Indications contemplated herein shall be the property of EOC.

Section 8.03 Prosecution and Maintenance of Patent Rights.

(a) As between the Parties, Aadi shall have the right to control the preparation, filing, prosecution, and maintenance of the Aadi Patents in the Territory. Aadi shall have the right, but not the obligation, at its own cost, file, prosecute, and maintain all Aadi Patents in the Territory. [***]. In any event, Aadi shall have final decision-making authority with respect to such prosecution matters. [***].

(b) In the event that any Joint Invention is created hereunder, at either Party's request, the Parties shall discuss a mutually acceptable filing and prosecution strategy for any Joint Patent; provided that absent such agreement, [***] shall control the preparation, filing, prosecution, and maintenance of the Joint Patents, as set forth in this Section 8.03(b). [***] shall keep [***] reasonably informed of the prosecution of the Joint Patents and shall provide [***] with copies of all material correspondence received from any patent authority in connection therewith. Further, [***] shall notify [***] of any decision to cease prosecution of any Joint Patents. [***] will consider [***] comments on prosecution of Joint Patents but will have final decision-making authority under this Section 8.03(c). [***] will promptly reimburse [***] for [***] any reasonable out-of-pocket costs incurred by [***] in connection with such prosecution activities.

(c) [***] shall keep [***] reasonably informed and provide Aadi with a reasonable opportunity to consult with [***] regarding prosecution of any Patent that claims Product-related Licensed IPR (“**Product-related Licensed Patents**”), provided that [***] shall retain final decision-making authority with respect thereto.

(d) Each Party agrees to bring to the attention of the other Party any Third Party Patent it discovers, or has discovered, and which relates to the subject matter of this Agreement. Each Party shall provide the other Party all reasonable assistance and cooperation in the prosecution efforts under this Section 8.03, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

(e) If Aadi decides to discontinue prosecution of any Aadi Patent, not file a continuation application requested to be filed by EOC or not maintain any Aadi Patent, Aadi shall provide EOC with notice of such decision at least [***] prior to any lapse or abandonment (or last possible filing date) thereof, or if earlier, promptly after its election not to file such application or maintain such patent, as applicable. [***]. EOC's prosecution rights with respect to [***] Patents under this Section 8.03(e) will be limited to pursuing only claims solely directed to [***], and EOC may not pursue any other claims without the prior written consent of Aadi. If EOC assumes prosecution responsibility pursuant to this Section 8.03(e), EOC shall keep Aadi full informed of such prosecution and provide Aadi with copies of material correspondence (including applications, office actions, responses, etc.) relating to prosecution of any [***] Patent being prosecuted by EOC. Aadi may provide instructions, comments and suggestions with respect to any material actions to be taken by EOC, and EOC shall follow Aadi's instructions with respect to [***] Patents. EOC shall consult with Aadi before taking any action that would have a material adverse impact on the scope of claims within [***] Patents and EOC shall follow Aadi's instructions. To facilitate

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Aadi's right to instruct, EOC shall provide copies of all such material correspondence and any proposed responses thereto by EOC at least [***] prior to any filing or response deadlines, or within [***] of EOC's receipt of any official correspondence if such correspondence only allows for [***] or less to respond, and Aadi shall provide any comments or instructions promptly and in sufficient time to allow EOC to meet applicable filing requirements.

Section 8.04 Enforcement Rights.

(a) **Infringement by Third Parties in the Territory.** [***] shall have the initial right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to initiate, maintain, and control any legal action on account of any infringement (i) within the Territory of any Joint Patent or (ii) Product-related Licensed Patent which infringement adversely affects or is reasonably expected to adversely affect any Product outside of the Territory by a Third Party, by counsel of its own choice. [***] shall promptly notify [***] in writing of its intention to initiate legal action against a Third Party for such infringement within the Territory. If [***] exercises its first right, [***] will, at [***] expense, provide [***] cooperation as reasonably necessary, including being named as a party. With respect to such actions, proceedings or settlements [***], [***] shall have the right, in [***] sole discretion and at [***] expense, to join or otherwise participate in such legal action in the Territory with legal counsel selected by [***]. If [***] does not exercise its first right within [***] days after a written request from [***] to do so, [***] will thereafter have the right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to initiate, maintain, and control such legal action by counsel of its choice, provided that [***] (B) [***] shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Product-related Licensed Patent or Joint Patent without the prior written consent of [***], which consent (with respect to the Product-related Licensed Patents) shall not be unreasonably withheld, delayed or conditioned. In the event that [***] initiates and thereafter maintains such legal action against a Third Party for infringement of a Joint Patent or Product-related Licensed Patent in the Territory, [***], at [***] expense, will provide [***] cooperation as reasonably necessary, including agreeing to be named as a party to such legal action.

(b) As between the Parties, [***] shall have the sole right, but not the obligation, at its expense and in its own name or in the name of any of its licensors, partners or Affiliates, to initiate, maintain, and control any legal action on account of any infringement within the Territory of any [***] Patent by a Third Party, by counsel of its own choice. [***] shall promptly notify [***] in writing of any intention to initiate legal action against a Third Party for such infringement within the Territory. If [***] exercises its right, [***] will, at [***] expense, provide [***] or any of its licensors, partners or Affiliates, cooperation as reasonably necessary, including being named as a party, including any necessary use of [***] name required to prosecute such litigation.

(c) The Party first having Knowledge that any Aadi Patent, Joint Patent or Product-related Licensed Patent claiming or covering Inventions that are necessary or useful to Exploit the Product within or outside the Territory is infringed, or misappropriated by a Third Party, or suspected of being infringed or misappropriated by a Third Party within or outside the Territory shall promptly notify the other Party thereof in writing. Such notice shall set forth the facts of that infringement, misappropriation, or suspected infringement or misappropriation in reasonable detail.

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(d) **Third Party Infringement Claims Against Product in the Territory.** If a Third Party asserts that a Patent or other right owned or controlled by it is infringed by the Development or Commercialization of the Product in the Territory, [***] shall have the initial right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to defend, control and settle such legal action with counsel of its own choice, provided that any such settlement shall require [***] written consent. Each Party shall notify the other Party in writing within [***] after receiving notice of any such legal action and following such notice, the Parties shall promptly meet to discuss the defense of such claim, and shall, as appropriate, enter into a joint defense agreement with respect to the common interest privilege protecting communications regarding such claim in a form reasonably acceptable to the Parties. If [***] exercises its first right, [***] will, upon [***] reasonable request, provide [***] cooperation as reasonably necessary; provided [***] shall reimburse for reasonable costs and expenses directly related to such cooperation. If [***] does not exercise its first right, [***] will thereafter have the right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to defend and control such legal action on [***] behalf, at its own expense and with counsel of its choice; provided that any settlement shall require [***] written consent.

(e) **Allocation of Expenses and Recoveries.** Except as otherwise agreed by the Parties in writing, the Party controlling the legal action under Section 8.04 shall be solely responsible for any expenses incurred by such party as a result of such action. Any recovery obtained by [***] as a result of any proceeding described in Section 8.04(b), by settlement or otherwise, shall be applied in the following order of priority: (i) first, to reimburse [***] costs in connection with such proceeding paid by [***] (including paid by [***] to reimburse its licensor or partner's costs in connection with such proceeding or to reimburse [***] costs pursuant to Section 8.04(b)) and not otherwise recovered, (ii) second, to reimburse any unreimbursed costs of [***] (excluding outside counsel fees) permitted to be reimbursed under Section 8.04(b), (iii) third, if the action relates to an infringing Product, (A) with regard to the remainder of the recovery, [***], and [***], and (B) any portion of the recovery for [***] will be [***], and (iv) fourth, if the action does not relate to an infringing Product, with regard to the remainder of the recovery, [***]. If monetary damages are recovered in any action described in Section 8.04(a), such amounts shall be allocated first to the reimbursement of any expenses incurred by the Parties in such action, and any remaining amounts shall be shared as follows: [***]. If such recovery is insufficient to reimburse the expenses of the Parties, then each Party shall receive a pro rata portion of the recovery based on each Party's expenses incurred in such action. If [***] exercises its right, in its sole discretion and at its own expense, to join or otherwise participate in any legal action described in Section 8.04(a) in the Territory with legal counsel selected by [***], any remaining amounts (after fully reimbursing the expenses of the Parties) shall be shared in proportion to the Parties' expenses incurred in such action.

