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

FORM 10-Q

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

for the quarterly period ended June 30, 2020

OR

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

COMMISSION FILE NUMBER: 001-37590

CERECOR INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)
540 Gaither Road, Suite 400
Rockville, Maryland 20850
(Address of principal executive offices)

45-0705648
(I.R.S. Employer Identification No.)
(410) 522-8707
(Registrant's telephone number,
including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value	CERC	Nasdaq Capital Market

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☐
Emerging growth company ☒

Accelerated filer ☒
Smaller reporting company ☒

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

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 August 4, 2020, the registrant had 74,900,047 shares of common stock outstanding.

CERECOR INC.

FORM 10-Q

For the Quarter Ended June 30, 2020

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	
a) <u>Condensed Consolidated Balance Sheets as of June 30, 2020 (Unaudited) and December 31, 2019</u>	<u>3</u>
b) <u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Six Months Ended June 30, 2020 and 2019</u>	<u>4</u>
c) <u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Six Months Ended June 30, 2020 and 2019</u>	<u>5</u>
d) <u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the Three and Six Months Ended June 30, 2020 and 2019</u>	<u>8</u>
e) <u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	<u>11</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>33</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>45</u>
<u>Item 4. Controls and Procedures</u>	<u>45</u>
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>46</u>
<u>Item 1A. Risk Factors</u>	<u>46</u>
<u>Item 6. Exhibits</u>	<u>47</u>
<u>SIGNATURES</u>	<u>48</u>

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements.
CERECOR INC. and SUBSIDIARIES
Condensed Consolidated Balance Sheets

	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,390,553	\$ 3,609,438
Accounts receivable, net	2,031,682	1,001,645
Other receivables	1,953,036	4,240,572
Inventory, net	12,196	21,334
Prepaid expenses and other current assets	823,900	706,968
Restricted cash, current portion	33,449	17,535
Investment in Aytu	—	7,628,947
Current assets of discontinued operations	—	497,577
Total current assets	50,244,816	17,724,016
Property and equipment, net	1,740,610	1,447,663
Intangible assets, net	2,292,175	2,426,258
Goodwill	14,409,088	14,409,088
Restricted cash, net of current portion	180,336	101,945
Deferred tax asset, net	337,797	—
Total assets	<u>\$ 69,204,822</u>	<u>\$ 36,108,970</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,557,702	\$ 2,077,524
Accrued expenses and other current liabilities	6,487,658	5,640,252
Income taxes payable	—	551,671
Current liabilities of discontinued operations	5,549,751	3,891,012
Total current liabilities	14,595,111	12,160,459
Royalty obligation	2,000,000	—
Deferred tax liability, net	—	85,981
Other long-term liabilities	2,031,560	1,111,965
Long-term liabilities of discontinued operations	—	1,755,000
Total liabilities	18,626,671	15,113,405
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 74,900,047 and 44,384,222 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	74,899	44,384
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at June 30, 2020 and December 31, 2019; 1,257,143 and 2,857,143 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	1,257	2,857
Additional paid-in capital	199,191,022	135,238,941
Accumulated deficit	(148,689,027)	(114,290,617)
Total stockholders' equity	50,578,151	20,995,565
Total liabilities and stockholders' equity	<u>\$ 69,204,822</u>	<u>\$ 36,108,970</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES
Condensed Consolidated Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product revenue, net	\$ 1,337,764	\$ 1,391,942	\$ 4,091,628	\$ 3,968,310
Total revenues, net	1,337,764	1,391,942	4,091,628	3,968,310
Operating expenses:				
Cost of product sales	77,580	(1,496,677)	144,139	(744,128)
Research and development	5,916,869	3,712,596	10,684,619	7,113,785
Acquired in-process research and development	—	—	25,549,344	—
General and administrative	6,101,475	2,340,634	8,777,088	5,016,243
Sales and marketing	653,265	325,861	1,329,790	722,137
Amortization expense	403,500	334,747	834,083	669,495
Change in fair value of contingent consideration	—	(1,277,150)	—	(1,256,210)
Total operating expenses	13,152,689	3,940,011	47,319,063	11,521,322
Loss from continuing operations	(11,814,925)	(2,548,069)	(43,227,435)	(7,553,012)
Other income (expense):				
Change in fair value of Investment in Aytu	(1,872,031)	—	5,207,789	—
Change in fair value of warrant liability and unit purchase option liability	2,647	18,910	13,928	(28,668)
Other income (expense), net	395,800	—	395,800	(9,400)
Interest income, net	8,711	38,412	18,501	68,632
Total other (expense) income, net from continuing operations	(1,464,873)	57,322	5,636,018	30,564
Loss from continuing operations before taxes	(13,279,798)	(2,490,747)	(37,591,417)	(7,522,448)
Income tax (benefit) expense	(453,957)	53,446	(2,610,812)	184,119
Loss from continuing operations	\$ (12,825,841)	\$ (2,544,193)	\$ (34,980,605)	\$ (7,706,567)
(Loss) income from discontinued operations, net of tax	(455,463)	(3,678,906)	582,195	(5,970,580)
Net loss	\$ (13,281,304)	\$ (6,223,099)	\$ (34,398,410)	\$ (13,677,147)
Net (loss) income per share of common stock, basic and diluted:				
Continuing operations	\$ (0.18)	\$ (0.05)	\$ (0.53)	\$ (0.14)
Discontinued operations	(0.01)	(0.06)	0.01	(0.10)
Net loss per share of common stock, basic and diluted	\$ (0.19)	\$ (0.11)	\$ (0.52)	\$ (0.24)
Net (loss) income per share of preferred stock, basic and diluted:				
Continuing operations	\$ (0.93)	\$ (0.23)	\$ (2.66)	\$ (0.68)
Discontinued operations	(0.03)	(0.32)	0.04	(0.53)
Net loss per share of preferred stock, basic and diluted	\$ (0.96)	\$ (0.55)	\$ (2.62)	\$ (1.21)

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (Unaudited)

	Six Months Ended June 30,	
	2020	2019
Operating activities		
Net loss	\$ (34,398,410)	\$ (13,677,147)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	878,949	2,203,423
Impairment of intangible assets	—	1,449,121
Stock-based compensation	3,901,897	1,123,402
Acquired in-process research and development	25,549,344	—
Deferred taxes	(423,778)	18,870
Amortization of inventory fair value associated with acquisition of TRx and Avadel's pediatric products	—	40,240
Change in fair value of Investment in Aytu	(5,207,789)	—
Change in fair value of warrant liability and unit purchase option liability	(13,928)	28,668
Change in value of Guarantee	(1,755,000)	—
Change in fair value of contingent consideration	—	(811,948)
Changes in assets and liabilities:		
Accounts receivable, net	(532,460)	297,267
Other receivables	(1,851,867)	5,326,000
Inventory, net	9,138	452,931
Prepaid expenses and other assets	(23,782)	664,454
Accounts payable	82,674	(666)
Income taxes payable	288,329	(639,784)
Accrued expenses and other liabilities	(815,014)	(6,313,686)
Lease liability, net	17,510	—
Net cash used in operating activities	(14,294,187)	(9,838,855)
Investing activities		
Proceeds from sale of Investment in Aytu, net	12,836,736	—
Net cash paid in merger with Aevi	(1,250,650)	—
Purchase of property and equipment	—	(256,926)
Net cash provided by (used in) investing activities	11,586,086	(256,926)
Financing activities		
Proceeds from underwritten public offering, net	35,427,963	8,975,960
Proceeds from registered direct offering, net	5,136,184	—
Proceeds from sale of shares pursuant to common stock private placement, net	3,887,991	—
Proceeds from exercise of stock options and warrants	92,342	256,816
Proceeds from shares purchased through employee stock purchase plan	132,910	127,537
Restricted Stock Units withheld for taxes	(93,869)	(18,057)
Payment of contingent consideration	—	(379,255)
Payment of long-term debt	—	(48,684)
Net cash provided by financing activities	44,583,521	8,914,317
Increase (decrease) in cash, cash equivalents and restricted cash	41,875,420	(1,181,464)
Cash, cash equivalents, and restricted cash at beginning of period	3,728,918	10,746,756
Cash, cash equivalents, and restricted cash at end of period	\$ 45,604,338	\$ 9,565,292
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ —	\$ 525,000
Cash paid for taxes	\$ 316,000	\$ 852,025
Supplemental disclosures of non-cash activities		
Issuance of common stock in Aevi Merger	\$ 15,495,578	\$ —
Leased asset obtained in exchange for new operating lease liability	\$ 376,448	\$ 743,025

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

	June 30,	
	2020	2019
Cash and cash equivalents	\$ 45,390,553	\$ 9,386,865
Restricted cash, current	33,449	26,265
Restricted cash, non-current	180,336	152,162
Total cash, cash equivalents and restricted cash	<u>\$ 45,604,338</u>	<u>\$ 9,565,292</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited)

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Three Months Ended June 30, 2020							
Balance, March 31, 2020	59,560,252	\$ 59,560	1,257,143	\$ 1,257	\$ 160,935,648	\$ (135,407,723)	\$ 25,588,742
Issuance of shares of common stock in underwritten public offering, net of offering costs	15,180,000	15,180		—	35,412,783	—	35,427,963
Exercise of stock options and warrants	25,071	25		—	18,110	—	18,135
Restricted Stock Units vested during period	111,667	111		—	(111)	—	—
Restricted Stock Units withheld for taxes	(35,279)	(35)		—	(93,834)	—	(93,869)
Shares purchased through employee stock purchase plan	58,336	58		—	132,852	—	132,910
Stock-based compensation		—		—	2,785,574	—	2,785,574
Net loss		—		—	—	(13,281,304)	(13,281,304)
Balance, June 30, 2020	<u>74,900,047</u>	<u>\$ 74,899</u>	<u>1,257,143</u>	<u>\$ 1,257</u>	<u>\$ 199,191,022</u>	<u>\$ (148,689,027)</u>	<u>\$ 50,578,151</u>

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Six Months Ended June 30, 2020							
Balance, December 31, 2019	44,384,222	\$ 44,384	2,857,143	\$ 2,857	\$ 135,238,941	\$ (114,290,617)	\$ 20,995,565
Conversion of preferred stock to common stock	8,000,000	8,000	(1,600,000)	(1,600)	(6,400)	—	—
Issuance of shares related to Aevi Merger	3,893,361	3,894		—	15,491,684	—	15,495,578
Issuance of shares pursuant to registered direct offering, net of offering costs	1,306,282	1,306		—	5,134,878	—	5,136,184
Issuance of shares pursuant to common stock private placement, net of offering costs	1,951,219	1,951		—	3,886,040	—	3,887,991
Issuance of shares of common stock in underwritten public offering, net of offering costs	15,180,000	15,180		—	35,412,783	—	35,427,963
Exercise of stock options and warrants	50,239	50		—	92,292	—	92,342
Restricted Stock Units vested during period	111,667	111		—	(111)	—	—
Restricted Stock Units withheld for taxes	(35,279)	(35)		—	(93,834)	—	(93,869)
Shares purchased through employee stock purchase plan	58,336	58		—	132,852	—	132,910
Stock-based compensation		—		—	3,901,897	—	3,901,897
Net loss		—		—	—	(34,398,410)	(34,398,410)
Balance, June 30, 2020	<u>74,900,047</u>	<u>\$ 74,899</u>	<u>1,257,143</u>	<u>\$ 1,257</u>	<u>\$ 199,191,022</u>	<u>\$ (148,689,027)</u>	<u>\$ 50,578,151</u>

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Three Months Ended June 30, 2019							
Balance, March 31, 2019	42,753,659	\$ 42,754	2,857,143	\$ 2,857	\$ 128,747,037	\$ (105,672,118)	\$ 23,120,530
Exercise of stock options and warrants	43,125	43		—	162,596	—	162,639
Restricted Stock Units vested during period	61,250	61		—	(61)	—	—
Restricted Stock Units withheld for taxes	(3,723)	(4)		—	(18,053)	—	(18,057)
Shares purchased through employee stock purchase plan	43,940	44		—	127,493	—	127,537
Stock-based compensation		—		—	526,709	—	526,709
Net loss		—		—	—	(6,223,099)	(6,223,099)
Balance, June 30, 2019	42,898,251	\$ 42,898	2,857,143	\$ 2,857	\$ 129,545,721	\$ (111,895,217)	\$ 17,696,259

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Six Months Ended June 30, 2019							
Balance, December 31, 2018	40,804,189	\$ 40,804	2,857,143	\$ 2,857	\$ 119,082,157	\$ (98,218,070)	\$ 20,907,748
Issuance of shares of common stock in underwritten public offering, net of offering costs	1,818,182	1,818		—	8,974,142	—	8,975,960
Exercise of stock options and warrants	74,413	74		—	256,742	—	256,816
Restricted Stock Units vested during period	161,250	162		—	(162)	—	—
Restricted Stock Units withheld for taxes	(3,723)	(4)		—	(18,053)	—	(18,057)
Shares purchased through employee stock purchase plan	43,940	44		—	127,493	—	127,537
Stock-based compensation		—		—	1,123,402	—	1,123,402
Net loss		—		—	—	(13,677,147)	(13,677,147)
Balance, June 30, 2019	42,898,251	\$ 42,898	2,857,143	\$ 2,857	\$ 129,545,721	\$ (111,895,217)	\$ 17,696,259

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES**Notes to Unaudited Condensed Consolidated Financial Statements****1. Business**

Cerecor Inc. (the "Company" or "Cerecor") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies that address unmet patient needs within rare pediatric and orphan diseases. The Company's pediatric rare disease pipeline includes CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs"). The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease Designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of each new drug application ("NDA"). The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-002 is an anti-LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes) monoclonal antibody being developed for the treatment of COVID-19 acute respiratory distress syndrome ("ARDS") and Pediatric-onset Crohn's Disease. CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations and has been granted ODD and RPDD by the FDA, thus potentially qualifying the Company to receive a PRV upon approval of an NDA. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Still's Disease ("AOSD") and Multiple Myeloma.

The Company continues to explore strategic alternatives for its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions. The Company has been in discussions with Simon Pedder, a former member of its Board of Directors, about potentially transferring its non-core neurology pipeline assets, CERC-301 and CERC-406, to a new company formed by Dr. Pedder, although it has not agreed to binding terms, and any such transaction might not happen until the second half of 2020, if at all.

On June 11, 2020, the Company closed on an underwritten public offering of 15,180,000 shares of its common stock (inclusive of 1,980,000 shares that were sold pursuant to the underwriter's full exercise of its option to purchase additional shares of Cerecor's common stock) for net proceeds of approximately \$35.4 million.

On February 3, 2020, the Company consummated its two-step merger (the "Merger") with Aevi Genomic Medicine, Inc. ("Aevi") in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated December 5, 2019. The Merger consideration included stock valued at approximately \$15.5 million, resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of a \$4.1 million loan that Cerecor loaned Aevi in December 2019 (the "Aevi Loan"), and contingent value rights ("CVRs") for up to an additional \$6.5 million in subsequent payments based on development milestones. As part of the Merger, Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007, expanding Cerecor's pipeline to six clinical stage assets being developed for rare pediatric and orphan diseases. Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Aevi Chief Executive Officer Mike Cola for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi Chief Scientific Officer Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer, and appointed Mike Cola and Dr. Sol Barer to the Company's Board of Directors. Dr. Neil was promoted to Cerecor's Chief Scientific Officer in March 2020. See Note 6 for more information.

During the fourth quarter of 2019, the Company entered into, and closed, an asset purchase agreement (the "Aytu Purchase Agreement") with Aytu BioScience, Inc. ("Aytu") to sell the Company's rights, title and interest in, assets relating to its pediatric portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™ (the "Pediatric Portfolio"), as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts (the "Aytu Divestiture"). Aytu paid consideration of \$4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock (the "Investment"), and assumed certain of the Company's liabilities, including the Company's payment obligations payable to Deerfield CSF, LLC of \$15.1 million and other liabilities of \$11.0 million. The Company recognized a gain of \$8.0 million upon the closing of the Aytu Divestiture for the year ended December 31, 2019. As a result of the sale of the Pediatric Portfolio, the Pediatric Portfolio met all conditions required in order to be classified as discontinued operations. Therefore, operating results from the Pediatric Portfolio are reported within income (loss) from discontinued operations, net of tax for all periods presented. In addition, assets and liabilities related to the Pediatric Portfolio are reported as assets and liabilities of discontinued operations in the accompanying condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019. See Note 3 for more information regarding the Aytu Divestiture and its accounting treatment, including the nature of the Company's involvement subsequent to the divestiture.

Cerecor was incorporated and commenced operation in 2011 and completed its initial public offering in October 2015.

Liquidity

In June 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock (inclusive of 1,980,000 shares that were sold pursuant to the underwriter's full exercise of its option to purchase additional shares of Cerecor's common stock) for net proceeds of approximately \$35.4 million. In March 2020, the Company entered into a securities purchase agreement with its largest stockholder, Armistice Capital, LLC ("Armistice"), pursuant to which the Company sold 1,951,219 shares of the Company's common stock for net proceeds of approximately \$3.9 million. In February 2020, the Company closed a registered direct offering with institutional investors of 1,306,282 shares of the Company's common stock for net proceeds of approximately \$.1 million. See Note 9 for more information regarding these financings. Additionally, in April 2020, the Company converted its shares of Aytu preferred stock that were acquired in the fourth quarter of 2019 and subsequently sold that common stock, which generated net proceeds of approximately \$12.8 million. As of June 30, 2020, Cerecor had \$45.4 million in cash and cash equivalents.

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. For the six months ended June 30, 2020, Cerecor generated a net loss of \$34.4 million and negative cash flow from operations of \$14.3 million. As of June 30, 2020, Cerecor had an accumulated deficit of \$148.7 million.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, the Company expects to incur additional losses in the future in connection with its research and development activities and will require additional financing to fund its operations and to continue to execute its business strategy. The Company plans to use its current cash on hand, the anticipated cash flows from the Company's profits from Millipred product sales and/or the potential proceeds from a possible out-license or sale of Millipred to a third party to offset costs related to its pipeline assets, business development, and costs associated with its organizational infrastructure; however, Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional equity and/or debt capital, sell assets and/or obtain government funding; however, there can be no assurance that it will be able to do so nor that such activities will generate sufficient amounts, if any, on terms acceptable to the Company.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will be dependent on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential sale of any PRVs it receives, in order to support its cost structure and pipeline asset development.

These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements included in this Quarterly Report were issued. To alleviate these conditions, the Company is evaluating the potential out-licensing or sale of Millipred, its non-core neurology pipeline assets and/or some combination of rights to future PRV sales, equity or debt financings, collaborations, other out-licensing arrangements, strategic alliances, federal and private grants, marketing, other distribution or licensing arrangements, or the sale of current or future assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. Due to the uncertainty regarding future financings and/or other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report were issued.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated balance sheet at December 31, 2019 has been derived from audited

financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC"). Certain prior period amounts have been reclassified to conform to the current year presentation, as described below.

The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the December 31, 2019 audited consolidated financial statements.

Significant Accounting Policies

During the six months ended June 30, 2020, there were no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 11, 2020, except for the policy related to the Payroll Protection Program Loan and the recently adopted accounting standards described below.

Payroll Protection Program Loan

The Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") provides stimulus measures, including the Payroll Protection Loan Program ("PPP"), to provide certain small businesses with liquidity to support their operations (such as to retain employees and maintain payroll and lease payments) during the COVID-19 pandemic. Cerecor received a \$0.4 million PPP Loan during the second quarter of 2020. PPP Loans have a 1% fixed annual interest rate and mature in two years, however are eligible for forgiveness under certain conditions. If there is reasonable assurance that the PPP Loan will be forgiven, the Company may elect to account for the loan either as debt under ASC 470 or as a government grant. If accounted for as a government grant, the Company may elect to present the loan as either a credit in the income statement within other income or as reduction to the related expense. As discussed in Note 14, as of June 30, 2020, the Company believes it meets the criteria for forgiveness including having incurred the related expenses prior to June 30, 2020. Therefore, the Company elected to recognize the PPP Loan as other income within the accompanying condensed consolidated statement of operations for the three and six months ended June 30, 2020.

Recently Adopted Accounting Pronouncements

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein.

Upon adoption of the new standard on January 1, 2020, the Company began recognizing an allowance using a forward-looking approach to estimate the expected credit loss related to financial assets. The Company began monitoring the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. Over 95% of sales were generated from three major industry wholesalers for the three and six months ended June 30, 2020. Additionally, pursuant to the new standard, at each reporting period, the Company adjusts the Guarantee liability through earnings based on expected credit losses in accordance with Topic 326. The Company evaluated the impact of the adoption of this standard on its financial statements, concluding there was no significant impact on the Company's results of operations, financial position, cash flows or disclosures.

Fair Value Measurements

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement." This new standard modifies certain disclosure requirements on fair value measurements. This new standard became effective for the Company on January 1, 2020. The Company evaluated the impact of the adoption of this new standard on its financial statements, concluding there was no significant impact.

Income Tax Simplification

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740)(ASU 2019-12)", which provides final guidance that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation that is applicable to the Company, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences among other changes. For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued. An entity that elects early adoption must adopt all the amendments in the same period. The Company elected to early adopt the ASU 2019-12 as of January 1, 2020. Management concluded that the adoption of the new standard did not have a material impact to income taxes reported on the financial statements for the three and six months ended June 30, 2020.

3. Aytu Divestiture

Overview of Sale of Pediatric Portfolio and Related Commercial Infrastructure to Aytu BioScience

On October 10, 2019, the Company entered into the Aytu Purchase Agreement to sell the Company's rights, title and interest in assets relating to its Pediatric Portfolio, namely Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal™ ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™ as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts. The Aytu Divestiture closed on November 1, 2019. Aytu paid consideration of \$4.5 million in cash and approximately 9.8 million shares of Aytu convertible preferred stock, and assumed certain of the Company's liabilities, including the Company's payment obligations payable to Deerfield CSF, LLC of \$ 15.1 million and certain other liabilities of \$11.0 million primarily related to contingent consideration, Medicaid rebates and sales returns. In addition, Aytu assumed future contractual obligations under existing license agreements associated with the Pediatric Portfolio. Armistice, a significant stockholder of the Company and Armistice's Chief Investment Officer, Steve Boyd, serves on each company's board of directors.

Upon closing the Aytu Divestiture, Cerecor terminated all of its sales force personnel, which included those offered employment by Aytu, as well as any remaining sales force personnel. Additionally, Cerecor retained all rights to Millipred®. Pursuant to a transition services agreement entered into between Aytu and Cerecor, Aytu is managing Millipred® commercial operations for a monthly fee of \$12,000 for up to 18 months or until the Company establishes an independent commercial infrastructure for the product.

Deerfield Guarantee

On November 1, 2019, in conjunction with the closing of the Aytu Divestiture, the Company entered into a Guarantee in favor of Deerfield CSF, LLC ("Deerfield"), which guarantees the payment by Aytu of the assumed liabilities to Deerfield, which includes the debt obligation ("Fixed Payment Guarantee") and the contingent consideration related to future potential royalties on Avadel's pediatric products ("Deferred Payment Guarantee"), collectively referred to as the "Guarantee". Additionally, on November 1, 2019, the Company entered into a Contribution Agreement with Armistice and Avadel that governs contribution rights and obligations of the Company, Armistice and Avadel with respect to amounts that are paid by Armistice and Avadel to Deerfield under certain guarantees made by Armistice and Avadel to Deerfield.

The debt obligation assumed by Aytu consists of fixed monthly payments to Deerfield of \$0.1 million until January 2021 and an additional balloon payment of \$15.0 million to Deerfield on January 31, 2021. In May 2020, Aytu paid the \$ 15.0 million balloon payment to Deerfield before it came due, thus satisfying that portion of the debt obligation assumed as part of the divestiture. Therefore, Cerecor's Fixed Payment Guarantee will end on January 31, 2021, upon the final monthly payment of \$0.1 million. The contingent consideration assumed by Aytu consists of quarterly deferred payments equal to 15% of net sales of certain Pediatric Portfolio or at least \$0.3 million paid in arrears each quarter until the earlier of (i) February 5, 2026, or (ii) when \$12.5 million in aggregate deferred payments have been paid to Deerfield. Of the contingent consideration, \$3.2 million was paid to Deerfield prior to the Aytu Divestiture and therefore as of November 1, 2019, Aytu was responsible for the remaining \$9.3 million. Aytu is required to pay an amount equal to at least \$0.1 million per month. Cerecor's Deferred Payment Guarantee will end upon the earlier of (i) February 5, 2026, or (ii) upon \$12.5 million in aggregate deferred payments has been paid to Deerfield. Cerecor is required to make payment under the Guarantee upon demand by Deerfield, which Deerfield can demand at any time if all or any part of the fixed payments and/or deferred payments are not paid by Aytu when due or upon breach of a covenant. As of June 30, 2020, the estimated maximum potential amount of future payments under the Guarantee was \$9.0 million, consisting of \$0.6 million for the Fixed Payment Guarantee and \$8.4 million for the Deferred Payment Guarantee (utilizing the \$0.3 million per quarter minimum payment).

The fair value of the Guarantee, which relates to the Company's obligation to make future payments if Aytu defaults, was determined at the time of the divestiture as the difference between (i) the estimated fair value of the debt and contingent payments, respectively, using Cerecor's estimated cost of debt and (ii) the estimated fair value of the debt and contingent payments, respectively, using Aytu's estimated cost of debt. Subsequent to the close of the Aytu Divestiture, at each reporting period, the value of the Guarantee is determined based on the expected credit loss of the Guarantee with changes recorded in (loss) income from discontinued operations, net of tax within the consolidated statements of operations. In 2020, Aytu's credit rating significantly improved as a result of recent developments to Aytu's business, including but not limited to, recent financings and expansion of its revenue products that substantially enhanced Aytu's cash position and its ability to meet its financial commitments. Based on these facts, management concluded that the expected credit loss of the Guarantee was de minimis as of March 31, 2020 and June 30, 2020. Therefore, no change in value was recognized in income from discontinued operations, net of tax within the accompanying condensed consolidated statement of operations for the three months ended June 30, 2020 and a \$1.8 million gain on the change in value was recognized in income from discontinued operations, net of tax within the accompanying condensed consolidated statement of operations for the six months ended June 30, 2019.

Discontinued Operations

As a result of the sale of the Pediatric Portfolio, the operating results from the Pediatric Portfolio are reported as (loss) income from discontinued operations, net of tax in the accompanying condensed consolidated statements of operations. Accordingly, the accompanying condensed consolidated financial statements for the three and six months ended June 30, 2020 and 2019 and as of December 31, 2019 reflect the operations and related assets and liabilities of the Pediatric Portfolio as a discontinued operation.

The following tables summarizes the assets and liabilities of the discontinued operations as of June 30, 2020 and December 31, 2019:

	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Accounts receivable, net	\$ —	\$ 497,577
Total current assets of discontinued operations	\$ —	\$ 497,577
Liabilities		
Current liabilities:		
Accounts payable	\$ —	\$ 387,975
Accrued expenses and other current liabilities	5,549,751	3,503,037
Total current liabilities of discontinued operations	5,549,751	3,891,012
Other long-term liabilities	—	1,755,000
Total long-term liabilities of discontinued operations	\$ —	\$ 1,755,000

Cerecor retains continuing involvement with the divested Pediatric Portfolio related to future sales returns made after November 1, 2019 of sales of the Pediatric Portfolio prior to the close date of the Aytu Divestiture and the Deerfield Guarantee (discussed in detail above).

Pursuant to the Aytu Purchase Agreement, Aytu assumed sales returns of the Pediatric Portfolio made after the closing date of November 1, 2019 and primarily relating to sales prior to November 1, 2019 only to the extent such post-Closing sales returns exceed \$2.0 million and are less than \$2.8 million (in other words, Aytu will only assume \$0.8 million of such returns). Therefore, Cerecor is liable for future sales returns of the Pediatric Portfolio sold prior to November 1, 2019 in excess of the \$0.8 million assumed by Aytu. As of June 30, 2020, the Company estimated its sales return reserve from discontinued operations to be \$1.6 million, which is included above in accrued expenses and other current liabilities from discontinued operations. Changes in the Company's estimate of sales returns related to the Pediatric Portfolio is included within discontinued operations on the statement of operations and is shown within product sales, net in the table summarizing the results of discontinued operations below. In future periods, as additional information becomes available to the Company, the Company expects to recognize expense (or a benefit) related to actual sales returns of the Pediatric Portfolio in excess (or less than) the returns reserve recorded as of November 1, 2019, which will be recognized within discontinued operations. The Company expects this involvement to continue until sales returns are no longer accepted on sales of the Pediatric Portfolio made prior to November 1, 2019, which, in line with the products' return policies,

returns on these products may be accepted through 2023. The remaining liability within accrued expenses and other liabilities of discontinued operations as of June 30, 2020 largely relates to cash Cerecor collected on behalf of Aytu for post-divestiture sales of the Pediatric Portfolio, which will be remitted to Aytu. The collection of accounts receivable from Cerecor to Aytu was fully transitioned to Aytu during the second quarter of 2020.