(f) **Settlement of Third Party Claims for Infringement in the Territory; Payment of Third Party Royalties.** If a Third Party asserts that a Patent or other right owned or controlled by it is infringed by the Development or Commercialization or other Exploitation of the Product in the Territory, and as a result of settlement procedures or litigation under Section 8.04 (d), EOC is required to pay the Third Party a royalty or make any payment of any kind for the right to sell the Product in the Territory, such expense shall be borne solely by EOC [***].

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(g) **Oppositions by Parties.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination, or other attack upon the validity, title, or enforceability of any Patents Controlled by a Third Party in the Territory that claim the use or sale or other Exploitation of the Product, such Party shall so notify the other Party in writing, and the Parties shall promptly confer to discuss whether to bring such action or the manner in which to settle such action; provided, if the Parties cannot reach agreement on whether to bring such action within [***] of such written notice, then such issue shall be subject to the dispute resolution procedures of Article XIII. The Party not bringing an action under this Section 8.04(f) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall otherwise cooperate fully with the Party bringing such action at the other Party's expense.

(h) **Oppositions by Third Parties.** If any Joint Patent or Product-related IPR in the Territory becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, third party observation interference, or other attack upon the validity, title, or enforceability thereof in the Territory, then the Party having the right to prosecute such Patent at such time pursuant to Section 8.03 shall control such defense, at its sole cost. The prosecuting Party shall permit the non-prosecuting Party to participate in the proceeding to the extent permissible under law, and to be represented by its own counsel in such proceeding, at the non-prosecuting Party's expense. The non-prosecuting Party shall reasonably cooperate with the prosecuting Party in such proceeding. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third Party action at its own expense. Any recoveries obtained in such action shall be shared, as set forth in Section 8.04(e). In the event an Aadi Patent becomes the subject of any such proceeding commenced by a Third Party, as between the Parties, Aadi shall have the right to take and control the action, in accordance with the provisions of Section 8.04(b) hereof. Any costs incurred or recovery obtained with respect to such litigation, proceeding or settlement shall be borne or retained by Aadi.

(i) **Protective Order.** If, in any action brought pursuant to this Section 8.04 any information is the subject of a protective order that may be reviewed by counsel only, the Parties will endeavor to structure such protective order so as to enable their respective internal counsel to be included as permitted reviewers of such information.

(j) **Patent Marking.** EOC shall mark all Products in accordance with Applicable Laws, including the applicable patent marking laws, and shall require all of its Affiliates and Sublicensees to do the same.

ARTICLE IX. REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 9.01 Representations, Warranties, and Covenants.

(a) Each of the Parties hereby represents and warrants to the other Party that:

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(i) such Party is lawful entity duly incorporated in their respective controlling jurisdiction. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery, and performance of the Agreement by such Party does not conflict with any company bylaw, agreement, instrument, or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation, order, or policy of any court, Governmental Body, or administrative or other agency having jurisdiction over it;

(ii) such Party has not, and during the Tenn will not, grant any right to any Third Party relating to its respective Patents, Know-How and Trademark which would conflict with the rights granted to the other Party hereunder;

(iii) such Party will at all times and in all material respects comply with all Applicable Laws relating to its activities under this Agreement; and

(iv) such Party shall implement appropriate processes and controls with respect to technology and work flow methodologies in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of personally identifiable information in accordance with Applicable Laws, provided that each Party acknowledges and agrees that no material personally identifiable information will be shared between the Parties under this Agreement.

(b) Aadi represents, warrants and covenants as of the Effective Date (or as of such other/additional time as may be explicitly specified below) to EOC that:

(i) With respect to the Abraxis License, Aadi is the sole and exclusive owner or exclusive licensee (exclusive as to Abraxis as well) of the entire right, title and interest of the Aadi Technology licensed under the Abraxis License Agreement as of the Effective Date and throughout the Tenn. Aadi has and shall keep throughout the Term of this Agreement (except to the extent lost due to any action or omission of EOC in breach of this Agreement) all rights and authorizations (including any authorizations required pursuant to the Abraxis License Agreement) necessary to grant to EOC the licenses under the Aadi Technology granted herein, and has the right to grant the licenses in accordance with this Agreement. To Aadi's Knowledge, no other Person has such rights or authorizations (or such person has granted or will grant such right or authorization to Aadi during the Term) to grant such licenses to any other Person in the Territory. The Aadi Technology is not subject to any encumbrance, lien or claim of ownership by any Third Party. [***].

(ii) To Aadi's Knowledge, all applicable fees due to patent authorities with respect to the filing and prosecution of the Aadi Patents existing as of the Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with Applicable Law or patent authority rules and regulations).

(iii) [***].

(iv) Aadi has provided a true, complete and accurate copy of the Abraxis License Agreement to EOC. Except as disclosed to EOC prior to the Effective Date, each of Aadi and to Aadi's Knowledge, Abraxis has complied in all material respects with the terms of, and Aadi has

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not received notice from Abraxis or any Third Party asserting any breach of or giving notice to terminate, the Abraxis License Agreement. [***]. Aadi shall comply in all material respects with the terms of, and not terminate or cause Abraxis or any Third Party to terminate, the Abraxis License Agreement during the Term this Agreement.

(v) Aadi has not been debarred by the FDA, is not subject to any similar sanction of other Regulatory Health Authorities in the Territory, and is not subject to any such debarment or similar sanction by any such Regulatory Health Authority, and Aadi has not used, and will not engage, in any capacity, in connection with this Agreement, any Person who either has been debarred by such a Regulatory Health Authority, or is the subject of a conviction described in Section 306 of the FFDCa (21 U.S.C. §335a). Aadi shall inform EOC in writing immediately if it or any Person engaged by Aadi who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FFDCa (21 U.S.C. §335a) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Aadi's Knowledge, is threatened, relating to the debarment or conviction of Aadi or any such Person performing services hereunder.

(vi) Aadi shall perform, or shall cause its Affiliates or other licensees or sublicensee to perform, its obligations and responsibilities under this Agreement in compliance with this Agreement, all Applicable Laws, applicable FDA (or foreign equivalent) requirements, including, without limitation, then-current GLP and GCP.

(c) EOC represents, warrants and covenants as of the Effective Date (or as of such other/additional time as may be explicitly specified below) to Aadi that:

(i) EOC has not been debarred by the FDA (and is not subject to any similar sanction of other Regulatory Health Authorities in the Territory), and is not subject to any such debarment or similar sanction by any such Regulatory Health Authority, and EOC has not used, and will not engage, in any capacity, in connection with this Agreement, any Person who either has been debarred by such a Regulatory Health Authority, or is the subject of a conviction described in Section 306 of the FFDCa (21 U.S.C. §335a). EOC shall inform Aadi in writing immediately if it or any Person engaged by EOC who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FFDCa (21 U.S.C. §335a), or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to EOC's Knowledge, is threatened, relating to the debarment or conviction of EOC or any such Person performing services hereunder.

(ii) To the extent permissible under Applicable Laws, each employee and contractor of EOC performing obligations under this Agreement shall, prior to conducting any such obligations hereunder, be obligated by Applicable Law, or written contract to (i) promptly disclose to EOC of all Inventions and Know-How conceived or reduced to practice by such employee or contractor during any performance under this Agreement, (ii) automatically assign to EOC all right, title and interest in and to all such Inventions and Know-How and all Intellectual Property Rights therein, including all Product- related Inventions and Product-related Data, and (iii) adhere to similar obligations of confidentiality as are set forth in this Agreement. EOC shall not knowingly engage in any activities that use the Inventions covered or claimed in the Aadi Patents, or any Aadi Know-How a manner that is outside the scope of the license rights expressly granted to it hereunder.

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(iii) EOC shall perform, or cause its Affiliates or Sublicensee to perform, its obligations and responsibilities under this Agreement in compliance with this Agreement, all Applicable Laws, applicable NMPA (or foreign equivalent) requirements, including, without limitation, then-current GLP and GCP.