The following table summarizes the results of discontinued operations for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Product revenue, net	\$ (455,463)	\$ 3,057,462	\$ (1,172,805)	\$ 5,892,537
Operating expenses:				
Cost of product sales	—	1,354,855	—	2,550,199
General and administrative	—	41,374	—	82,747
Sales and marketing	—	2,610,990	—	5,323,616
Amortization expense	—	744,099	—	1,488,199
Impairment of intangible assets	—	1,449,121	—	1,449,121
Change in fair value of contingent consideration	—	284,800	—	444,261
Total operating expenses	—	6,485,239	—	11,338,143
Other (expense) income:				
Change in value of Guarantee	—	—	1,755,000	—
Interest expense, net	—	(238,158)	—	(476,316)
Total other (expense) income	—	(238,158)	1,755,000	(476,316)
(Loss) income from discontinued operations before tax	(455,463)	(3,665,935)	582,195	(5,921,922)
Income tax expense	—	12,971	—	48,658
(Loss) income from discontinued operations, net of tax	\$ (455,463)	\$ (3,678,906)	\$ 582,195	\$ (5,970,580)

The significant non-cash operating items from the discontinued operations for the six months ended June 30, 2020 and 2019 are contained below. There were no non-cash investing items from the discontinued operations for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30,	
	2020	2019
Operating activities		
Amortization	\$ —	\$ 1,488,199
Impairment of intangible assets	—	1,449,121
Stock-based compensation, excluding amount included within gain on sale of Pediatric Portfolio	—	202,330
Change in fair value of contingent consideration liability	—	444,261
Change in value of Guarantee	(1,755,000)	—

4. Revenue from Contracts with Customers

The Company generates substantially all of its revenue from sales of prescription drugs to its customers. Revenue from sales of prescription drugs was \$1.3 million and \$1.4 million for the three months ended June 30, 2020 and 2019, respectively. Revenue from sales of prescription drugs was \$4.1 million and \$4.0 million for the six months ended June 30, 2020 and 2019, respectively.

As is typical in the pharmaceutical industry, the Company sells its prescription drugs in the United States primarily through wholesale distributors and a specialty contracted pharmacy. Wholesale distributors account for substantially all of the Company's net

product revenues and trade receivables. In addition, the Company earns revenue from sales of its prescription drugs directly to retail pharmacies. For the three months ended June 30, 2020, the Company's three largest customers accounted for approximately 50%, 30%, and 18% of the Company's total net product revenues from sale of prescription drugs from continuing operations. For the six months ended June 30, 2020, the Company's three largest customers accounted for approximately 44%, 29%, and 26% of the Company's total net product revenues from sale of prescription drugs from continuing operations.

5. Net Loss Per Share

The Company computes earnings per share ("EPS") using the two-class method. The two-class method of computing EPS is an earnings allocation formula that determines EPS for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings. The Company has two classes of stock outstanding, common stock and preferred stock. The preferred stock was issued in December 2018, upon Armistice exercising warrants to acquire an aggregate of 2,857,143 shares of the Series B Convertible Preferred Stock ("convertible preferred stock"). The convertible preferred stock has the same rights and preferences as the Company's common stock, other than being non-voting, and is convertible into shares of common stock on a 1-for-5 ratio. During the first quarter of 2020, Armistice converted 1.6 million shares of Series B Convertible Preferred Stock into 8.0 million shares of Cerecor's common stock. Under the two-class method, the convertible preferred stock is considered a separate class of stock for EPS purposes and therefore basic and diluted EPS is provided below for both common stock and preferred stock.

EPS for common stock and EPS for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. In applying the two-class method, undistributed earnings are allocated to common stock and preferred stock based on the weighted average shares outstanding during the period, which assumes the convertible preferred stock has been converted to common stock.

Diluted net (loss) income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; (ii) common stock to be issued upon the assumed conversion of the Company's unit purchase option (the "UPO") shares issued in 2015 to the underwriters of the Company's initial public offering ("IPO"), which are included under the "if-converted method" when dilutive; and (iii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses.

The following table sets forth the computation of basic and diluted net (loss) income per share of common stock and preferred stock for the three and six months ended June 30, 2020 and 2019, which includes both classes of participating securities:

	Three Months Ended June 30, 2020			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net loss	\$ (11,659,008)	\$ (414,027)	\$ (1,166,833)	\$ (41,436)
Denominator:				
Weighted average shares	62,806,926	62,806,926	1,257,143	1,257,143
Basic and diluted net loss per share	<u>\$ (0.18)</u>	<u>\$ (0.01)</u>	<u>\$ (0.93)</u>	<u>\$ (0.03)</u>

	Three Months Ended June 30, 2019			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net loss	\$ (1,907,520)	\$ (2,758,276)	\$ (636,673)	\$ (920,630)
Denominator:				
Weighted average shares	42,801,045	42,801,045	2,857,143	2,857,143
Basic and diluted net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>	<u>\$ (0.23)</u>	<u>\$ (0.32)</u>

	Six Months Ended June 30, 2020			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net (loss) income	\$ (31,098,910)	\$ 517,591	\$ (3,881,695)	\$ 64,604
Denominator:				
Weighted average shares	58,370,843	58,370,843	1,457,143	1,457,143
Basic and diluted net (loss) income per share	<u>\$ (0.53)</u>	<u>\$ 0.01</u>	<u>\$ (2.66)</u>	<u>\$ 0.04</u>

	Six Months Ended June 30, 2019			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net loss	\$ (5,752,395)	\$ (4,456,606)	\$ (1,954,172)	\$ (1,513,974)
Denominator:				
Weighted average shares	42,052,100	42,052,100	2,857,143	2,857,143
Basic and diluted net loss per share	<u>\$ (0.14)</u>	<u>\$ (0.10)</u>	<u>\$ (0.68)</u>	<u>\$ (0.53)</u>

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three months ended June 30, 2020 and 2019, as they could have been anti-dilutive:

	Three and Six Months Ended June 30,	
	2020	2019
Stock options	9,363,265	5,476,547
Warrants on common stock	4,024,708	4,024,708
Restricted Stock Units	155,833	278,750
Underwriters' unit purchase option	40,000	40,000

6. Asset Acquisition

Aevi Merger

On February 3, 2020, the Company consummated its two-step merger with Aevi, in accordance with the terms of the Merger Agreement dated December 5, 2019, by and between Cerecor, Genie Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Cerecor ("Merger Sub"), Second Genie Merger Sub, LLC ("Second Merger Sub"), a Delaware limited liability company

and wholly owned subsidiary of Cerecor, and Aevi. On February 3, 2020, Merger Sub merged with and into Aevi, with Aevi as the surviving corporation, and as part of the same transaction, Aevi then merged with and into Second Merger Sub, with Second Merger Sub as the surviving entity. The surviving entity from the second merger was renamed Aevi Genomic Medicine, LLC and is disregarded as an entity separate from Cerecor for U.S. federal income tax purposes. Cerecor retained its public reporting and current NASDAQ listing status. Effective upon the consummation of the Merger, Cerecor entered into an employment agreement with Aevi CEO Mike Cola for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi CSO Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer, and appointed Mike Cola and Dr. Sol Barer to the Company's Board of Directors. Dr. Neil was promoted to Cerecor's Chief Scientific Officer in March 2020. Additionally, the Company extended employment agreements to seven other individuals who were previously employed by Aevi.

The Merger consideration included stock valued at approximately \$15.5 million, resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of a \$4.1 million loan that Cerecor loaned Aevi in December 2019 contingent value rights for up to an additional \$6.5 million in subsequent payments based on certain development milestones, payable in either shares of the Company's common stock or in cash at the election of the Company, and transaction costs of \$1.5 million.

The fair value of the common stock transferred at closing was approximately \$5.5 million using the Company's closing stock price on February 3, 2020. The assets acquired consisted primarily of \$24.0 million of acquired in-process research and development ("IPR&D"), \$0.3 million of cash and \$0.7 million of assembled workforce. The Company assumed net liabilities of \$5.1 million. The Company recorded this transaction as an asset purchase as opposed to a business combination as management concluded that substantially all the value received was related to one group of similar identifiable assets which was the IPR&D for two early phase therapies for rare and orphan diseases (CERC-006 and CERC-007). The Company considered these assets similar due to similarities in the risks of development, stage of development, regulatory pathway, patient populations and economics of commercialization. The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense in the Company's consolidated statement of operations because the IPR&D asset has no alternate use due to the stage of development. The \$1.5 million of transaction costs incurred were recorded to acquired IPR&D expense. The assembled workforce asset was recorded to intangible assets and will be amortized over an estimated useful life of two years.

The contingent consideration of up to an additional \$6.5 million relates to two future development milestones. The first milestone is the enrollment of a patient in a Phase II study related to CERC-002 for use in Pediatric Onset Crohn's Disease, CERC-006 or CERC-007 prior to February 3, 2022. If this milestone is met, the Company is required to make a milestone payment of \$2.0 million. The second milestone is the receipt of a NDA approval for either CERC-006 or CERC-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of \$4.5 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company. The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of the consummation of the Merger on February 3, 2020 and as of June 30, 2020, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

7. Fair Value Measurements

ASC No. 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

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

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

	June 30, 2020		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	\$ 43,800,469	\$ —	\$ —
Investment in Aytu	\$ —	\$ —	\$ —
Liabilities			
Warrant liability**	\$ —	\$ —	\$ 20
Unit purchase option liability**	\$ —	\$ —	\$ 106
	December 31, 2019		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	\$ 2,240,230	\$ —	\$ —
Investment in Aytu	\$ —	\$ 7,628,947	\$ —
Liabilities			
Warrant liability**	\$ —	\$ —	\$ 3,460
Unit purchase option liability**	\$ —	\$ —	\$ 10,594

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

**Warrant liability and UPO liability are reflected in accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheets.

As of June 30, 2020 and December 31, 2019, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and other current liabilities, warrant liability, and the underwriters' unit purchase option liability. The carrying amounts reported in the accompanying condensed consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts.

Level 2 Valuation

As part of the consideration for the Aytu Divestiture, Aytu issued to Cerecor 9,805,845 shares of Aytu Series G Convertible Preferred Stock (the "Aytu Series G Preferred Stock" or "Aytu Preferred Stock"). Subsequent to the initial measurement, at each reporting period, the Investment in Aytu was remeasured at the current fair value with the change in fair value recorded to other income, net in the accompanying statements of operations.

In April 2020, Cerecor was permitted to convert the Aytu Preferred Stock into 9,805,845 shares of Aytu's common stock (the "Aytu Common Shares"), and subsequently sold all of the Aytu Common Shares in a series of transactions in April, pursuant to an effective registration statement, which generated net proceeds of approximately \$12.8 million. The sale resulted in a realized gain of \$5.2 million, which was recognized in change in fair value of Investment in Aytu within the accompanying condensed consolidated statement of operations for the six months ended June 30, 2020.

Level 3 Valuation

The tables presented below are a summary of changes in the fair value of the Company's Level 3 valuations for the warrant liability, UPO liability and contingent consideration for the six months ended June 30, 2020 and 2019:

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2019	\$ 3,460	\$ 10,594	\$ —	\$ 14,054
Change in fair value	(3,440)	(10,488)	—	(13,928)
Balance at June 30, 2020	\$ 20	\$ 106	\$ —	\$ 126

	Warrant liability	Unit purchase option liability	Contingent consideration	Total
Balance at December 31, 2018	\$ 2,950	\$ 7,216	\$ 1,256,210	\$ 1,266,376
Change in fair value	8,570	20,098	(1,256,210)	(1,227,542)
Balance at June 30, 2019	\$ 11,520	\$ 27,314	\$ —	\$ 38,834

In 2014, the Company issued warrants to purchase 625,208 shares of convertible preferred stock. Upon the closing of the Company's initial public offering ("IPO") in October 2015, these warrants became warrants to purchase 22,328 shares of common stock, in accordance with their terms. The warrants expire in October 2020. The warrants represent a freestanding financial instrument that is indexed to an obligation, which the Company refers to as the warrant liability. The warrant liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified to stockholders' equity. The fair value of the warrant liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of June 30, 2020, include (i) volatility of 74.2%, (ii) risk free interest rate of 0.16%, (iii) strike price of \$8.40, (iv) fair value of common stock of \$2.60, and (v) expected life of 0.3 years.

The underwriters' UPO was issued to the underwriters of the Company's IPO in 2015 and provides the underwriters the option to purchase up to a total of 40,000 units. The units underlying the UPO will be, immediately upon exercise, separated into shares of common stock, underwriters' Class A warrants and underwriters' Class B warrants (such warrants together referred to as the Underwriters' Warrants). The Underwriters' Warrants were warrants to purchase shares of common stock. The Class B warrants expired in April 2017 and the Class A warrants expired in October 2018, while the UPO expires in October 2020. The Company classifies the UPO as a liability, as it is a freestanding marked-to-market derivative instrument that is precluded from being classified in stockholders' equity. The UPO liability is marked-to-market each reporting period with the change in fair value recorded to other income, net in the accompanying statements of operations until the UPO is exercised, expires or other facts and circumstances lead the UPO to be reclassified to stockholders' equity. The fair value of the UPO liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the simulation model for valuing the UPO as of June 30, 2020, include (i) volatility of 74.2%, (ii) risk free interest rate of 0.16%, (iii) unit strike price of \$7.47, (iv) fair value of underlying equity of \$2.60, and (v) expected life of 0.3 years.

The Company's historical business acquisition of TRx Pharmaceuticals, LLC ("TRx") in November 2017 (the "TRx Acquisition") involved the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones. The fair value of contingent consideration was determined at the acquisition date utilizing unobservable inputs such as the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liabilities were remeasured at the current fair value with changes recorded in the consolidated statement of operations.

The consideration for the TRx Acquisition included certain potential contingent payments. First, pursuant to the TRx Purchase Agreement, the Company would have been required to pay \$3.0 million to the sellers if the gross profit related to TRx products equaled or exceeded \$2.6 million in 2018. The Company did not achieve this contingent event in 2018 and therefore no value was assigned to the contingent payout as of December 31, 2018. Additionally, the Company was required to pay the following: (1) \$2.0 million upon the transfer of the Ulesfia NDA to the Company ("NDA Transfer Milestone"), and (2) \$2.0 million upon FDA approval of a new dosage of Ulesfia ("FDA Approval Milestone"). However, as part of the settlement the Company entered into during the second quarter of 2019 with Lachlan Pharmaceuticals, an Irish company controlled by the previous owners of TRx, the Company gave up its right to sell Ulesfia, except for a limited amount of inventory on hand until that inventory is sold or expired. As a result, the settlement released the Company from the potential contingent payments related to the NDA Transfer Milestone and FDA Approval Milestone and therefore no value was assigned to the two milestones as of June 30, 2020 or as of June 30, 2019.

Effective upon the consummation of the Aevi Merger during the first quarter of 2020, Cerecor entered into an employment agreement with Aevi CEO Mike Cola for him to serve as Cerecor's Chief Executive Officer and an employment agreement with Aevi CSO Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer. Additionally, the Company extended employment agreements to seven other individuals who were previously employed by Aevi. As a result, the Company recognized an assembled workforce intangible asset of \$0.7 million which is a Level 3 non-recurring fair value measurement. The Company utilized the replacement cost method to estimate the fair value of the assembled workforce, which considers the costs Cerecor would have incurred to replace a comparable workforce to the workforce acquired from Aevi. Such costs include, but are not limited to, recruiting costs, training costs and cost of lost productivity. The replacement costs were estimated based on a percentage of each employee's salary. The assembled workforce intangible asset will be amortized over a useful life of two years.