(iv) There are no legal claims, judgments, or settlements against EOC or any of its Affiliates, or pending or, to EOC's Knowledge, threatened, legal claims, or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations. There are no pending allegations, internal investigations or government inquiries or investigations involving EOC or any of its Affiliates relating to compliance with antitrust, anti-competition, anti-bribery or corruption laws and EOC is not aware of any facts or circumstances that would give rise to any violations thereof.

(v) EOC has, or can readily obtain, sufficient technical, clinical, and regulatory expertise and financial resources to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Commercialization, and obtaining Regulatory Approval and to meet its obligations that come due pursuant to this Agreement.

(vi) During the Term, EOC will only engage clinical trial sites under the Development Plan that conduct all clinical trials in compliance with Applicable Laws, including GCP, and are approved by the NMPA or the applicable Regulatory Authority.

(vii) EOC shall not take any action that would reasonably be expected to materially adversely affect the Development or Commercialization of Products outside the Territory or the Field.

(viii) EOC shall comply in all material respects with the terms of the Abraxis License Agreement applicable to EOC during the Term this Agreement.

(ix) Neither EOC nor any of its Affiliates is developing or attempting to develop a generic version of Abraxane®.

Section 9.02 No Debarment. In the course of the Development of the Product in the Territory in accordance with this Agreement and during the term of this Agreement, neither Party will use, any employee or consultant that is debarred by any Regulatory Health Authority or, to the best of such Party's Knowledge, is the subject of debarment proceedings by any Regulatory Health Authority. If either Party learns that its employee or consultant performing on behalf under this Agreement has been debarred by any Regulatory Health Authority, or has become the subject of debarment proceedings by any Regulatory Health Authority, such Party shall so promptly notify the other Party and shall prohibit such employee or consultant from performing on its behalf under this Agreement. The foregoing shall be without prejudice to the warranties stipulated in Section 9.01(b)(v).

Section 9.03 Privacy, Anti-Bribery, and Anti-Corruption Compliance.

(a) Compliance with Privacy Laws. Each Party shall implement appropriate processes and controls with respect to technology and work flow methodologies in connection with its

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activities under or in connection with this Agreement so as to protect the security and privacy of personally identifiable information in accordance with Applicable Law.

(b) Compliance with Applicable Anti-Corruption Laws. Each party understands and agrees that it has complied and will continue to comply with all applicable Anti-Corruption Laws in connection with this Agreement.

(i) Each Party represents and warrants that no payments of money or anything of value have been or will be offered, promised, or paid, whether directly or indirectly, by any of its directors, officers, employees, Affiliates, or third party representatives to any Government Official in connection with this Agreement: (a) to influence any official act or decision of any Government Official; (b) to induce any Government Official to do or omit to do any act in violation of lawful duty; (c) to secure any improper business advantage; or (d) to improperly obtain or retain business for, or otherwise direct business to, any Party in connection with this Agreement.

(ii) Each Party warrants and represents that, in connection with this Agreement, such Party, its directors, officers, employees, and third party representatives: (a) have not and will not request, accept, offer, promise, or give any bribe, kickback, or other corrupt payment to any person, including any representative of any commercial entity; and (b) have not and will not request, offer, promise, or give any financial or other advantage to induce another person to perform a function or activity in order to secure any improper business advantage or to improperly obtain or retain business for, or otherwise direct business in any way relating to this Agreement.

(iii) Each Party warrants and represents that (a) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of the Agreement, and (b) it shall maintain arms-length relations with all Third Parties with which it deals for or on behalf of the other party in performance of the Agreement.

(c) Notification of Investigations into Potential Non-Compliance with Anti-Corruption Laws. Each Party warrants and represents that it will promptly inform the other party if such party, or any of its directors, officers, employees, Affiliates, third party representatives, or Sublicensees becomes aware of any allegations, internal investigations or government inquiries or investigations involving such party or any of its Affiliates relating to compliance with antitrust, anti-competition, anti-bribery or corruption laws in connection with this Agreement or becomes aware of any facts or circumstances that would give rise to any violations thereof, including without limitation any meeting, interview, inspection, or audit requested by any Governmental Body.

(d) Cooperation with Due Diligence and Investigations. Each Party will provide reasonable cooperation in connection with any good faith investigation conducted by the other party into potential violations of applicable Anti-Corruption Laws or compliance with Section 9.03(b) in connection with this Agreement. Each Party will provide reasonable cooperation in responding to the good faith requests of the other Party to review compliance with the obligations set forth in this Section 9.03.

(e) Compliance Program. Each Party will adopt, implement, and/or update and, throughout the course of this Agreement, have, maintain, and enforce an appropriate and risk-

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based anti-corruption compliance program designed to reasonably ensure compliance with the representations, warranties and covenants contained in this Section 9.03 of the Agreement and applicable Anti-Corruption Compliance Laws, including without limitation the implementation of risk-based due diligence procedures on any potential Sublicensee or Third Party with which such Party may enter into a contract in connection with this Agreement. Any such agreements shall be in writing and shall contain anti-corruption representations, warranties and covenants no less restrictive than those set forth in this Section 9.03.

(f) Periodic Compliance Certifications. On an [***] following the execution of this Agreement, or as reasonably requested in good faith by the other Party, each Party agrees to submit a compliance certificate to the other Party which [***].

(g) NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE IX, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF EITHER PARTY; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

ARTICLE X. RECORD RETENTION, AUDIT AND USE OF NAME

Section 10.01 Records Retention; Audit.

(a) Each Party shall keep or cause to be kept accurate records of account in accordance with P.R.0 GAAP, in the case of EOC, and in accordance with U.S. GAAP, in the case of Aadi, showing information that is necessary for the accurate determination of the Cost of Goods, the royalties and other payments due under Article VI, or any other payment due hereunder. Such records or books of account shall be kept until the [***] in which the Product or Combination Product is sold (in the case of royalty or other payments due under Section 6.04) or in the period for which any other payment hereunder is required to be made. For clarity, EOC shall cause its Affiliates to keep, and shall require pursuant to a written agreement that any Sublicensee or Third Party Subcontractor performing activities hereunder keep accurate records or books of account in a manner that will permit such Party to comply with its obligations under the foregoing sentence.

(b) Upon the written request of the other Party, each Party shall permit a qualified accounting firm acceptable to both Parties to inspect during regular business hours and no more than [***], and going back no more than [***] preceding the current Calendar Year, all or any part of the audited Party's records and books necessary to check the accuracy of any [***] calculated or payments made or required to be made hereunder. Such inspection requires a [***] prior written notice and shall not interfere with the regular business operation of the Party being inspected. The accounting firm shall enter into appropriate obligations with the audited Party to treat all information it receives during its inspection in confidence. The accounting firm shall disclose to Aadi and EOC only whether [***] calculated or the payments made are correct and details concerning any discrepancies, but no other information shall be disclosed to the Party requesting the inspection. The charges of the accounting firm shall be paid by the Party requesting the

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inspection, except that if the [***] being audited have been overcalculated, or the payments being audited have been underpaid or the costs being reimbursed have been overstated, in each case by more than [***], the charges will be paid by the Party whose records and books are being inspected. Any failure by a Party to exercise its rights under this Section 10.01 with respect to a Calendar Year within the [***] allotted therefor shall constitute a waiver by such Party of its right to later object to any payments made by the other Party under this Agreement during such Calendar Year.

Section 10.02 **Publicity Review.** Subject to the further provisions of this Section 10.02, no Party shall originate any written publicity, news release, or other announcement relating to this Agreement or to performance hereunder or the existence of an arrangement between the Parties (collectively, “**Written Disclosure**”), without the prior prompt review of a copy of the materials proposed to be disclosed and written approval of the other Party. This Section 10.02 shall not prohibit the disclosure under Section 7.04(a). Notwithstanding the foregoing provisions of this Section 10.02, each Party may make any public Written Disclosure it believes in good faith based upon the advice of counsel is required under the Securities Laws of the United States, Hong Kong SAR or P. R. China, or any listing or trading agreement concerning its publicly traded securities, or under any applicable securities laws, or any rule or order of stock exchange; provided that, prior to making such Written Disclosure, Aadi or EOC shall, where reasonably practicable and legally permitted, provide the other Party with a copy of the materials proposed to be disclosed and an opportunity to promptly review and comment on the proposed Written Disclosure. To the extent that EOC reasonably requests that any information in the materials proposed to be disclosed be deleted, Aadi shall use reasonable efforts to request confidential treatment of such information pursuant to Rule 406 of the Securities Act of 1933 or Rule 24b-2 of the Securities Exchange Act of 1934, as applicable (or any other applicable regulation relating to the confidential treatment of information) so that any information that EOC reasonably requests to be deleted, to the extent permitted by the applicable government agency, are omitted from such materials.. For clarity, Aadi shall have the right to issue press releases and other public announcements regarding the Development or Commercialization of the Product outside of the Territory without the prior review or written approval of EOC.

Section 10.03 **Use of Names.** Neither Party shall use the name, insignia, symbol, Trademark, trade name or logotype of the other Party or its Affiliates or Abraxis or its affiliates in relation to this transaction or otherwise in any public announcement, press release, or other public document without the prior written consent of such other Party; provided, however, that either Party may use the name of the other Party in any document required to be filed with any government authority, including without limitation the FDA and the Securities and Exchange Commission, or foreign equivalent bodies, or otherwise as may be required by Applicable Law, provided that such disclosure shall be governed by Section 7.04. Further, the restrictions imposed on each Party under this Section 10.03 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to Article VII.

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ARTICLE XI. TERM AND TERMINATION

Section 11.01 Term. The term of this Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the date on which all of EOC's payment obligations under Article VI have been performed or have expired (the “**Term**”).

Section 11.02 Termination Rights.

(a) **Termination for Cause.** Subject to the provisions of this Section 11.02, if either Party (the “**Breaching Party**”) shall have committed a material breach of any of its material obligations under this Agreement (which, for the avoidance of doubt, shall include but shall not be limited to (i) either Party's material failure to meet its obligations under Article W hereof, (ii) Aadi's material failure to properly perform its obligations under this Agreement [***], (iii) EOC's failure to make payments when due hereunder; and [***] and if capable of cure, such material breach shall remain uncured and shall be continuing for a period of [***] following the Breaching Party's receipt of notice of such breach from the other Party (the “**Non-Breaching Party**”) stating the Non-Breaching Party's intent to terminate this Agreement in its entirety pursuant to this Section 11.02(a) if such breach remains uncured, then, in addition to any and all other rights and remedies that may be available, the Non-Breaching Party shall have the right to terminate this Agreement upon the expiration of such [***] period (subject, however, to the provisions set forth below in this Section 11.02(a)) immediately by giving notice to the Breaching Party. Notwithstanding the above, if (i) [***], (x) [***], and (iii) [***], and (iv) [***].

(b) **Termination for Challenge of Aadi Patents.** Prior to its expiration, Aadi may terminate this Agreement in its entirety immediately by written notice to EOC if EOC or its Affiliate or Sublicensee, or any Third Party assigned or designated by EOC, [***] in connection with a challenge to the validity, scope, enforceability, inventorship or ownership of or otherwise opposes any Aadi Patent or corresponding Patents, including in connection with an opposition proceeding or re-examination, inside or outside the Territory. Without limiting the foregoing, if a Sublicensee of EOC challenges validity, scope, enforceability, inventorship or ownership of or otherwise opposes any Aadi Patent or corresponding Patents under which such Sublicensee is sublicensed or corresponding Patents, including in connection with an opposition proceeding or reexamination, inside or outside of the Territory, then EOC shall terminate such sublicense. EOC shall include provisions in all agreements under which a Sublicensee obtains a sublicense under any Aadi Patent consistent with this Section 11.02(b), including providing that if the Sublicensee challenges the validity or enforceability of or otherwise opposes any such Patent under which the Sublicensee is sublicensed, EOC may terminate such sublicense.

(c) **Termination for Insolvency.** A Party may terminate this Agreement effective immediately upon written notice to the other Party if at any time during the Term, the other Party (the “**Debtor**”) (i) has a case commenced by or against it under the Bankruptcy Code, (ii) files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings, (iii) assigns all or a substantial portion of its assets for the benefit of creditors, (iv) has a receiver or custodian appointed for the Debtor's business, or (v) has a substantial part of its business being subject to attachment or similar process; provided, however, that in the event of any involuntary case under the Bankruptcy Code or other bankruptcy liquidation or receivership proceedings, the first Party

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shall not be entitled to terminate this Agreement pursuant to this subsection (c) if the case is dismissed within [***] after the commencement thereof.

(d) **Termination for Convenience.** Prior to its expiration, this Agreement may be terminated in its entirety at any time by EOC effective upon [***] notice or longer in its sole discretion with prior written notice to Aadi.

Section 11.03 Consequences of a EOC Triggered Termination. In the event (a) Aadi terminates this Agreement pursuant to Section 11.02(a) for EOC's material breach; (b) Aadi terminates this Agreement pursuant to Section 11.02(b) for patent challenge by EOC; (c) Aadi terminates this Agreement pursuant to Section 11.02(c) for EOC's insolvency; or (d) EOC terminates this Agreement pursuant to Section 11.02(d), (a termination as per (a) through (d) being a “**EOC Triggered Termination**”), both Aadi and EOC shall, subject to Section 11.03(a), continue to be obligated during the termination notice period (as applicable) to perform as far as reasonably practicable all of its obligations under this Agreement and any other agreements concluded between the Parties in accordance with this Agreement. In addition, as a result of a EOC Triggered Termination the following shall apply (without prejudice to the terminating party's other rights and remedies at law or in equity):

(a) All licenses and rights to the Aadi Technology granted to EOC (together with all sublicenses granted by EOC) hereunder shall terminate automatically without further action required on the part of Aadi as of the effective date of such termination, except to the extent expressly set forth in this Section 11.03. EOC shall be responsible at its own cost and expense for the wind-down of EOC's and its Affiliates' and Sublicensees' Development and Commercialization activities for the Product and the extent reasonably requested by Aadi, EOC shall reasonably cooperate to transfer responsibilities and activities related to its Development and Commercialization activities to Aadi in an orderly fashion so as to not disrupt current Development and Commercialization efforts in the Territory.

(b) Each Party shall return all data, files, records and other Materials in its possession or Control containing or comprising the other Party's Confidential Information to which such first Party does not retain rights hereunder (except one copy thereof, which may be retained by the returning Party solely for legal archive purposes). For the avoidance of doubt, EOC shall return all Aadi Know-How, including but not limited to all clinical trial data and records, regulatory submissions and correspondence, and marketing and sales information, all to the extent related to the Product.

(c) EOC shall, upon Aadi's request, where permitted under Applicable Laws, as promptly as reasonably practical transfer to Aadi all INDs, NDAs, Drug Approval Applications, and Regulatory Approvals with respect to the Product in the Territory (if any) and shall provide a right of reference with respect thereto, and shall take such other actions and execute such other instruments, assignments, and documents as may be necessary to affect the transfer of rights hereunder to Aadi. Without limiting the generality of the foregoing, EOC agrees to submit (or cause its Affiliate or Sublicensee, as applicable, to submit) to the NMPA and other Regulatory Health Authorities where reasonably appropriate and permitted under Applicable Laws in jurisdictions in which any regulatory filings have been made with respect to the Product, within [***] Days after the effective date of such termination, a letter (with copy to Aadi) notifying the

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NMPA and such other Regulatory Health Authorities of the transfer of any regulatory filings for the Product in such jurisdictions from EOC or its Affiliate or Sublicensee to Aadi. Additionally, EOC will provide Aadi with copies of regulatory filings useful or necessary to practice the rights granted to it under this Section 11.03 and upon Aadi's written request, shall at its cost and expense, provide to Aadi copies of all material related documentation, including material non-clinical, preclinical and clinical data and Regulatory Documentation that are held by or reasonably available to EOC, its Affiliates or Sublicensees. The Parties shall discuss and establish appropriate arrangements with respect to safety and safety database activities for the Product, provided that Aadi will assume all safety data and safety database activities for the Product no later than [***] after termination.