No other changes in valuation techniques or inputs occurred during the six months ended June 30, 2020 and 2019. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the six months ended June 30, 2020 and 2019.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of June 30, 2020 and December 31, 2019 consisted of the following:

	As of	
	June 30, 2020	December 31, 2019
Research and development expenses	\$ 1,899,830	\$ 920,901
Compensation and benefits	1,670,669	1,591,964
General and administrative	912,943	360,016
Sales and marketing	212,807	120,056
Sales returns and allowances	1,144,427	2,284,175
Medicaid rebates	101,458	118,271
Lease liability, current	431,543	155,815
Other	113,981	89,054
Total accrued expenses and other current liabilities	<u>\$ 6,487,658</u>	<u>\$ 5,640,252</u>

During the first quarter of 2020, the Company and an executive entered into a separation agreement in which the executive resigned his employment at the Company effective June 30, 2020. Following June 30, 2020, the former executive will receive continued payments of his base salary for a total of nine months, which resulted in an accrual of \$0.3 million recognized in accrued expenses and other current liabilities on the Company's accompanying condensed consolidated balance sheet as of June 30, 2020 and is shown within the compensation and benefits line above.

Additionally, during the second quarter of 2020, the Company and an executive entered into a separation agreement in which the executive resigned his employment effective April 24, 2020. The former executive serves as an advisor to the Company's Board of Directors and will continue to serve in such role until December 2021 or until terminated by either party upon thirty days' written notice. The former executive will receive \$0.8 million in severance, which will be paid over 18 months beginning when his role as advisor to the Board ends. The Company recognized a \$0.8 million severance accrual in other long-term liabilities on the Company's accompanying condensed consolidated balance sheet as of June 30, 2020.

9. Capital Structure

According to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock, common stock and preferred stock. At June 30, 2020, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of \$0.001 per share.

On December 26, 2018, the Company filed a Certificate of Designation of Preferences of Series B Non-Voting Convertible Preferred Stock ("Series B Convertible Preferred Stock" or "convertible preferred stock") of Cerecor Inc. (the "Certificate of Designation of the Series B Preferred Stock") classifying and designating the rights, preferences and privileges of the Series B Convertible Preferred Stock. The Certificate of Designation of the Series B Convertible Preferred Stock authorized 2,857,143 shares

of convertible preferred stock. The Series B Convertible Preferred Stock converts to shares of common stock on a 1-for-5 ratio and has the same rights, preferences, and privileges as common stock other than it holds no voting rights.

Common Stock

June 2020 Financing

On June 11, 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock (inclusive of 1,980,000 shares that were sold pursuant to the underwriter's full exercise of its option to purchase additional shares of Cerecor's common stock) for net proceeds of approximately \$35.4 million. Armistice participated in the offering by purchasing 2,000,000 shares of common stock, on the same terms as all other investors. Additionally, certain of the Company's officers participated in the offering by purchasing an aggregate of 110,000 shares of common stock, on the same terms as all other investors.

March 2020 Financing

On March 17, 2020, the Company entered into a securities purchase agreement with Armistice pursuant to which the Company sold 1,951,219 shares of the Company's common stock for net proceeds of approximately \$3.9 million.

February 2020 Financing

On February 6, 2020, the Company closed a registered direct offering with certain institutional investors for the sale by the Company of 1,306,282 shares of the Company's common stock for net proceeds of approximately \$5.1 million. Armistice participated in the offering by purchasing 1,256,282 shares of common stock from the Company, on the same terms as all other investors.

Aevi Merger

On February 3, 2020, under the terms of the Aevi Merger noted above in Note 6, the Company issued 3.9 million shares of common stock.

September 2019 Armistice Private Placement

On September 4, 2019, the Company entered into a securities purchase agreement with Armistice, pursuant to which the Company sold 1,200,000 shares of the Company's common stock for net proceeds of approximately \$3.7 million.

March 2019 Common Stock Offering

On March 8, 2019, the Company closed on an underwritten public offering of common stock for 1,818,182 shares of common stock of the Company for net proceeds of approximately \$9.0 million. Armistice participated in the offering by purchasing 363,637 shares of common stock of the Company, on the same terms as all other investors.

Voting

The common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends

The holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Holders of the Company's common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Company's common stock.

Common Stock Warrants

At June 30, 2020, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
22,328*	\$ 8.40	October 2020
2,380*	\$ 8.68	May 2022
4,000,000	\$ 12.50	June 2024
4,024,708		

*Accounted for as a liability instrument (see Note 7)

Convertible Preferred Stock

December 2018 Armistice Private Placement

On December 27, 2018, the Company entered into a series of transactions as part of a private placement with its largest stockholder, Armistice, whose Chief Investment Officer, Steve Boyd, is a Cerecor director, in order to generate cash to continue to develop its pipeline assets and for general corporate purposes. The transactions are considered one transaction for accounting purposes. As part of the transaction, the Company exchanged common stock warrants issued on April 27, 2017 to Armistice for the purchase of up to 14,285,714 shares of the Company's common stock at an exercise price of \$0.40 per share (the "original warrants") for like-kind warrants to purchase up to 2,857,143 shares of the Company's newly designated Series B Convertible Preferred Stock with an exercise price of \$2.00 per share (the "exchanged warrants"). Armistice immediately exercised the exchanged warrants and acquired an aggregate of 2,857,143 shares of the convertible preferred stock. Net proceeds of the transaction were approximately \$5.7 million for the year ended December 31, 2018. In order to provide Armistice an incentive to exercise the exchanged warrants, the Company also entered into a securities purchase agreement with Armistice in December 2018 pursuant to which the Company issued warrants for 4,000,000 shares of common stock of the Company with a term of 5.5 years and an exercise price of \$12.50 per share (the "incentive warrants").

During the first quarter of 2020, Armistice converted 1,600,000 shares of Series B Convertible Preferred Stock (of its 2,857,143 million shares of convertible preferred stock) into 8,000,000 shares of Cerecor's common stock.

Voting

Holders of the Company's convertible preferred stock are not entitled to vote.

Dividends

The holders of convertible preferred stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of the Company's convertible preferred stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities.

Rights and Preferences

Each share of convertible preferred stock converts to shares of common stock on a 1-for-5 ratio. There are no other preemptive or subscription rights and there are no redemption or sinking fund provisions applicable to the Company's common stock.

10. Stock-Based Compensation

2016 Equity Incentive Plan

On April 5, 2016, the Company's board of directors adopted the 2016 Equity Incentive Plan (the "2016 Plan") as the successor to the 2015 Omnibus Plan (the "2015 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on May 18, 2016 (the "2016 Plan Effective Date"). Upon the 2016 Plan Effective Date, the 2016 Plan reserved and authorized up to 600,000 additional shares of common stock for issuance, as well as 464,476 unallocated shares remaining available for grant of new awards under the 2015 Plan. An Amended and Restated 2016 Equity Incentive Plan (the "2016 Amended Plan") was approved by the Company's stockholders in May 2018, which increased the share reserve by an additional 1.4 million shares. A Second Amended and Restated 2016 Equity Incentive Plan (the "2016 Second Amended Plan") was approved by the Company's stockholders in August 2019, which increased the share reserve by an additional 850,000 shares. A Third Amended and Restated Equity Incentive Plan (the "2016 Third Amended Plan") was approved by the Company's stockholders in June 2020 which increased the share reserve by an additional 2,014,400 shares. During the term of the 2016 Third Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. As of June 30, 2020, there were 3,464,032 shares available for future issuance under the 2016 Third Amended Plan.

Option grants expire after ten years. Employee options typically vest over three or four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. Options granted to directors typically vest over one or three years. Directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. Stock-based compensation expense includes expense related to stock options, restricted stock units and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the three and six months ended June 30, 2020 and 2019 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	\$ 390,506	\$ 120,709	\$ 772,275	\$ 178,085
General and administrative	2,307,998	196,211	2,987,598	665,336
Sales and marketing	87,070	56,823	142,024	77,651
Total stock-based compensation, continuing operations	2,785,574	373,743	3,901,897	921,072
Total stock-based compensation, discontinued operations	—	152,966	—	202,330
Total stock-based compensation	<u>\$ 2,785,574</u>	<u>\$ 526,709</u>	<u>\$ 3,901,897</u>	<u>\$ 1,123,402</u>

Stock options with service-based vesting conditions

The Company has granted awards that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periods. A summary of option activity for the six months ended June 30, 2020 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)
Balance at December 31, 2019	4,180,606	\$ 4.80	\$ 2.67	7.9
Granted	5,165,956	\$ 3.52	\$ 2.24	
Exercised	(50,239)	\$ 1.84	\$ 1.22	
Forfeited	(629,300)	\$ 3.26	\$ 1.95	
Expired	(303,758)	\$ 5.30	\$ 3.03	
Balance at June 30, 2020	<u>8,363,265</u>	<u>\$ 4.13</u>	<u>\$ 2.45</u>	<u>7.8</u>
Exercisable at June 30, 2020	<u>2,719,729</u>	<u>\$ 4.67</u>	<u>\$ 2.60</u>	<u>5.1</u>

In February 2020, the Company granted options to purchase 2.4 million shares of common stock as inducement option grants, pursuant to NASDAQ Listing Rule 5635(c)(4), to certain executives who joined the Company in connection with the Aevi Merger. In

March 2020, our Chief Executive Officer entered into an amended employment agreement in which his base salary in cash was reduced from an annual rate of \$50,000 to an annual rate of \$35,568 (the "Reduction"). In consideration for the Reduction, on a quarterly basis, the Company grants stock options, which vest immediately (the "Salary Options"), for the purchase of a number of shares of the Company's common stock with a total value (based on the Black-Scholes valuation methodology) based on a pro rata total annual value of \$414,432 of the foregone salary. Finally, in April 2020, the Company granted options with service-based vesting conditions as part of its annual grant to employees.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of June 30, 2020, the aggregate intrinsic value of options outstanding was \$0.7 million. The aggregate intrinsic value of options currently exercisable as of June 30, 2020 was \$0.6 million. There were 844,978 options that vested during the six months ended June 30, 2020 with a weighted average exercise price of \$4.96 per share. The total grant date fair value of shares which vested during the six months ended June 30, 2020 was \$2.3 million.

The Company recognized stock-based compensation expense of \$1.7 million and \$2.5 million related to stock options with service-based vesting conditions for the three and six months ended June 30, 2020, respectively. At June 30, 2020, there was \$11.1 million of total unrecognized compensation cost related to unvested service-based vesting condition awards. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.2 years.

Stock options with market-based vesting conditions

The Company has granted options that contain market-based vesting conditions. The following table summarizes the Company's market-based option activity for the six months ended June 30, 2020:

	Options Outstanding			Aggregate intrinsic value (1)
	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	
Balance at December 31, 2019	300,000	\$ 4.98	9.4	
Granted	1,000,000	\$ 3.29	10	
Forfeited	(300,000)			
Balance at June 30, 2020	1,000,000	\$ 3.29	10	
Exercisable at June 30, 2020	500,000			\$ 45,000

(1) The aggregate intrinsic value in the above table represents the total pre-tax amount that a participant would receive if the option had been exercised on the last day of the respective fiscal period. Options with a market value less than its exercise value are not included in the intrinsic value amount.

During the second quarter of 2020, 300,000 unvested market-based stock options were forfeited as a result of the resignation of an executive during the quarter. The forfeiture resulted in the reversal of the full expense previously recognized to date on this award of \$0.4 million, which was recorded to general and administrative expense for the three and six months ended June 30, 2020.

On June 18, 2020, the Company granted its recently appointed Chairman of the Board an option to purchase 1,000,000 shares of Company common stock with market-based vesting conditions. 500,000 of the shares vested immediately on the date of grant with an exercise price of the closing stock price on the date of grant of \$51.25. 250,000 of the shares vest upon the Company's common stock reaching a 50% premium to the stock price on June 18, 2020 and will have an exercise price of the stock at that time and 250,000 of the shares vest upon the Company's common stock reaching a 75% premium to the stock price on June 18, 2020 and will have an exercise price of stock at that time. Each vesting tranche represents a unique requisite service period and therefore the compensation cost for each vesting tranche is recognized on a straight-line basis over its respective vesting period.

The Company recognized stock-based compensation expense of \$0.5 million and \$0.6 million related to stock options with market-based vesting conditions for the three and six months ended June 30, 2020, respectively, which includes the reversal of the former Executive Chairman's forfeited options and the expense related to the market-based options granted during the quarter. At June 30, 2020, there was \$0.7 million of total unrecognized compensation cost related to unvested market-based vesting conditions awards. This compensation cost is expected to be recognized over a weighted-average period of 0.7 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options granted to employees and members of the board of directors under the Black-Scholes valuation model for the six months ended June 30, 2020:

Service-based options	
Expected dividend yield	—%
Expected volatility	69.9% - 79.9%
Expected life (in years)	1.75 - 6.25
Risk-free interest rate	0.19% - 1.48%

Restricted Stock Units

The Company has granted restricted stock units ("RSU") to certain employees. The Company measures the fair value of the restricted awards using the stock price on the date of the grant. The restricted shares typically vest annually over a four-year period beginning on the first anniversary of the award. The following table summarizes the Company's RSU activity for the six months ended June 30, 2020:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Unvested RSUs at December 31, 2019	267,500	\$ 4.92
Granted	—	
Vested	(111,667)	\$ 4.93
Unvested RSUs at June 30, 2020	155,833	\$ 4.91

The Company recognized stock-based compensation expense of \$0.6 million and \$0.8 million related to RSUs for the three and six months ended June 30, 2020, respectively. At June 30, 2020, there was \$43,202 of total unrecognized compensation cost related to the RSU grants. This compensation cost is expected to be recognized over a weighted-average period of 2.0 years.

Employee Stock Purchase Plan

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

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

Upon the ESPP Effective Date, the Company reserved and authorized up to 500,000 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP shall automatically increase by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, and (ii) 500,000 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. The number of shares were increased by 443,842 on January 1, 2020. As of June 30, 2020, 1,504,388 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Stock Purchase Plans*, the ability to purchase shares of the

Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of \$54,590 and \$0.1 million, respectively, for the three and six months ended June 30, 2020.

11. Income Taxes

The Company recognized an income tax benefit of \$0.5 million and \$2.6 million for the three and six months ended June 30, 2020, respectively. The benefit recognized was a result of a current year tax law change and the ability of the Company to now carry back certain losses due to the CARES Act. The tax provisions within the CARES Act included temporary changes regarding the utilization and five year carry back of losses generated in 2018, 2019 and 2020, temporary changes regarding interest deductions, technical corrections from prior tax legislation related to qualified improvement property, and various other measures. In the second quarter of 2020, the Company filed a refund claim with the Internal Revenue Service related to its 2017 tax liability by carrying back losses not previously claimed. In June 2020, the state of Maryland issued a report announcing that the state decoupled from the CARES Act loss carryback provisions for the 2020 year only, but carrybacks are presently allowed under current law for 2018 and 2019. As a result, the Company recognized a \$2.2 million benefit in the first quarter of 2020 related to the federal tax carryback and an additional \$0.5 million in the second quarter of 2020 related to the Maryland tax carryback. The Company intends to file a claim related to the Maryland tax liability during the third quarter of 2020. The expense recognized for the three and six months ended June 30, 2019 of \$0.1 million and \$0.2 million, respectively, was a result of interest on an unpaid tax liability related to the 2017 tax year and state taxes.

12. Leases

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

The annual base rent for the Company's corporate headquarters located in Rockville, Maryland (the "Headquarters' Lease") is \$161,671, subject to annual 2.5% increases over the term of the lease. The lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company makes its first annual fixed rent payment, which occurred in January 2020. The Company has the option to extend the lease two times, each for a period of five years, and may terminate the lease as of the sixth anniversary of the first annual fixed rent payment, upon the payment of a termination fee. As of the lease commencement date, it was not reasonably certain that the Company will exercise the renewal periods or early terminate the lease and therefore the end date of the lease for accounting purposes is January 31, 2030. The Company entered into a sublease for additional administrative office space in Chesterbrook, Pennsylvania in May 2020 (the "Chesterbrook Lease"). The annual base rent for the Chesterbrook Lease is \$280,185. The lease expires in November 2021. The weighted average remaining term of the operating leases at June 30, 2020 was 7.7 years.

Supplemental balance sheet information related to the leased property is as follows:

	As of	
	June 30, 2020	December 31, 2019
Property and equipment, net	\$ 1,056,441	\$ 718,626
Accrued expenses and other current liabilities	\$ 431,543	\$ 155,815
Other long-term liabilities	1,191,560	1,111,965
Total operating lease liabilities	\$ 1,623,103	\$ 1,267,780

The operating lease right-of-use ("ROU") assets are included in property and equipment and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our condensed consolidated balance sheets. The Company utilized a weighted average discount rate of 7.2% to determine the present value of the lease payments.

The components of lease expense for the three and six months ended June 30, 2020 and 2019 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost*	\$ 87,199	\$ 39,534	\$ 141,708	\$ 94,140

*Includes short-term leases, which are immaterial.

The following table shows a maturity analysis of the operating lease liability as of June 30, 2020:

	Undiscounted Cash Flows	
July 1, 2020 through December 31, 2020	\$	220,689
2021		426,346
2022		173,748
2023		178,092
2024		182,544
2025		187,108
Thereafter		813,638
Total lease payments	\$	2,182,165
Less implied interest		(559,062)
Total	\$	1,623,103

13. Commitments and Contingencies

Litigation

Litigation - General

The Company may become party to various contractual disputes, litigation, and potential claims arising in the ordinary course of business. The Company currently does not believe that the resolution of such matters will have a material adverse effect on its financial position or results of operations except as otherwise disclosed in this report.

TRx 2018 Target Gross Profit Dispute

As part of the TRx Acquisition, pursuant to the TRx Purchase Agreement, the Company was required to pay \$3.0 million to the former TRx owners if the gross profit, as defined in the TRx Purchase Agreement, related to TRx products equaled or exceeded \$12.6 million in 2018. The Company believes it did not achieve this contingent event in 2018 and therefore, no amount is due to the former TRx owners. However, during the second quarter of 2019, the former TRx owners disputed the Company's calculation of gross profit under the TRx Purchase Agreement, arguing the Company met the \$12.6 million target in 2018. Pursuant to the TRx Purchase Agreement, the dispute was submitted to an independent accounting firm for resolution during the third quarter of 2019. The dispute was resolved on October 8, 2019, with the independent accounting firm ruling in favor of the Company.

However, on December 19, 2019, Cerecor received a letter from an attorney on behalf of the former TRx owners dated December 18, 2019 that enclosed a draft complaint seeking relief against Cerecor and one of the members of its board of directors. The parties met for a pre-lawsuit mediation in June 2020, however no resolution was reached. As of the date of this filing, no lawsuit has been filed. The proposed complaint indicates that the former TRx owners would seek the following relief: (a) \$3.0 million on the grounds that commercially reasonable efforts to sell the acquired TRx products would have resulted in the gross profit earn-out target being reached; (b) that the \$3.0 million amount be trebled as a result of Cerecor's alleged improper conduct; (c) \$9.2 million as a result of alleged losses resulting from the alleged improper treatment of the former TRx owners as affiliates; and (d) the removal of any restrictions on the former TRx owners shares of common stock in Cerecor. Cerecor disputes that the former TRx owners are entitled to the relief sought and intends to vigorously defend against any lawsuit filed on behalf of the former TRx owners. A loss in this matter is possible in a range of \$0 to \$18.2 million. As a loss in this matter is not considered probable, there has been no accrual recorded as of June 30, 2020.

Karbinal Royalty Make-Whole Provision

On February 16, 2018, in connection with the acquisition of Avadel's pediatric products, the Company entered into a supply and distribution agreement with TRIS Pharma (the "Karbinal Agreement"). As part of this agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2033. The Company was required to pay TRIS a royalty make whole payment ("Make-Whole Payments") of \$0 for each unit under the 70,000 units annual minimum sales commitment through 2033.

As a part of the Aytu Divestiture, which closed on November 1, 2019, the Company assigned all payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the "TRIS Obligations") to Aytu. However, under the original license agreement, the Company could ultimately be liable for TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

Millipred License and Supply Agreement

The Company has a License and Supply Agreement for Millipred with Watson Laboratories, Inc., which is now part of Teva Pharmaceutical Industries Ltd. ("Teva"). Pursuant to the License and Supply Agreement, the Company is required to make license payments of \$75,000 in February and August of each year through April 2021, and purchase inventory on an ad-hoc basis. The License and Supply Agreement expires on April 1, 2021, however if neither party terminates the agreement prior to April 1, 2021, then the agreement will automatically renew for successive one-year periods. Effective upon the consummation of the Merger, Cerecor appointed Dr. Sol Barer to the Company's Board of Directors. Dr. Barer also serves as Teva's Chairman of the Board.

Possible Future Milestone Proceeds for Out-Licensed Compounds

CERC-611 License Assignment

On August 8, 2019, the Company entered into an assignment of license agreement (the "Assignment Agreement") with ES Therapeutics, LLC ("ES Therapeutics"), a wholly-owned subsidiary of Armistice, a significant stockholder of the Company. Pursuant to the Assignment Agreement, the Company assigned and transferred its rights, title, interest, and obligations with respect to CERC-611 to ES Therapeutics. The Company initially licensed the compound from Eli Lilly Company ("Lilly") in September 2016. Under the Assignment Agreement, Armistice paid the Company an upfront payment of \$0.1 million. The Company recognized the payment as license and other revenue for the year ended December 31, 2019. The Assignment Agreement also provides for: (a) a \$7.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching \$750.0 million; and (b) a \$12.5 million milestone payment to the Company upon cumulative net sales of licensed products reaching \$1.3 billion. The Assignment Agreement also released the Company of obligations related to CERC-611, including the \$1.3 million contingent payment to Lilly upon the first subject dosage of CERC-611 in a multiple ascending dose study. The Assignment Agreement also releases the Company from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones, including the first commercial sale, and milestone payments and royalty on net sales upon commercialization of the compound.

CERC-501 Sale to Janssen

In August 2017, the Company sold its worldwide rights to CERC-501 to Janssen Pharmaceuticals, Inc. ("Janssen") in exchange for initial gross proceeds of \$25.0 million. There is a potential future \$20.0 million regulatory milestone payment to the Company upon acceptance of an NDA for any indication. The terms of the agreement provide that Janssen will assume ongoing clinical trials and be responsible for any new development and commercialization of CERC-501.

Related Party and Acquisition Related Contingent Liabilities

CERC-006 Royalty Agreement with Certain Related Parties

As discussed in detail in Note 6, on February 3, 2020, the Company consummated a Merger with Aevi. Effective upon the closing of the Merger, Cerecor entered into an employment agreement with Mike Cola for him to serve as Cerecor's Chief Executive Officer and with Dr. Garry Neil for him to serve as Cerecor's Chief Medical Officer.

Prior to Cerecor entering into the Merger Agreement, in July 2019, Aevi entered into a royalty agreement with Mike Cola, our current Chief Executive Officer, Joseph J. Grano, Jr., Kathleen Jane Grano, Joseph C. Grano, The Grano Children's Trust, Joseph C. Grano, trustee and LeoGroup Private Investment Access, LLC on behalf of Garry A. Neil, our current Chief Medical Officer (collectively, the "Investors") in exchange for a one-time aggregate payment of \$2 million (the "Royalty Agreement"). Collectively, the Investors will be entitled to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of Astellas Pharma Inc.'s second generation mTORC1/2 inhibitor, CERC-006. At any time beginning three years after the date of the first public launch of CERC-006, Cerecor may exercise, at its sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to Investors of an aggregate of 75% of the net present value of the royalty payments. A majority of the independent members of the board of directors and the audit committee of Aevi approved the Royalty Agreement.

Cerecor assumed this Royalty Agreement upon closing of the Merger with Aevi and it is recorded within royalty obligation within the Company's accompanying condensed consolidated balance sheet as of June 30, 2020. Because there is a significant related party relationship between the Company and the Investors, the Company treated its obligation to make royalty payments under the Royalty Agreement as an implicit obligation to repay the funds advanced by the Investors. As the Company makes royalty payments in accordance with the Royalty Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which would result in a corresponding increase in the liability balance.

Aevi Merger possible future milestone payments

As detailed in Note 6, on February 3, 2020, the Company consummated its merger with Aevi, thus acquiring the rights to three early stage compounds for rare and orphan diseases (CERC-002, CERC-006 and CERC-007) and one other preclinical orphan disease compound, CERC-005. Consideration for the transaction included approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, forgiveness of a \$4.1 million loan that Cerecor loaned Aevi in December 2019, and certain contingent development milestones worth up to an additional \$6.5 million.

The contingent consideration of up to an additional \$6.5 million relates to two future development milestones. The first milestone is the enrollment of a patient in a Phase II study related to CERC-002 for use in Pediatric Onset Crohn's Disease, CERC-006 or CERC-007 prior to February 3, 2022. If this milestone is met, the Company is required to make a milestone payment of \$2.0 million. The second milestone is the receipt of a NDA approval for either CERC-006 or CERC-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of \$4.5 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of the consummation of the Merger on February 3, 2020 and as of June 30, 2020, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

Ichorion Asset Acquisition possible future milestone payments

On September 24, 2018, the Company acquired Ichorion Therapeutics, Inc. (the "Ichorion Acquisition") thus acquiring three compounds for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803) and one other preclinical orphan disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. Consideration for the transaction included approximately 5.8 million shares of the Company's common stock (adjusted for estimated working capital) and certain contingent development milestones worth up to an additional \$15.0 million. The Company recorded this transaction as an asset acquisition.

The contingent consideration of up to an additional \$15.0 million relates to three future development milestones for the acquired compounds. The first milestone is the first product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of \$6.0 million. The second milestone is the second product being approved for marketing by the FDA on or prior to December 31, 2021. If this milestone is met, the Company is required to make a milestone payment of \$5.0 million. The third milestone is a protide molecule being approved by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of \$4.0 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of the Company.

The contingent consideration related to the development milestones will be recognized if and when such milestones are probable and can be reasonably estimated. As of June 30, 2020, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

14. Payroll Protection Program Loan

The CARES Act provides stimulus measures, including the Payroll Protection Loan Program ("PPP"), to provide certain small businesses with liquidity to support their operations during the COVID-19 pandemic. Cerecor received a \$0.4 million PPP Loan during the second quarter of 2020. PPP Loans have a 1% fixed annual interest rate and mature in two years, however are eligible for forgiveness under certain conditions. Cerecor used the loaned funds during the second quarter of 2020 to retain employees and maintain payroll and lease payments, as specified under the Paycheck Protection Program Rule. The Company believes it meets the criteria for forgiveness and plans to submit an application for forgiveness with its lender in the second half of 2020. Once approved by the lender, the lender will submit the forgiveness application to the Small Business Administration (the "SBA") for ultimate

approval. The SBA has 90 days from receipt to approve or reject the forgiveness application. The Company incurred the related expense prior to June 30, 2020 and recognized the PPP Loan of \$0.4 million as other income within the accompanying condensed consolidated statement of operations for the three and six months ended June 30, 2020.

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

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "may," "might," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or other similar words (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, technology enhancements, possible changes in legislation, and other statements that are not historical. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," as well as in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 11, 2020, and in our other filings with the SEC. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2019 appearing in our Annual Report on Form 10-K filed with the SEC on March 11, 2020.

Overview

Cerecor Inc. (the "Company" or "Cerecor") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies that address unmet patient needs within rare pediatric and orphan diseases. The Company's pediatric rare disease pipeline includes CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are therapies for inherited metabolic disorders known as Congenital Disorders of Glycosylation ("CDGs"). The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease Designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of each new drug application ("NDA"). The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-002 is an anti-LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes) monoclonal antibody being developed for the treatment of COVID-19 acute respiratory distress syndrome ("ARDS") and Pediatric-onset Crohn's Disease. CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations and has been granted ODD and RPDD by the FDA, thus potentially qualifying the Company to receive a PRV upon approval of an NDA. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Still's Disease ("AOSD") and Multiple Myeloma.

The Company continues to explore strategic alternatives for its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions. The Company has been in discussions with Simon Pedder, a former member of its Board of Directors, about potentially transferring its non-core neurology pipeline assets, CERC-301 and CERC-406, to a new company formed by Dr. Pedder, although it has not agreed to binding terms, and any such transaction might not happen until the second half of 2020, if at all.

Recent Developments

On June 11, 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock (inclusive of 1,980,000 shares that were sold pursuant to the underwriter's full exercise of its option to purchase additional shares of Cerecor's common stock) for net proceeds of approximately \$35.4 million. Armistice Capital, LLC ("Armistice"), whose Chief Investment Officer Steve Boyd is a Cerecor director, participated in the offering by purchasing 2,000,000 shares of common stock, on the same terms as all other investors. Additionally, certain of the Company's officers participated in the offering by purchasing an aggregate of 110,000 shares of common stock, on the same terms as all other investors.

Research and Development Update

In July 2020, the Company announced that the first patient was enrolled in a proof-of-concept trial evaluating the safety and efficacy of the anti-LIGHT monoclonal antibody, CERC-002, in patients with COVID-19 cytokine storm-induced ARDS. The proof-of-concept, randomized, multicenter, double-blind, placebo-controlled trial will enroll approximately 82 subjects hospitalized with COVID-19 ARDS. The primary objective of the study is to demonstrate that treatment with CERC-002 results in fewer instances of respiratory failure and death versus the standard of care. Top-line data is expected in the fourth quarter of 2020. Prior to enrollment, in May 2020, the Company received clearance from the FDA to proceed with the proof-of-concept trial. The scientific rationale for the proof-of-concept trial is supported by recent biomarker data demonstrating elevated levels of LIGHT in patients hospitalized with COVID-19 cytokine storm-induced ARDS.