(d) Except where expressly provided for otherwise in this Agreement, to the extent requested by Aadi, EOC will assign (or cause its Affiliates or Sublicensees to assign) to Aadi, at Aadi's request, all of EOC's (or its Affiliates') rights and obligations under agreements with Third Parties with respect to (i) the conduct of clinical trials for the Product, including Agreements with CROs, clinical sites and investigators that relate to clinical trials in support of Regulatory Approvals in the Territory, and (ii) any other Third Party agreements involving the Development or Commercialization of the Product, unless in each of (i) or (ii), such agreement is not permitted to be assigned pursuant to its terms or relates to products other than the Product, in which case EOC will cooperate with Aadi in all reasonable respects to transfer as promptly as reasonably practical to Aadi the benefit of such contract in another mutually acceptable manner and upon Aadi's request facilitate discussions between Aadi and such Third Parties to assist Aadi in entering into a direct agreement with such Third Parties and, to the extent that EOC or its Affiliate is performing any activities described in (i) or (ii) above, reasonably cooperating with Aadi to transfer such activities to Aadi or its designee and continuing to perform such activities on Aadi's behalf for a reasonable time after termination until such transfer is completed.

(e) To the extent they are assignable and as requested by Aadi, EOC shall execute any documents necessary to transfer to Aadi rights under any Third Party licenses obtained by EOC pursuant to and during the course of the term of this Agreement for the purpose of Exploiting the Product, and Aadi shall thereafter be responsible for all costs, expenses and obligations associated with such Third Party licenses.

(f) Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties of any liability, including without limitation any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation which accrued hereunder prior to the effective date of such termination. In the event of such termination, this Section 11.03 shall survive in addition to others specified in this Agreement to survive in such event.

(g) At Aadi's election and request, EOC shall transfer to Aadi or its designee any or all inventory relating to the Product then in the possession or control of EOC, its Affiliates or Sublicensees; provided that, Aadi will pay EOC a price equal to the price paid by EOC for such transferred Product. To the extent not so transferred to Aadi, EOC shall be entitled, during a period of [***] following the EOC Triggered Termination to sell any inventory of Product that remains

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on hand as of the date of the termination, so long as EOC pays to Aadi the royalties and milestones applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement and for such purpose, EOC shall have the right to use the Product-related IPR and the Aadi Technology licensed hereunder.

(h) Notwithstanding anything else set forth in this Agreement, (i) EOC shall not have any obligations to continue any Development or Commercialization with respect to particular doses of the Product if EOC has terminated this Agreement pursuant to Section 11.02(a) and Section 11.02(d) due to any material safety concerns regarding such doses, as determined by the JSC; and (ii) should Aadi elect to pursue any Development or Commercialization of Product following any such termination by EOC, Aadi shall, without prejudice to or limitation of any other or further obligations under this Agreement (including Section 12.01(b)), indemnify EOC for any Third Party claims arising from such material safety concerning Aadi's Development or Commercialization after the effective date of such termination as set forth in Section 12.01(b).

(i) Effective upon the termination of this Agreement, the licenses granted by EOC to Aadi pursuant to Section 8.02 shall continue following the effective date of termination, provided that following the effective date of termination, all references in Section 8.02 to "outside the Territory" shall be replaced with "worldwide". Promptly after the date of termination of this Agreement, EOC shall transfer and assign, and shall ensure that its Affiliates transfer and assign, to Aadi, at no cost to Aadi, all Product Trademarks relating to any Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logo of EOC or its Affiliates or Sublicensees). Aadi and its Affiliates and licensees shall have the right to use other identifiers specific to the Product (e.g., EOC compound identifiers). EOC shall also transfer to Aadi any in-process applications for generic names for the Product.

(j) If, at the time of such termination, EOC or its Affiliates or Sublicensees are conducting any clinical trial of the Product, then, at Aadi's election on a [***]: (i) EOC shall, and shall cause its Affiliates and Sublicensees to, cooperate with Aadi to transfer the conduct of such clinical trial to Aadi or its designee and complete such transfer promptly and, in any case, within [***] after the termination effective date; and (ii) EOC shall, at its cost and expense, orderly wind-down the conduct of any such clinical trial that is not assumed by Aadi according to the preceding clause (i).

(k) In the event of an EOC Triggered Termination, EOC shall fully compensate Aadi for all reasonable costs or expenses incurred by it or its Affiliates in connection with performing any of the activities contemplated by Section 11.03.

(l) The foregoing under Section 11.03(a) to Section 11.03(k) shall be in addition and without prejudice to any other remedies that may be available to Aadi due to EOC's breach under this Agreement, including but not limited to any claims regarding payments, costs, expenses, money damages made, suffered or incurred by Aadi in relation to the performance and termination of this Agreement.

Section 11.04 Consequences of Termination by EOC for Aadi's breach or insolvency. If EOC terminates this Agreement pursuant to Section 11.02(a) as a result of a material breach by Aadi or

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Section 11.02(c) for an insolvency or other transaction described therein affecting Aadi, the following shall apply:

(a) The terms and obligations under Section 11.03 (except 11.03(k)) shall apply as if such termination were a EOC Triggered Termination.

(b) [***].

(c) The foregoing under Section 11.04(a) to Section 11.04(c) shall be in addition and without prejudice to any other remedies that may be available to EOC due to Aadi's breach under this Agreement, including but not limited to any claims regarding payments, costs, expenses, money damages made, suffered or incurred by EOC in relation to the performance and termination of this Agreement.

(d) Except where expressly provided for otherwise in this Agreement, termination of this Agreement by either Party shall not relieve the Parties of any liability, including without limitation any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation which accrued hereunder prior to the effective date of such termination. In the event of such termination, this Section 11.04 shall survive in addition to others specified in this Agreement to survive in such event.

(e) Notwithstanding anything to the contrary, if EOC would have the right to terminate this Agreement pursuant to Section 11.02(a) as a result of a material breach by Aadi or Section 11.02(c) for an insolvency or other transaction described therein affecting Aadi, EOC may elect not to terminate this Agreement, and in such case (i) all licenses granted to EOC for the Product in the Territory shall continue subject to the terms of this Agreement; and (ii) EOC may exercise its available rights and remedies in accordance with this Agreement for the damages incurred as a result of any material breach by Aadi.

Section 11.05 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for the purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code or equivalent provisions of applicable legislation in any other jurisdiction. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code, or equivalent provisions of applicable legislation in any other jurisdiction.

Section 11.06 Survival of Rights and Obligations. The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein. In the event of expiration or termination of this Agreement for any reason, the provisions that are expressly intended to survive such expiration or termination shall survive, including without limitation the following provisions: [***].

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Section 11.07 Accrued Rights. Termination or expiration of the Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration, including without limitation damages arising from any breach hereunder. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement.

ARTICLE XII. INDEMNIFICATION
Section 12.01 Indemnification.

(a) EOC hereby agrees to indemnify, defend, and hold harmless Aadi, its Affiliates, Abraxis, which the Parties agree is a third party beneficiary of this Agreement, and any Marketing Authorization Transferee and each of its and their respective employees, officers, directors and agents (individually and collectively, “**Aadi Indemnitee(s)**”) from and against any and all Losses incurred by or imposed on any of Aadi Indemnitees resulting from or arising out of or in connection with any suits, claims, actions, demands, or other proceedings made or brought by a Sublicensee or other Third Party (collectively, “**Third Party Claims**”) to the extent that they result from or arise out of: (i) [***]; (ii) [***]; (iii) [***], and (iv) [***]; except in any case, to the extent such Losses are Losses (x) [***].

(b) Aadi hereby agrees to indemnify, defend and hold harmless EOC, its Affiliates, and each of its and their respective employees, officers, directors and agents (individually and collectively, “**EOC Indemnitee(s)**”) from and against any and all Losses incurred by or imposed on any of EOC Indemnitees resulting from or arising out of or in connection with any Third Party Claims that result from or arise out of: (i) [***]; (ii) [***]; (iii) [***], and (iv) [***]; except in any case, to the extent such Losses are Losses (x) [***].