In May 2020, Cerecor entered into an Amended and Restated Clinical Development and Option Agreement (the "New CDOA") with Kyowa Kirin Co., Ltd., formerly known as Kyowa Hakko Kirin Co., Ltd ("KKC") relating to the development and potential commercialization of CERC-002 in the treatment of COVID-19 ARDS. The New CDOA grants Cerecor an additional option to obtain exclusive rights for the development, manufacture and commercialization of CERC-002 in the treatment, prevention, and diagnosis of acute lung injury ("ALI") and ARDS, for an initial license fee in the low single-digit millions of dollars upon exercise of the option. The New CDOA includes additional terms, such as certain regulatory milestone payments and profit sharing specifically related to CERC-002 in the ARDS/ALI Field.

During the second quarter of 2020, the Company concluded its CDG FIRST trial, which was a retrospective trial evaluating the use of monosaccharide replacement therapy in PGMI-CDG, MPI-CDG and LADII-CDG. The Company plans to use data from this trial to inform future trial design and endpoints for forthcoming pivotal trials for the CERC-800s.

During the first quarter of 2020, the Company paused its Phase 1b open-label, multi-center, dose-escalation proof-of-concept study for CERC-002 for the treatment of Pediatric-onset Crohn's Disease due to a moratorium placed on endoscopy as a result of COVID-19. The Company resumed this trial in July 2020.

In the third quarter of 2020, the FDA granted ODD and RPDD to CERC-006. There are numerous benefits associated with receipt of ODD, which include seven-year marketing exclusivity (upon FDA approval) in the United States, exemption of FDA application fees and tax credits for qualified clinical trials. RPDD provides potential eligibility for receipt of a PRV upon approval of an NDA.

The following chart summarizes key information about our emerging clinical-stage rare disease pipeline and anticipated research & development milestones:

Core Research & Development Areas	Therapeutic Area	Program	Mechanism of Action	Lead Indication	Development Stage				Anticipated Milestone*
					Preclin	Phase 1	Phase 2	Pivotal Trial	
Immunology	Inflammation	CERC-002	Anti-LIGHT mAb	ARDS					Initial Data 4Q 2020
		CERC-002	Anti-LIGHT mAb	Crohn's					Initial Data 1Q 2021
		CERC-007	Anti-IL-18 mAb	AOSD					Initial Data 2Q 2021
Oncology	Blood Cancers	CERC-007	Anti-IL-18 mAb	Multiple Myeloma					Initial Data 1Q21
Rare Genetic Disorders	Complex Lymphatic Malformations	CERC-006	Dual mTOR inhibitor	Complex Lymphatic Malformations					Initial Data 2Q 2021 ⁽¹⁾
	Congenital Disorders of Glycosylation	CERC-801	D-Galactose replacement	PGM1-CDG					Pivotal Trial Data 2021
		CERC-802	D-Mannose replacement	MPI-CDG					Pivotal Trial Data 2021
		CERC-803	L-Fucose replacement	LADII-CDG					IND 2H20
Footnotes: <i>*The anticipated milestones within are forward-looking statements that are subject to significant risks and uncertainties and therefore subject to change based on various factors (many of which are beyond the Company's control). Refer to the Company's Risk Factors disclosed in Item 1A in this Quarterly Report on Form 10-Q.</i>									
⁽¹⁾ Current timing of this milestone is being re-evaluated due to possible COVID-19 related CMC delays.									

Our Strategy

Our strategy for increasing shareholder value includes:

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

Results of Operations

During the fourth quarter of 2019, the Company sold to Aytu BioScience its rights, titles and interest in, assets relating to its Pediatric Portfolio as well as the corresponding commercial infrastructure consisting of the right to offer employment to Cerecor's sales force and the assignment of supporting commercial contracts, retaining as our only commercial product, Millipred, an oral prednisolone indicated across a wide variety of inflammatory conditions (the "Aytu Divestiture"). As a result, the Pediatric Portfolio met all conditions required in order to be classified as discontinued operations. Accordingly, unless otherwise noted, the following section focuses on results of operations from continuing operations only for all periods discussed.

Comparison of the Three Months Ended June 30, 2020 and 2019

Product Revenue, net

Net product revenue was \$1.3 million for the three months ended June 30, 2020, which was relatively consistent with the net product revenue for the three months ended June 30, 2019 of \$1.4 million.

Cost of Product Sales

Cost of product sales was \$0.1 million for the three months ended June 30, 2020, as compared to \$(1.5) million for the three months ended June 30, 2019. The \$1.5 million reversal of expense for the three months ended June 30, 2019 was driven by a settlement agreement the Company entered into related to the Ulesfia product during the second quarter of 2019, which fully released the Company of its minimum purchase obligations and minimum royalty provisions related to the Ulesfia product.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Preclinical expenses	\$ 1,572	\$ 667
Clinical expenses	1,347	1,691
CMC expenses	1,204	755
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	1,201	474
Stock-based compensation expense	391	121
Other	202	5
	<u>\$ 5,917</u>	<u>\$ 3,713</u>

Research and development expenses increased \$2.2 million for the three months ended June 30, 2020 compared to the same period in 2019. The overall increase was driven by an increase in research and development activities in the current year as the Company expanded its pipeline assets as a result of the Aevi Merger and continued to develop its existing pipeline assets during the quarter.

Preclinical expenses increased \$0.9 million primarily due to additional spending related to the Aevi Merger. Chemistry, Manufacturing, and Controls ("CMC") expenses increased \$0.4 million for the three months ended June 30, 2020 compared to the same period in 2019 due to additional spending on manufacturing to support clinical development as a result of the Company acquiring the rights to additional assets from the Aevi Merger. These increases were partially offset by a \$0.3 million decrease in clinical expenses driven by minimal spend on clinical development of CERC-301 as the Company began exploring strategic alternatives for the asset during 2019.

Salaries, benefits and related costs increased by \$0.7 million compared to the same period in 2019 mainly due to an increase in headcount as a result of the Aevi Merger and salary-related costs to grow our research and development activities as we continue to invest in our expanded pipeline. Stock-based compensation increased by \$0.3 million mainly due to an increase in stock option grants as a result of the increased headcount due to the Aevi Merger and the Company's annual stock option grant in April 2020.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	\$ 1,756	\$ 1,226
Legal, consulting and other professional expenses	1,804	774
Stock-based compensation expense	2,286	196
Other	255	145
	<u>\$ 6,101</u>	<u>\$ 2,341</u>

General and administrative expenses were \$6.1 million for the three months ended June 30, 2020, which represents a \$3.8 million increase from the prior period. The increase was largely driven by a \$2.1 million increase in stock-based compensation expense as a result of \$0.8 million of expense recognized related to an equity award granted to the Company's Chairman of the Board during the second quarter of 2020, expense recognized related to the modifications of certain former executives' and board members' equity awards due to leadership changes during the quarter and an increase in stock option grants as a result of the Company's annual grant in April 2020 and increased headcount as a result of the Aevi Merger. Additionally, legal, consulting and other professional expenses increased by \$1.0 million due to increased patent costs driven by the additional assets acquired as part of Aevi Merger, increased recruiting costs, and increased legal fees related to leadership changes and contract reviews performed. Salaries, benefits and related costs increased \$0.5 million mainly due to a severance accrual related to the resignation of an executive during the second quarter of 2020.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	\$ 183	\$ 121
Stock-based compensation expense	87	57
Advertising and marketing expense	366	148
Other	17	—
	<u>\$ 653</u>	<u>\$ 326</u>

Sales and marketing expenses of continuing operations consist of expenses related to advertising and marketing initiatives to support the go-to-market strategy of our pipeline assets and the respective salaries and stock-based compensation to support such initiatives. The overall \$0.3 million increase for the three months ended June 30, 2020 as compared to the same period in 2019 was primarily driven by a \$0.2 million increase in advertising and marketing expense related to market research and a \$0.1 million increase in salaries, benefits and related costs driven by increased headcount to support such initiatives.

Amortization Expense

The following table summarizes our amortization expense for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Amortization of intangible assets	\$ 404	\$ 335

Amortization expense of the continuing operations relates to the amortization of the Company's acquired Millipred product marketing rights and amortization of the assembled workforce acquired as part of the Aevi Merger. As a result of the asset acquisition accounting treatment of the Aevi Merger in the first quarter of 2020, the Company recorded an assembled workforce intangible asset of \$0.7 million, which was assigned a two-year useful life. Therefore, the \$0.1 million increase to amortization expense for the three months ended June 30, 2020 as compared to the prior period was primarily driven by the amortization expense of the assembled workforce acquired as part of the Aevi Merger.

Other (Expense) Income, Net

The following table summarizes our other income (expense), net for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Change in fair value of Investment in Aytu	\$ (1,872)	\$ —
Change in fair value of warrant liability and unit purchase option liability	3	19
Other income (expense), net	396	—
Interest income, net	9	38
	<u>\$ (1,464)</u>	<u>\$ 57</u>

Other expense, net increased \$1.5 million for the three months ended June 30, 2020 as compared to the prior period. Other expense, net is mainly comprised of a \$1.9 million loss on change in the fair value of the Company's Investment in Aytu. As consideration of the Aytu Divestiture in November 2019, the Company received 9,805,845 shares of Aytu Series G Preferred Stock, which was remeasured at the current fair value each reporting period with the change in fair value recorded to other (expense) income, net in the accompanying statements of operations. In April 2020, the Company converted its shares of Aytu Preferred Stock into approximately 9.8 million shares of common and sold that common stock for net proceeds of approximately \$12.8 million. Therefore, the Company's Investment in Aytu was \$0 as of June 30, 2020, which represented a \$1.9 million loss on change in the fair value for the three months ended June 30, 2020. The loss was driven by a decrease in Aytu's stock price from March 31, 2020 to the dates the Company sold its shares of Aytu common stock in mid-April 2020.

The increase in other expense, net was partially offset by other income recognized on the \$0.4 million Payroll Protection Program ("PPP") Loan received by the Company during the second quarter of 2020. The PPP Loan Program is part of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") which serves to provide certain small businesses with liquidity to support their operations during the COVID-19 pandemic. PPP Loans are eligible for forgiveness under certain conditions. The Company believes it meets the criteria for forgiveness and plans to submit an application for forgiveness during the third quarter of 2020. Therefore, the Company recognized \$0.4 million as other income for the three months ended June 30, 2020.

Income Tax (Benefit) Expense

The following table summarizes our income tax (benefit) expense for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Income tax (benefit) expense	\$ (454)	\$ 53

The Company recognized an income tax benefit of \$0.5 million for the three months ended June 30, 2020 and income tax expense of \$0.1 million for the three months ended June 30, 2019. The 2020 tax benefit recognized was a result of a current year tax law change and the ability of the Company to now carry back certain losses related to the CARES Act and related state tax provisions. The expense recognized for the three months ended June 30, 2019 was a result of interest on an unpaid tax liability related to the 2017 tax year and state taxes.

Comparison of the Six Months Ended June 30, 2020 and 2019

Product Revenue, net

Net product revenue was \$4.1 million for the six months ended June 30, 2020, which was relatively consistent with the net product revenue for the six months ended June 30, 2019.

Cost of Product Sales

Cost of product sales were \$0.1 million for the six months ended June 30, 2020, as compared to \$(0.7) million for the six months ended June 30, 2019. During the second quarter of 2019, the Company entered into a settlement agreement related to the

Ulesfia product, which fully released the Company of its minimum purchase obligations and minimum royalty provisions related to the Ulesfia product resulting in a reversal of expense of approximately \$1.6 million. The reversal of expense was partially offset by minimum royalty obligations related to the Ulesfia product recognized in the first quarter of 2019 prior to entering into the settlement agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Preclinical expenses	\$ 2,818	\$ 1,547
Clinical expenses	1,944	3,280
CMC expenses	2,370	1,190
Internal expenses not allocated to programs:		
Salaries, benefits and related costs	2,514	908
Stock-based compensation expense	772	178
Other	267	11
	<u>\$ 10,685</u>	<u>\$ 7,114</u>

Research and development expenses increased \$3.6 million for the six months ended June 30, 2020 compared to the same period in 2019. The overall increase was driven by an increase in research and development activities in the current year as the Company expanded its pipeline assets as a result of the Aevi Merger and continued to develop its existing pipeline assets during the quarter.

Salaries, benefits and related costs increased by \$1.6 million compared to the same period in 2019 mainly due to an increase in headcount as a result of the Aevi Merger and salary-related costs to grow our research and development activities as we continue to invest in our expanded pipeline. Additionally, the Company recognized \$0.3 million of severance within salaries, benefits and related costs for the six months ended June 30, 2020 related to a separation agreement entered into with a research and development executive during the first quarter of 2020. There was no severance for the six months ended June 30, 2019.

Preclinical expenses increased \$1.3 million primarily due to additional spending related to the Aevi Merger. Similarly, Chemistry, Manufacturing, and Controls ("CMC") expenses increased \$1.2 million for the six months ended June 30, 2020 compared to the same period in 2019 due to additional spending on manufacturing to support development of the Company's expanded pipeline. These increases were partially offset by a \$1.3 million decrease in clinical expenses driven by minimal spend on clinical development of the Company's non-core neurology assets as the Company began exploring strategic alternatives for the asset during 2019.

Acquired In-Process Research and Development Expenses

On February 3, 2020, the Company consummated its merger with Aevi, which was recorded as an asset acquisition. As a result, the Company acquired \$25.5 million of in-process research and development ("IPR&D") for two clinical stage pipeline assets for rare and orphan diseases (CERC-006 and CERC-007). The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense as the IPR&D asset has no other alternate use due to the stage of development. There was no acquired in-process research and development expense for the six months ended June 30, 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	\$ 2,768	\$ 2,456
Legal, consulting and other professional expenses	2,588	1,661
Stock-based compensation expense	2,992	665
Other	429	235
	<u>\$ 8,777</u>	<u>\$ 5,017</u>

General and administrative expenses increased \$3.8 million for the six months ended June 30, 2020 compared to the same period in 2019. The increase was largely driven by a \$2.3 million increase to stock-based compensation expense as a result of \$0.8 million of expense recognized related to an equity award granted to the Company's Chairman of the Board during the second quarter of 2020, expense recognized related to the modifications of certain former executives' and board members' equity awards due to leadership changes during the quarter and an increase in stock option grants as a result of the Company's annual grant in April 2020 and increased headcount as a result of the Aevi Merger. Legal, consulting and other professional expenses increased by \$0.9 million due to increased patent costs driven by the additional assets acquired as part of the Aevi Merger, increased recruiting costs, and increased legal fees related to leadership changes and contract reviews performed. Additionally, salaries, benefits and related costs increased \$0.3 million mainly due to a severance accrual related to the resignation of an executive during the second quarter of 2020.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Salaries, benefits and related costs	\$ 317	\$ 306
Stock-based compensation expense	142	78
Advertising and marketing expense	848	338
Other	23	—
	<u>\$ 1,330</u>	<u>\$ 722</u>

Sales and marketing expenses of continuing operations consist of expenses related to advertising and marketing initiatives to support the go-to-market strategy of our pipeline assets and the respective salaries and stock-based compensation to support such initiatives. The overall \$0.6 million increase for the six months ended June 30, 2020 as compared to the same period in 2019 was primarily driven by a \$0.5 million increase in advertising and marketing expense related to market research and a \$0.1 million increase in stock-based compensation expense driven by an increase in stock option grants as a result of the Company's annual grant in April 2020 and increased headcount as a result of the Aevi Merger which closed during the first quarter of 2020.

Amortization Expense

The following table summarizes our amortization expense for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Amortization of intangible assets	834	669

Amortization expense of the continuing operations relates to the amortization of the Company's acquired Millipred product marketing rights and amortization of the assembled workforces acquired as part of the Ichorion Acquisition and Aevi Merger. As a result of the asset acquisition accounting treatment of the Aevi Merger in the first quarter of 2020, the Company recorded an assembled workforce intangible asset of \$0.7 million, which was assigned a two-year useful life. Therefore, the \$0.2

million increase to amortization expense for the six months ended June, 2020 as compared to the prior period was primarily driven by the amortization expense of the assembled workforce acquired as part of the Aevi Merger.

Other Income, Net

The following table summarizes our other income (expense), net for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Change in fair value of Investment in Aytu	5,208	—
Change in fair value of warrant liability and unit purchase option liability	14	(29)
Other income (expense), net	396	(9)
Interest income, net	19	69
	<u>\$ 5,637</u>	<u>\$ 31</u>

Other income, net increased \$5.6 million for the six months ended June 30, 2020 as compared to the prior period. Other income, net is mainly comprised of a \$5.2 million gain on change in the fair value of the Company's Investment in Aytu. As consideration of the Aytu Divestiture in November 2019, the Company received 9,805,845 shares of Aytu Series G Preferred Stock, which was remeasured at the current fair value each reporting period with the change in fair value recorded to other (expense) income, net in the accompanying statements of operations. In April 2020, the Company converted its shares of Aytu Preferred Stock into approximately 9.8 million shares of common and sold that common stock for net proceeds of approximately \$12.8 million, thus representing a realized gain of \$5.2 million from December 31, 2019, which was recognized in the change in fair value of Investment in Aytu within the accompanying condensed consolidated statement of operations. The gain was primarily driven by a significant increase in Aytu's stock price from December 31, 2019 to the dates the Company sold its shares of Aytu common stock in mid-April 2020.

Additionally, the Company recognized \$0.4 million of other income for the six months ended June 30, 2020 related to the PPP Loan received during the second quarter of 2020. The PPP Loan Program is part of the CARES Act, which serves to provide certain small businesses with liquidity to support their operations during the COVID-19 pandemic. PPP Loans are eligible for forgiveness under certain conditions. The Company believes it meets the criteria for forgiveness and submitted an application for forgiveness in July 2020. Therefore, the Company recognized \$0.4 million as other income for the three months ended June 30, 2020.

Income Tax (Benefit) Expense

The following table summarizes our income tax (benefit) expense for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Income tax (benefit) expense	(2,611)	184

The Company recognized an income tax benefit of \$2.6 million for the six months ended June 30, 2020 and income tax expense of \$0.2 million for the six months ended June 30, 2019. The tax benefit recognized for the six months ended June 30, 2020 was a result of a current year tax law change and the ability of the Company to now carry back certain losses related to the CARES Act and related state tax provisions. The expense recognized for the six months ended June 30, 2019 was a result of interest on an unpaid tax liability related to the 2017 tax year and state taxes

Liquidity and Capital Resources

In June 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock (inclusive of 1,980,000 shares that were sold pursuant to the underwriter's full exercise of its option to purchase additional shares of Cerecor's common stock) for net proceeds of approximately \$35.4 million. In March 2020, the Company entered into a securities purchase agreement with its largest stockholder, Armistice Capital, LLC ("Armistice"), pursuant to which the Company sold 1,951,219 shares of the Company's common stock for net proceeds of approximately \$3.9 million. In February 2020, the Company closed a registered direct offering with institutional investors of 1,306,282 shares of the Company's common stock for net proceeds of

approximately \$5.1 million. See Note 9 for more information regarding these financings. Additionally, in April 2020, the Company converted its shares of Aytu preferred stock that were acquired in the fourth quarter of 2019 and subsequently sold that common stock, which generated net proceeds of approximately \$12.8 million. As of June 30, 2020, Cerecor had \$45.4 million in cash and cash equivalents.

In order to meet its cash flow needs, the Company applies a disciplined decision-making methodology as it evaluates the optimal allocation of the Company's resources between investing in the Company's existing pipeline assets and acquisitions or in-licensing of new assets. For the six months ended June 30, 2020, Cerecor generated a net loss of \$34.4 million and negative cash flow from operations of \$14.3 million. As of June 30, 2020, Cerecor had an accumulated deficit of \$148.7 million.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern; however, the Company expects to incur additional losses in the future in connection with its research and development activities and will require additional financing to fund its operations and to continue to execute its business strategy. The Company plans to use its current cash on hand, the anticipated cash flows from the Company's profits from Millipred product sales and/or the potential proceeds from a possible out-license or sale of Millipred to a third party to offset costs related to its pipeline assets, business development, and costs associated with its organizational infrastructure; however, Cerecor expects to continue to incur significant expenses and operating losses for the immediate future as it continues to invest in the Company's pipeline assets. The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional equity and/or debt capital, sell assets and/or obtain government funding; however, there can be no assurance that it will be able to do so nor that such activities will generate sufficient amounts, if any, on terms acceptable to the Company.

Over the long term, the Company's ultimate ability to achieve and maintain profitability will be dependent on, among other things, the development, regulatory approval, and commercialization of its pipeline assets, and the potential sale of any PRVs it receives, in order to support its cost structure and pipeline asset development.

These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements included in this Quarterly Report were issued. To alleviate these conditions, the Company is evaluating the potential out-licensing or sale of Millipred, its non-core neurology pipeline assets and/or some combination of rights to future PRV sales, equity or debt financings, collaborations, other out-licensing arrangements, strategic alliances, federal and private grants, marketing, other distribution or licensing arrangements, or the sale of current or future assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. Due to the uncertainty regarding future financings and/or other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report were issued.

Uses of Liquidity

The Company uses cash to fund research and development expenses related to its core asset pipeline, business development and costs associated with its organizational infrastructure.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (14,294)	\$ (9,839)
Investing activities	11,586	(257)
Financing activities	44,583	8,914
Net increase (decrease) in cash and cash equivalents	\$ 41,875	\$ (1,182)

Net cash used in operating activities

Net cash used in operating activities was \$14.3 million for the six months ended June 30, 2020, consisting primarily of a net loss of \$34.4 million, which was driven by increased research and development activities as the Company continued to fund its pipeline of development assets, and non-cash adjustments to reconcile net loss to net cash used in operating activities including a \$5.2 million realized gain related to the change in fair value of the Investment in Aytu and a \$1.8 million gain related to the change in value of the Guarantee associated with the Aytu Divestiture. This decrease was offset by the following non-cash adjustments: non-cash acquired IPR&D expense of \$25.5 million and non-cash stock-based compensation of \$3.9 million. Additionally, changes in net assets, increased by a net \$2.8 million, mainly driven by a \$1.9 million increase in other receivables. Other receivables increased mainly due to a \$2.2 million income tax receivable.

Net cash used in operating activities was \$9.8 million for the six months ended June 30, 2019 and consisted primarily of a net loss of \$13.7 million, which was driven by increased research and development activities as the Company continued to fund its pipeline of development assets and also by increased sales and marketing expenses incurred to support commercial sales activities. The net loss was partially offset by non-cash depreciation and amortization of \$2.2 million, non-cash impairment of intangible assets of \$1.4 million related to the impairment of an intangible asset (of discontinued operations), non-cash stock-based compensation expense of \$1.1 million, and changes in working capital, primarily, a decrease in accrued expenses and other liabilities of \$6.3 million offset by a decrease in other receivables of \$5.3 million.

Net cash used in investing activities

Net cash provided by investing activities was \$11.6 million for the six months ended June 30, 2020 and consisted primarily of net proceeds of \$12.8 million from the sale of the common stock during the second quarter of 2020 underlying the Company's previous Investment in Aytu, slightly offset by transaction costs incurred as part of the Aevi Merger.

Net cash used in investing activities was \$0.3 million for the six months ended June 30, 2020 and consisted primarily of the purchase of property and equipment in connection with the Company occupying its corporate headquarters during the first quarter of 2019.

Net cash provided by financing activities

Net cash provided by financing activities was \$44.6 million for the six months ended June 30, 2020 and consisted primarily of net proceeds of \$35.4 million from an underwritten public offering of common stock for 15,180,000 shares of common stock of the Company. The Company also received \$5.1 million from a registered direct offering with certain institutional investors, which included Armistice, that closed in February 2020 for the sale of 1,306,282 shares of common stock of the Company and \$3.9 million from a private placement of equity securities with Armistice during March 2020.

Net cash provided by financing activities was \$8.9 million for the six months ended June 30, 2019 and consisted primarily of net proceeds of approximately \$9.0 million from the underwritten public offering of common stock for 1,818,182 shares of common stock of the Company. Additionally, for the six months ended June 30, 2019, the Company received \$0.3 million of proceeds from exercise of stock options and warrants and \$0.1 million of proceeds from sales of common stock under the employee stock purchase plan. The increase was partially offset by \$0.4 million payment of contingent consideration related to the Avadel pediatric product's acquisition.

Critical Accounting Policies, Estimates, and Assumptions

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements included in this Quarterly Report, which have been prepared in accordance with GAAP. In preparing the financial statements in conformity with GAAP, the Company makes estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements (including those relating to the Guarantee and Investment in Aytu), cash flows used in management's going concern assessment, income taxes, goodwill, and other intangible assets and clinical trial accruals. The Company believes, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise. Our most critical accounting estimates and assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 11, 2020 except for the recently adopted accounting standards described in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this

Quarterly Report on Form 10-Q. There have been no material changes to our critical accounting policies during the six months ended June 30, 2020

Off-Balance Sheet Arrangements

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

Recently Adopted Accounting Pronouncements

See Item 1 of Part I, “Notes to Unaudited Financial Statements,” Note 2, of this Quarterly Report on Form 10-Q.

JOBS Act

The JOBS Act contains provisions that, among other things, reduce reporting requirements for an “emerging growth company.” As an emerging growth company, we have elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

In November 2017, Cerecor acquired TRx Pharmaceuticals, LLC ("TRx") and its wholly-owned subsidiaries, including Zylera Pharmaceuticals, LLC, and its franchise of commercial medications (the "TRx Acquisition"). TRx was owned by Fremantle LLC ("Fremantle") and LRS International, LLC ("LRS", and collectively, the "former TRx owners"). A portion of the consideration for TRx Acquisition included shares of Cerecor common stock. The TRx Acquisition also included certain earn-outs for the former TRx owners for Cerecor achieving gross profit targets in the sales of the TRx acquired products. Currently, the former TRx owners beneficially own more than 10% of Cerecor's outstanding common stock.

On December 19, 2019, Cerecor, through its law firm, received a letter from an attorney on behalf of the former TRx owners dated December 18, 2019, which enclosed a draft complaint seeking relief against Cerecor and one of the members of its board of directors. The letter further threatened that if an immediate discussion regarding a settlement did not occur, that the lawsuit would be filed on December 24, 2019. The parties met for a pre-lawsuit mediation in June 2020, however no resolution was reached. As of the date of this filing, no lawsuit has been filed. The proposed complaint indicates that the former TRx owners would seek the following relief: (a) \$3,000,000 on the grounds that commercially reasonable efforts to sell the acquired TRx products would have resulted in the gross profit earn-out target being reached; (b) that the \$3,000,000 amount be trebled as a result of Cerecor's alleged improper conduct; (c) \$9,200,000 as a result of alleged losses resulting from the alleged improper treatment of the former TRx owners as affiliates; and (d) the removal of any restrictions on the former TRx owners' shares of common stock in Cerecor. Cerecor disputes that the former TRx owners are entitled to the relief sought and intends to vigorously defend against any lawsuit filed on behalf of the former TRx owners.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 11, 2020, our Quarterly Report on Form 10-Q filed with the SEC on May 7, 2020 and our Current Report on Form 8-K filed with the SEC on June 9, 2020 which could materially affect our business, financial condition, or future results. Our risk factors as of the date of this Quarterly Report on Form 10-Q have not changed materially from those described in the Form 10-K, 10-Q and 8-K referenced above. The risks described in the Form 10-K, 10-Q and 8-K referenced above are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, or future results of operations and the trading price of our common stock.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.25#	Employment Agreement, dated September 26, 2019, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 27, 2020).
10.26#	Letter Agreement, dated April 23, 2020, by and between Cerecor Inc. and Christopher Sullivan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on April 27, 2020).
10.27#	Separation Agreement, dated April 24, 2020, by and between Cerecor Inc. and Simon Pedder (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on April 27, 2020).
10.28*+	Amended and Restated Clinical Development and Option Agreement, dated May 28, 2020, by and between Aevi Genomic Medicine, LLC and Kyowa Kirin Co., Ltd., formerly known as Kyowa Hakko Kirin Co., Ltd.
10.29#	Cerecor Inc. Third amended and Restated 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 18, 2020).
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three and Six Months Ended June 30, 2020 and 2019; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Six Months Ended June 30, 2020 and 2019; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the Three and Six Months Ended June 30, 2020 and 2019; and (v) Notes to Unaudited Financial Statements
104	Cover Page Interactive Data File, formatted in iXBRL (included in Exhibit 101)

Management contract or compensatory agreement.

* Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

+ Filed herewith.

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

SIGNATURES

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

Cerecor Inc.

Date: August 6, 2020

/s/ Christopher Sullivan

Christopher Sullivan

Interim Chief Financial Officer

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

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

AMENDED AND RESTATED CLINICAL DEVELOPMENT AND OPTION AGREEMENT

This Amended and Restated Clinical Development and Plan A/B Option Agreement (this “**Agreement**”) is made and entered into effective as of this 28th day of May 2020 (the “**CDOA Effective Date**”), by and between **Kyowa Kirin Co., Ltd. (“KKC”)**, having a place of business at 1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan and formerly known as Kyowa Hakko Kirin Co., Ltd., and **Aevi Genomic Medicine, LLC (“Aevi”)**, a Delaware limited liability company and successor to Medgenics, Inc., a Delaware corporation. Each of KKC and Aevi may be referred to herein individually as a “**Party**” and together as the “**Parties**.”