Section 12.02 Mechanism.

(a) In the event that a Party (the “**Indemnified Party**”) is seeking indemnification under Section 12.01(a) or Section 12.01(b), it shall notify the other Party (the “**Indemnifying Party**”) in writing of the relevant Third Party Claim and the relevant Loss for which indemnification is being sought as soon as reasonably practicable after it becomes aware of such claim. Each such notice shall contain a description of the Third Party Claim and the nature and amount of the Loss claimed (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any such Third Party Claim or Losses. For the avoidance of doubt, all indemnification claims in respect of a Party, its Affiliates, and each of its and their respective employees, officers, directors and agents shall be made solely by such Party to this Agreement. The Indemnified Party shall permit the Indemnifying Party to assume direction and control of the defense of the relevant Third Party Claim (including without limitation the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim, provided that the Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert

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against any Indemnified Party's claim for indemnification. If the Parties cannot agree as to the application of Section 12.01(a) or 12.01(b) as to any Third Party Claim, pending resolution of the dispute pursuant to Section 13.02, the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 12.01(a) or 12.01(b) upon resolution of the underlying Third Party Claim.

(b) Notwithstanding Section 12.01, the failure to give timely notice to the Indemnifying Party shall not release the Indemnifying Party from any liability to the Indemnified Party to the extent the Indemnifying Party is not materially prejudiced thereby and, for the avoidance of doubt, the Indemnifying Party shall not be liable to the extent any Loss is caused by any delay by the Indemnified Party in providing such notice. Notwithstanding the provisions of Section 12.02(a) requiring the Indemnified Party to tender to the Indemnifying Party the exclusive ability to defend such claim, if the Indemnifying Party declines to or fails to timely assume control of the relevant Third Party Claim, the Indemnified Party shall be entitled to assume such control, conduct the defense of, and settle such claim, all at the sole costs and expense of the declining or failing Party; provided, however, that neither Party shall settle or dispose of any such claim in any manner that would adversely affect the rights or interests or admit fault, of the other Party without the prior written consent of such other Party, which shall not be unreasonably withheld, delayed or conditioned. Each Party, at the other Party's expense and reasonable request, shall cooperate with such other Party and its counsel in the course of the defense or settlement of any such claim, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information, and witnesses.

Section 12.03 Mitigation of Loss. Each Indemnified Party shall take and shall ensure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article XII. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

Section 12.04 Insurance. For clinical trials [***], EOC will procure and maintain comprehensive commercial general liability insurance, including product liability insurance, with aggregate occurrence limits of not less than [***] and with aggregate occurrence limit not less than [***], and subject to such deductibles, in each case, which are consistent, normal and customary in the pharmaceutical industry generally for Persons similarly situated. EOC shall upon request provide Aadi with a copy of its policies of insurance in this regard and EOC shall give Aadi not less than [***] of any amendments, cancellations and revisions thereto. EOC's insurance policy will be primary without right of contribution from any insurance by Abraxis. EOC shall, to the extent practicable, ensure that Aadi and Abraxis will be named as an additional insureds in such insurance policy. Notwithstanding and for clarity, 1) EOC's expense on insurance shall be capped at [***] and shall have the right to deduct the difference between the actual price EOC needs to pay to procure and maintain the foregoing amounts of insurance [***] from the Royalties to be paid by EOC to Aadi, subject to Section 6.04; 2) EOC shall not be required to procure insurance [***]; and 3) EOC shall be responsible for its liability if it doesn't procure or maintain insurance. The foregoing insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article XII.

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ARTICLE XIII. DISPUTE RESOLUTION

Section 13.01 Referral of Disputes to the Parties Senior Executives. Subject to the applicable provisions in Article III, in the event of any dispute between the Parties arising out of or in connection with this Agreement, either Party may, by written notice to the other, have such dispute referred to the Senior Executives for attempted resolution by good faith negotiations within [***] after such notice is received.

Section 13.02 Mechanism. Subject to Section 13.01, any dispute, controversy or claim arising out of or relating to this Agreement, including the existence, negotiation, validity, formation, interpretation, breach, performance or application of this Agreement shall be settled by binding arbitration administered by the ICC in accordance with its then-current ICC arbitration rules, as such rules may be modified by this Section 13.02 or otherwise by subsequent written agreement of the Parties. The number of arbitrators shall be [***], of whom the Parties shall select [***]. The seat of arbitration shall be New York, New York, U.S.A., and all proceedings and communications shall be in English. The Parties shall have the right to be represented by counsel. Any judgment or award rendered by the arbitrators shall be final and binding on the Parties. The Parties agree that such judgment or award may be enforced in any court of competent jurisdiction. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration, unless the arbitrators agree otherwise.

Section 13.03 Preliminary Injunctions. Notwithstanding anything to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any dispute.

Section 13.04 Patent and Trademark Disputes. Notwithstanding anything to the contrary, any and all issues regarding the scope, inventorship, construction, validity, or enforceability of Patents and Trademarks, as applicable, shall be submitted for resolution to the competent governmental authorities or the competent courts in accordance with the law of the competent jurisdiction in which such Patent's rights or Trademark's rights were granted or arose.

Section 13.05 Confidentiality. All proceedings and decisions of arbitrator(s) in connection with proceedings pursuant to Section 13.02 shall be deemed Confidential Information of each of the Parties and shall be subject to Article VII.

ARTICLE XIV. MISCELLANEOUS

Section 14.01 Assignment; Performance by Affiliates.

(a) Neither Party may assign any of its rights or obligations under this Agreement in any country in whole or in part without the prior written consent of the other Party, except that each Party shall have the right, without such consent, (i) [***]; and (ii) [***]; however, provided that both under (i) and (ii) the assignees shall have at least the same capability and capacity of such Party to perform any obligations and exercise any rights under this Agreement. In the event that a

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Party performs its obligations or exercises its rights under this Agreement through an Affiliate (without having assigned all of its rights and obligations to such Affiliate as permitted under this [Section 14.01](#)), doing so shall not relieve the relevant Party of its responsibilities for the performance of its obligations under this Agreement, and the relevant Party shall remain responsible for the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance). Notwithstanding the foregoing, Aadi may assign or pledge any or all of its rights to receive payment(s) under this Agreement.

(b) This Agreement shall survive any succession of interest permitted pursuant to [Section 14.01\(a\)\(ii\)](#), whether by Change of Control, merger, consolidation, reorganization, acquisition, stock purchase, asset purchase or other similar transaction, provided, that, in the event of such merger, consolidation, reorganization, acquisition, stock purchase, asset purchase or other similar transaction, no Intellectual Property Rights of the acquiring corporation shall be included in the technology licensed hereunder, unless such Intellectual Property Rights arise as a result of the performance of this Agreement by such corporation after such transaction becomes effective.

(c) This Agreement shall be binding upon and inure to the benefit of the successors, and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

Section 14.02 Force Majeure. In this Agreement, “**Force Majeure**” means an event which is beyond a non-performing Party’s reasonable control, including an act of God, strike, lock-out or other industrial/labor disputes (whether involving the workforce of the Party so prevented or of any other Person), war, riot, civil commotion, terrorist act, epidemic, quarantine, fire, flood, storm, earthquake, natural disaster, act of government or compliance with any law or governmental order, rule, regulation or direction, whether or not it is later held to be invalid. A Party that is prevented or delayed in its performance under this Agreement by an event of Force Majeure (a “**Force Majeure Party**”) shall, as soon as reasonably practical but no later than [***] after the occurrence of a Force Majeure event, give notice in writing to the other Party specifying the nature and extent of the event of Force Majeure, its anticipated duration and any action being taken to avoid or minimize its effect. Subject to providing such notice and to this [Section 14.02](#), the Force Majeure Party shall not be liable for delay in performance or for non-performance of its obligations under this Agreement, in whole or in part, except as otherwise provided in this Agreement, where non-performance or delay in performance has resulted from an event of Force Majeure. The suspension of performance allowed hereunder shall be of no greater scope and no longer duration than is reasonably required and the Force Majeure Party shall exert all reasonable efforts to avoid or remedy such Force Majeure. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder at the time of such Force Majeure because of such Force Majeure. If a Force Majeure persists for more than [***], the Parties will discuss in good faith the modification of the Parties’ obligations under this Agreement to mitigate the delays caused by such Force Majeure.

Section 14.03 Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

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Section 14.04 Notices. All notices, requests, waivers and other communications made hereunder shall be in writing and shall be deemed given (a) upon delivery, if delivered personally; (b) upon confirmation of receipt, if by electronic mail during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next Business Day, (c) [***] after deposit in the mail as registered or certified mail (unless earlier return receipt requested), (d) [***] after deposit with postage prepaid, or sent by internationally recognized overnight delivery service that maintains earlier records of delivery, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof).

If to Aadi, addressed to:

With a copy to:

[***]

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

[***]

If to EOC, addressed to:

[***]

With a copy to:

[***]

Section 14.05 Waiver. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a waiver of any other of such Party's rights or remedies provided in this Agreement.

Section 14.06 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then (a) the remainder of this Agreement, or the application of such term, covenant, or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term, covenant, or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law, and (b) the Parties covenant and agree to renegotiate any such term, covenant, or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant, or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

Section 14.07 Governing Law. This Agreement shall be governed by and interpreted under the laws of the State of New York, USA, without giving effect to any conflict of law principle that would otherwise result in the application of the laws of any State or jurisdiction other than the State of New York, USA.

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Section 14.08 Counterparts. This 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. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission in .PDF format or facsimile shall be sufficient to bind the Parties and as effective as delivery of a manually executed counterpart.

Section 14.09 Entire Agreement. This Agreement, including without limitation all exhibits attached hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions, and understandings between the Parties and supersedes and terminates all prior and contemporaneous agreements and understanding between the Parties, including without limitation the agreements set forth in Section 7.06. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as set forth in this Agreement. No subsequent alteration, amendment, change, or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

Section 14.10 Limitation of Liability. EXCEPT IN CIRCUMSTANCES OF [***], OR [***], IN NO EVENT SHALL EITHER PARTY OR ITS RESPECTIVE AFFILIATES AND SUBLICENSEES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS OR REVENUE. This Section 14.10 shall not limit either Party's obligations under Article VII or Article XII.

Section 14.11 No Partnership. It is expressly agreed that the relationship between Aadi and EOC shall not constitute a partnership, joint venture, or agency. Neither Aadi nor EOC 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 consent of such other Party to do so.

Section 14.12 Specific Performance; Injunctive Relief. Each Party hereto acknowledges that the other Party may be irreparably harmed and that there may be no adequate remedy at law for a breach of certain terms or provisions set forth under this Agreement. Therefore, each Party hereto hereby agrees that, in addition to any other remedies that may be available upon any breach, each Party shall have the right to seek specific performance, injunctive relief or any other remedies available to such Party at law or in equity without posting any bond or other undertaking in order to enforce such terms and provisions.

Section 14.13 Abraxis License. Aadi shall not execute any amendment to the Abraxis License that would affect EOC's rights hereunder without the prior written consent of EOC. To the extent that Abraxis notifies Aadi that any provision of this Agreement is inconsistent with any provision of the Abraxis License, the Parties shall promptly use best efforts to amend this Agreement to cure such inconsistency. Notwithstanding anything to the contrary herein, any such inconsistency shall not be deemed to be a breach by Aadi of this Agreement or a breach by Aadi of the Abraxis License for which EOC may terminate this Agreement and Aadi shall not be required to indemnify EOC pursuant to Section 12.01(b) as a result of any such inconsistency. If EOC does not agree to amend this Agreement to cure such inconsistency and Abraxis notifies Aadi that Aadi is in breach of the

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Abraxis License as a result of such inconsistency, then EOC shall be deemed to have materially breached this Agreement.

[SIGNATURE PAGE FOLLOWS]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

[SIGNATURE PAGE]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their respective duly authorized officers or representatives.

Aadi Bioscience, Inc.

By: /s/ Neil Desai
Name: Neil Desai
Title: Chief Executive Officer

EOC Pharma (Hong Kong) Limited

By:
Name: Xhaoming Zou
Title: Chief Executive Officer

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[SIGNATURE PAGE]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their respective duly authorized officers or representatives.

Aadi Bioscience, Inc.

By:
Name: Neil Desai
Title: Chief Executive Officer

EOC Pharma (Hong Kong) Limited

By: /s/ Xhaoming Zou
Name: Xhaoming Zou
Title: Chief Executive Officer

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EXHIBIT A

(Aadi Patents)

[***]

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EXHIBIT B

Listed Entities

[***]

EXHIBIT C

Provisions from Abraxis License

1. **Prohibitions.**

1.1 Neither EOC nor any of its Affiliates shall, directly or indirectly: (a) [***] with [***] outside the scope of the rights and license granted under this Agreement, (b) [***] whose primary endpoint is for any indication outside the Field, (c) [***] outside the Field or outside the Territory, (d) [***], (e) [***], except for Products as provided herein, in any jurisdiction, or (f) [***] for any use or indication outside the Field or outside the Territory. Neither EOC nor any of its Affiliates shall assist or encourage any Third Party to engage in or conduct any of the foregoing prohibited activities.

1.2 EOC further agrees that, in any agreement with any Sublicensee or any other Third Party involving the Aadi Know-How, the Aadi Patents, ABI-009 or Product, such Sublicensee or other Third Party:

(i) shall agree (a) to not use any Confidential Information of Abraxis or its Affiliates (as defined in the Abraxis License) except in the performance of rights and/or exercise of obligations under such Person's agreement with EOC with respect to ABI-009 or Product and (b) without limiting the foregoing, to not use any Confidential Information of Abraxis or its Affiliates (as defined in the Abraxis License) for any purposes described in clauses (a) through (f) of Section 1.2(ii) below; and

(ii) shall acknowledge that any sublicense of rights from EOC or its Affiliates does not include a license under the Aadi Know-How or Aadi Patents to: (a) [***] outside the scope of the rights and license granted under this Agreement, (b) [***] outside the Field, (c) [***] outside the Field or outside the Territory, (d) [***], (e) [***], except for Products as provided herein, in any jurisdiction, or (f) [***] outside the Field or outside the Territory; provided that, notwithstanding the foregoing, any Third Party provided access to Abraxis Protected Information (as defined in the Abraxis License) must abide by the restrictions in Section 1.1 as applicable to EOC and not the restrictions set forth in this Section 1.2.

2.1 **Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, EOC agrees, upon receiving or learning of any Confidential Information of the Abraxis or its Affiliates (as defined in the Abraxis License), to keep such Confidential Information confidential and agrees to not disclose or use such Confidential Information during and after the Term for any purpose other than as provided for in this Section 2. EOC shall advise its employees and consultants who might have access to Confidential Information of Abraxis of the confidential nature thereof and agrees that its employees and consultants shall be bound by obligations of confidentiality, nonuse and nondisclosure at least as stringent the terms of this Section 2.1 and Sections 2.2, 2.3, 2.5, 2.8, 2.9 and 2.10 of this Exhibit C. EOC shall not disclose any Confidential Information of Abraxis to any employee, consultant or other individual who does not have a need for such information.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

2.2 **Authorized Disclosure.** Notwithstanding the foregoing, EOC may disclose Confidential Information of Abraxis (a) to a Third Party to the extent such disclosure is reasonably necessary to exercise the rights granted to or retained by it under this Agreement; (b) to its advisors, investors, acquirers, or collaborators on a need to know basis and subject to obligations of confidentiality, nonuse and nondisclosure at least as stringent as those set forth in Sections 2.2, 2.3, 2.5, 2.8, 2.9 and 2.10 of this Exhibit C; and (c) in defending litigation, complying with applicable governmental regulations, or submitting information to tax or other governmental authorities (including Regulatory Authorities), provided that, if EOC is required pursuant to an order of a court of competent jurisdiction or other government order or judicial process to make any such disclosure of Confidential Information of Abraxis, to the extent it may legally do so, it will give reasonable advance written notice to Aadi of such disclosure and will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). Notwithstanding the foregoing authorized disclosures of Confidential Information of Abraxis or the provisions of Sections 7.02 (a) through (e) of the Abraxis License, subject to Section 2.6 of this Exhibit C, EOC is prohibited from disclosing, under any circumstances, any [***], including any information relating to [***], without Aadi's prior written consent; provided that, if EOC is required pursuant to a valid order of a court of competent jurisdiction or other government order or judicial process to make any such disclosure of any [***], EOC may disclose [***] if EOC has first given (i) written notice to Aadi within [***] of receipt of the document to which EOC is responding or at least [***] prior to any disclosure if such notice is less than [***] in advance of the required production of the applicable [***], (ii) Aadi an opportunity to review and approve any disclosures EOC intends to make in response to the applicable court or governmental order or judicial process, and (iii) Aadi [***] a reasonable opportunity to take appropriate action and cooperate with Aadi as necessary and requested by Aadi to obtain an appropriate protective order; provided further that, in each case, the [***] disclosed in response to such court or governmental order or judicial process will be limited to that information that is legally required to be disclosed in response to such court or governmental order or judicial process, as determined in good faith by counsel to EOC.

2.3 **Return of Confidential Information.** Upon termination or expiration of this Agreement EOC shall promptly return all of the Confidential Information of Abraxis, including all reproductions and copies thereof in any medium, except that EOC may retain one copy for its legal files; provided that any [***] must be returned by EOC upon request of Aadi without any copies being retained.

2.4 **Destruction of Confidential Information.** On Abraxis' request, EOC will destroy, or at Aadi's option return, and will cause the destruction or return of any Abraxis Protected Information in the possession or control of EOC, its Affiliates or Sublicensee or prior to any such Person entering into any partnering arrangement for nab-rapamycin, or prior to EOC being acquired by a Third Party.

2.5 **Unauthorized Use.** If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure.

2.6 [***]:

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

2.6.1 [***]

2.6.2 [***].

2.6.3 [***].

2.6.4 [***].

2.6.5 [***].

2.6.6 [***].

2.6.7 [***].

2.6.8 [***].

2.6.9 [***].

2.6.10 [***]

2.6.11 [***].

2.6.12 [***].

2.6.13 [***].

2.7 **Specific Restrictions on Use of Confidential Information.** To ensure adequate protection and maintenance of the confidentiality and economic value of [***], EOC acknowledges and agrees to the following:

2.7.1 **Prohibited Activities.** As a condition to this Agreement, which provides, inter alia, access to the [***], including [***], and licenses to the Aadi Know-How and Aadi Patent on the terms set forth herein, EOC covenants and agrees that, except for Products and the Authorized Purpose in accordance with this Agreement, EOC shall not, directly or indirectly:

- (a) make, develop, market or distribute, alone or in concert with others during the Term and [***] or (ii) [***], because doing so would result in EOC referring to or using [***] trade secrets, including [***] and [***]; and
- (b) without limiting the foregoing restrictions in Section 2.7.1(a) of this Exhibit C, make, develop, market, or distribute alone or in concert with others anywhere in the world, any pharmaceutical formulation or product manufactured by use of or with reference to any of [***] (or its Affiliates') Confidential Information, including [***], or Aadi Know-How or Aadi Patents or assist any other Person in doing the same (other than Aadi, [***] or any of their Affiliates (as defined in the Abraxis License)).

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

2.7.2 EOC further expressly agrees that its obligations in subsections 2.7.1(a) and (b) are reasonable and necessary to protect [***], including [***] and [***], and that [***] would be irreparably harmed if EOC breached its obligations.

2.7.3 EOC covenants and agrees that any proposed Sublicensee, successor, assign, or any other Affiliate shall be advised of these prohibitions and shall agree in a writing in favor of [***] and its Affiliates to be bound to the provisions of this Section 2, including this Section 2.7, as a condition of, and prior to seeking, Aadi's approval for the grant of a Sublicense to such Sublicensee, or the transfer or assignment of any of EOC's rights under this Agreement to a successor or assign or Affiliate.

2.7.4 EOC agrees that the contractual period of time set forth herein shall not limit or otherwise affect (a) the duration of trade secret rights under governing trade secret law, which may be substantially longer in time or (b) the duration of EOC's obligations pursuant to this Article 9.

2.8 **Publications.** EOC will provide Aadi with a copy of any proposed publication or presentation relating to ABI-009 or relating to the Aadi Know-how or Aadi Patents or otherwise mentioning [***] or its Affiliates (as defined in the Abraxis License) at least [***] prior to submission for publication or presentation. Any such publication or presentation shall be subject to reasonable review by Aadi and [***]. EOC will delete from the proposed disclosure any of [***] Confidential Information upon the request of Aadi. Aadi may require EOC to delay such publication or presentation for a period of up to [***] to allow Aadi or [***] to secure adequate Intellectual Property (as defined in the [***]) protection of [***] property that would be affected by the publication or presentation. EOC will not include the name of [***] or any of their Affiliates or the terms [***] in any publication or presentation without Aadi's prior written consent, which may be withheld in its sole discretion except that Aadi will not unreasonably withhold its consent to the use of any such names or terms if the use of such names or terms is necessary for compliance with applicable laws. In the event a proposed publication or presentation violates the foregoing restriction, Aadi has the right to require EOC to cancel the proposed publication or presentation or delete the prohibited terms or words. Required submissions on clinicaltrials.gov will be subject to the provisions of this Section 2.8, except that the period for Aadi's review will be limited to [***].

2.9 **Terms of Exhibit.** EOC agrees not to disclose to any Third Party the existence or the terms and conditions of this Exhibit without the prior approval of Aadi, except EOC may make such a disclosure: (a) [***]; or (c) [***], (i) EOC shall promptly notify Aadi and allow Aadi a reasonable opportunity to oppose with the governmental authority initiating the process and, to the extent allowable by law, to seek limitations on the portion of this Exhibit that is required to be disclosed; and (ii) any disclosure will be solely in the form of a redacted version of this Exhibit, such redacted version to be reasonably and mutually agreed upon by Aadi.

2.10 **Public Announcements.** EOC may not issue press releases or other similar public communications regarding this Exhibit C without the prior written consent of Aadi. The foregoing notwithstanding, communications required by applicable law or regulation will not require advance approval if (a) any such disclosure is limited to that information that is legally required to be disclosed; (b) a copy of the proposed communication is provided to Aadi at least [***] prior to release or communication thereof (or such lesser period as is necessitated in order to comply with

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

law or by an emergency situation due to unexpected circumstances); provided that, if Aadi does not reject or otherwise fails to approve such public announcement within such [***] period (or shorter period as applicable), the proposed communication will be deemed approved (subject, in any event, to EOC's nondisclosure and other obligations with respect to Confidential Information of Aadi under this Section 2); and (c) EOC considers in good faith the comments of Aadi. Further, EOC shall not employ or use the name of the [***] in any promotional materials or advertising without the prior express written permission of [***].

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

EXHIBIT D

(List of JSC Members)

Aadi Initial List of JSC Members:

[***]

EOC Initial List of JSC Members:

[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

EXHIBIT E

(Supply Terms)

Manufacturing Procedures. [***].

Subcontracting. [***].

Inspection Rights. [***].

Recall. [***].

Forecasts. [***].

Purchase Orders.

(a) [***].

(b) [***].

(c) [***].

(d) [***].

Delivery Terms and Risk of Loss. [***].

Non-conforming Product. [***].

Transfer Price. [***].

Payment Terms. [***].

Development Supply. [***].

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

EXHIBIT F

ABRAXIS ROYALTY RATE

[***]

Annual Net Sales as used in this Exhibit F shall have the definition set forth in the Abraxis License.

**CERTIFICATION 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 Aadi Bioscience, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Desai, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

By: _____ /s/ Neil Desai, Ph.D.
Neil Desai, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION 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 Aadi Bioscience, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lance Thibault, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

By: _____ /s/ Lance Thibault
Lance Thibault
Interim Chief Financial Officer
*(Principal Financial Officer and
Principal Accounting Officer)*