INTRODUCTION

WHEREAS, the Parties have entered into the Clinical Development and Option Agreement, effective as of June 6, 2016 (as amended by Amendment No. 1 to Clinical Development and Option Agreement dated October 10, 2017 and Amendment No. 2 to Clinical Development and Option Agreement dated December 17, 2018, the “**Original CDOA**”); and

WHEREAS, KKC possessed a quantity of Anti-LIGHT mAb and certain materials and possesses proprietary cell lines relating to thereto; and

WHEREAS, KKC has provided to Aevi certain quantities of Anti-LIGHT mAb (as defined in Section 1.7 of the license agreement attached hereto as **Exhibit B**) (the “**Existing Clinical Material**”) in accordance with a Material Transfer Agreement, dated April 5, 2016 (the “**Material Transfer Agreement**”), Confidential Information (as defined in Section 5.2.1) and certain Existing INDs (as defined in Section 1.1.3); and

WHEREAS, Aevi desires KKC to transfer to Aevi the recombinant CHOK1SV stable cell line expressing Anti-LIGHT mAb, which cell line is designated as (***) (the “**Master Cell Line**”); and

WHEREAS, Aevi has been using the Existing Clinical Materials, the Confidential Information, the Existing INDs and the Additional Antibody Material (as defined in Section 1.1.4) (collectively, the “**Materials**”) in connection with conducting the Adolescent Study (as defined in Section 2.3.1); and

WHEREAS, Aevi desires to use the Materials and the Master Cell Line in connection with conducting the COVID Study (as defined in Section 2.4.1); and

WHEREAS, Aevi desires to obtain exclusive options to obtain licenses under certain intellectual property controlled by KKC to develop, manufacture and commercialize products containing Anti-LIGHT mAb (“**Licensed Products**”) in certain fields; and

WHEREAS, KKC desires to allow Aevi to use the Materials solely as permitted under this Agreement and to grant such exclusive options to Aevi, all under the terms and conditions of this Agreement, which agreement amends and restates the Original CDOA.

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

Article 1 **TRANSFER**

1.1 Information and Materials Transfer.

1.1.1 **Master Cell Line.** Subject to (a) KKC obtaining any necessary consents as set forth in Section 2.9 and (b) Lonza agreeing to perform the activities contemplated by Section 2.6 on behalf of Aevi or the Lonza Technology being sublicensed to another contract manufacturer such that such contract manufacturer can perform the activities contemplated by Section 2.6 on behalf of Aevi, KKC will deliver to Aevi or its designee the Master Cell Line. Delivery will be made FCA (INCOTERMS 2020) KKC's Takasaki Plant at an address of 100-1 Hagiwara-machi, Takasaki-shi, Gunma 370-0013. The FCA shipment terms are incorporated into this Agreement.

1.1.2 **Information Transfer.** Pursuant to the Original CDOA, KKC provided Aevi with, and during the CDOA Term (as defined in Section 7.1) KKC will continue to provide Aevi with, the access (and subject to Section 2.8, such access will extend to such employees, advisors, consultants, contractors and other representatives of Aevi as Aevi specifies) to a virtual data room and to use all of the information contained therein, which will include but not be limited to information relating to the Materials, such as clinical study reports, investigator's brochures, and the Existing INDs (as defined in Section 1.1.3), free of charge. Any and all such information contained in the virtual data room will be Confidential Information of KKC and will be subject to Section 5.2. Aevi acknowledges that the virtual data room and the Confidential Information contained therein includes information owned by one or more of (a) La Jolla Institute for Immunology (formerly La Jolla Institute for Allergy and Immunology) ("**LJI**"), (b) Lonza Sales AG, a company incorporated and registered in Switzerland ("**Lonza**"), (c) Sanofi, as successor in interest to Sanofi-Aventis, a corporation organized under the laws of France, ("**Sanofi**"), and (d) Bristol-Myers Squibb Company ("**BMS**"), and/or their respective successors and assigns (LJI, Lonza, Sanofi, and BMS and/or their respective successors and assigns, collectively, the "**KKC Licensors**"). Aevi agrees that KKC or the KKC Licensors, as applicable, will retain any and all of their respective rights in the Confidential Information.

1.1.3 **Existing IND Transfer.** Pursuant to the Original CDOA, KKC transferred and assigned to Aevi all of KKC's and its Affiliates' rights in and to IND #(***) and IND #(***) (the "**Existing INDs**") and delivered to the United States Food and Drug Administration or a successor agency in the United States with responsibilities comparable to those of the United States Food and Drug Administration ("**FDA**") the letter required by 21 CFR Part 314.72 notifying FDA of the transfer of the Existing INDs to Aevi. If this Agreement expires or terminates prior to the exercise or expiration of the Plan A/B Option, Aevi will transfer and

assign to KKC or KKC's designee the Existing INDs and all amendments or supplements thereto submitted to FDA by or on behalf of Aevi within (***) after such expiration or termination of this Agreement. If the Plan A/B Option is exercised prior to the expiration or termination of this Agreement, Aevi will retain title to the Existing INDs and all amendments or supplements thereto submitted to FDA by or on behalf of Aevi pursuant to the Plan A/B License Agreement (as defined below). In this Agreement, a Party's "**Affiliate**" means, with respect to any person or entity, any other person or entity which controls, is controlled by, or is under common control with such person or entity. A person or entity will be regarded as in control of another entity if it owns or controls more than fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.1.4 Transfer of Antibodies and Hybridoma Cell Lines. Pursuant to the Original CDOA, KKC delivered to Aevi or its designee the anti-LIGHT antibodies and related hybridoma cell lines as listed in Exhibit E (the "**Additional Antibody Materials**").

1.2 Third Party Technology. Aevi acknowledges and agrees that the Materials, including without limitation the Confidential Information, may contain some material, patent and other technologies owned or otherwise controlled by Lonza (the "**Lonza Technology**") or Sanofi (the "**Sanofi Technology**"). Aevi agrees that KKC or Lonza or Sanofi, as applicable, will retain any and all of their respective rights in the Lonza Technology and the Sanofi Technology.

1.3 No Modifications. Aevi will use the Materials solely for the purpose of conducting the Initial Development (as defined below) and deciding whether to exercise the Plan A/B Option, as described below. Aevi will not modify the Materials under any circumstances, and will not use or disclose any of the Materials, including without limitation any of the Lonza Technology or the Sanofi Technology, unless such use or disclosure is expressly permitted hereunder.

Article 2

INITIAL DEVELOPMENT

2.1 Overview. Aevi will be permitted to conduct (a) requalification of the Existing Clinical Material (as set forth in Section 2.2), (b) the Adolescent Study and the COVID Study (as set forth in Sections 2.3, 2.4 and 2.5), (c) non-GMP process development of the Licensed Products (as set forth in Section 2.6), and (d) development of anti-LIGHT diagnostic tools (the activities set forth in clauses (a), (b), (c), and (d) are collectively referred to as the "**Initial Development**"). Aevi will use commercially reasonable efforts to conduct and complete the Initial Development. The Parties acknowledge and agree that KKC has not granted Aevi any license to commercialize (including but not limited to the activities relating to importing, exporting, marketing, promoting, distribution, offering for sale and selling) diagnostic tools that utilize any of the Additional Antibody Materials under this Agreement, the Plan A/B License Agreement (as defined in Section 4.1.4(b)) or the Plan C License Agreement (as defined in Section 4.2.3), and in the case that Aevi wishes to commercialize diagnostic tools using any of the Additional Antibody Materials, Aevi must obtain the license for commercialization of such diagnostic tools from KKC. Upon Aevi's written request, KKC will negotiate in good faith such a license with Aevi.

2.2 Requalification. Consistent with the Original CDOA, Aevi requalified the Existing Clinical Material and in connection therewith transferred the Existing Clinical Material to Authorized CRO and CMOs (as defined in Section 2.8) as necessary or desirable to requalify the Existing Clinical Material.

2.3 Adolescent Study.

2.3.1 Adolescent Study Protocol. Aevi has been using and will continue to use commercially reasonable efforts to conduct the clinical study with the protocol titled “Phase IB Escalating Dose, Open-label, Signal Finding Study to Evaluate the Safety, Tolerability, and Short Term Efficacy of the anti-LIGHT monoclonal KHK252067 in Adolescents (12-18 years of age) with Crohn’s disease resistant to anti-TNF alpha monoclonal antibodies, with and without loss of function mutations in decoy receptor 3 (DcR3) (anti-LIGHT in anti-TNF_{alpha} resistant Crohn’s disease (TRaCk LIGHT)” (the “**Adolescent Study**”), the protocol for which is attached hereto in Exhibit A (the “**Adolescent Study Protocol**”). The Adolescent Study is intended to preliminarily assess (but without sufficient statistical power) whether a certain genetic mutation may identify a pediatric orphan population that may be treatable with a Licensed Product. As further set forth in Section 3.1, Aevi will bear all costs and expenses, including but not limited to FTE costs and out-of-pocket costs, incurred by or on behalf of Aevi or its Affiliates and their contractors relating to the conduct of the Adolescent Study and the analysis of the results of the Adolescent Study.

2.3.2 Conduct of the Adolescent Study. The Adolescent Study will be conducted under the Existing INDs in the United States or under new INDs in Israel (“**Adolescent Study Territory**”) which will be amended by the Parties’ mutual written agreement and in accordance with the Adolescent Study Protocol. Aevi will act as the sponsor of the Adolescent Study and conduct the Adolescent Study subject to and in accordance with the terms and conditions of this Agreement, the Adolescent Study Protocol and all Applicable Law, including but not limited to applicable Good Clinical Practices. For clarity, in the event a Regulatory Authority or Applicable Law of a country in Adolescent Study Territory but outside the Territory (as defined in the license agreement attached hereto as Exhibit B) requires or orders Aevi to continue to provide clinical drugs after the completion of the Adolescent Study in such country, Aevi shall be responsible for undertaking such requirements or orders with respect to the Licensed Product in such country at its sole cost and expense, provided that KKC will have the exclusive right to Develop, Manufacture and Commercialize the Licensed Product in such country. “**Applicable Law**” means the laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the regulatory authorities applicable to the Initial Development or other activities conducted by the Parties under this Agreement, that may be in effect from time to time in the applicable jurisdiction. “**Good Clinical Practices**” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” including without limitation related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by any other applicable regulatory authority, as they may be updated from time to time. “**Good Laboratory Practices**” means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R.

Part 58, and comparable regulatory standards promulgated by any other applicable regulatory authority, as they may be updated from time to time. “**GMP**” means current Good manufacturing practices for the manufacture of products as are required by applicable regulatory authorities and Applicable Law. In the United States, GMP will be defined under the rules and regulations of the FDA, as the same may be amended from time to time.

2.4 COVID Study.

2.4.1 COVID Study Protocol. Aevi will use commercially reasonable efforts to conduct a clinical proof of concept study that investigates the efficacy and safety of the anti-LIGHT mAb in the treatment of COVID-19 acute respiratory distress syndrome (the “**COVID Study**”), the protocol for which will be substantially similar to the protocol hereto in Exhibit F (the “**COVID Study Protocol**”). As further set forth in Section 3.1, Aevi will bear all costs and expenses, including but not limited to FTE costs and out-of-pocket costs, incurred by or on behalf of Aevi or its Affiliates and their contractors relating to the conduct of the COVID Study and the analysis of the results of the COVID Study.

2.4.2 Conduct of the COVID Study. The COVID Study will be conducted in the United States under an Investigational New Drug Application owned by Aevi. Aevi will act as the sponsor of the COVID Study and conduct the COVID Study subject to and in accordance with the terms and conditions of this Agreement, the COVID Study Protocol and all Applicable Law, including but not limited to applicable Good Clinical Practices.

2.5 Regulatory Matters and Material Safety Issues.

2.5.1 Regulatory Matters. Aevi will formulate the regulatory strategy for the Adolescent Study and the COVID Study (collectively, the “**Studies**”) and lead all communications with the Regulatory Authorities and any independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of any human subjects involved in the Studies (each, an “**IRB**”) regarding the same; provided that Aevi will inform KKC of the results of all regulatory correspondence with such Regulatory Authorities within (***) after such regulatory meetings, and will provide KKC with written minutes of such regulatory meetings within (***) after they are received by Aevi. Notwithstanding any provision of this Agreement, Aevi may disclose information relating to the Materials to such Regulatory Authorities and any IRB as required or as believed necessary to obtain approval for conducting the Studies. Aevi will disclose to KKC any and all material correspondence between Aevi and such Regulatory Authorities regarding the Initial Development, including without limitation any information discussed with the FDA in the FDA Meeting (as defined in Section 2.7.2) and FDA minutes concerning the Initial Development, within (***) after receipt or transmission thereof. In addition to the above, Aevi will disclose to KKC any and all material correspondence between Aevi and Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services (“**BARDA**”) regarding the Initial Development, including without limitation any information discussed with BARDA and minutes thereof concerning the Initial Development, within (***) after receipt or transmission thereof.

2.5.2 Material Safety Issues. If either Party believes that either of the Studies should be terminated because it is necessary to protect the safety, health or welfare of subjects enrolled in any of the Studies due to the existence of a Material Safety Issue (as defined below), then the Parties will promptly meet and discuss in good faith the safety concerns raised by such Party and consider in good faith the input, questions and advice of the other Party. “**Material Safety Issue**” means a Party’s good faith belief that there is an unacceptable risk for harm in humans based upon the observation of serious adverse effects in humans after the Material has been administered to or taken by humans.

2.6 Non-GMP Process Development. Subject to (a) KKC obtaining any necessary consents as set forth in Section 2.9, (b) Lonza agreeing to perform the activities contemplated by this Section 2.6 on behalf of Aevi or the Lonza Technology being sublicensed to another contract manufacturer such that such contract manufacturer can perform the activities contemplated by this Section 2.6 on behalf of Aevi, and (c) the successful requalification of the Existing Clinical Material (as set forth in Section 2.2), Aevi will use commercially reasonable efforts to conduct or have conducted the non-GMP process development for the purpose of demonstrating that Aevi can manufacture Licensed Products that are biologically equivalent to the Existing Clinical Materials. As soon as reasonably practicable following the CDOA Effective Date, Aevi will provide to KKC a plan to effect the foregoing, which will include the identity of any person other than a Party or any of its Affiliates (each, a “**Third Party**”) that Aevi proposes to use in the conduct of such non-GMP process development.

2.7 Initial Development Data.

2.7.1 Records and Reporting. Aevi will maintain complete and accurate records of all work conducted with respect to the Initial Development, which, for clarity, includes records for work performed pursuant to the Material Transfer Agreement, including without limitation the “Testing Data” and “Requalification Data” (each as defined in the Material Transfer Agreement), and all other results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or on behalf of Aevi in the course of conducting the Initial Development (collectively, “**Initial Development Data**”). For clarity, the SAS datasets from the Studies will be included in the Initial Development Data. The Parties will hold a telephonic or in person meeting at least once each calendar quarter for sharing updates and discussing action plans on issues related to the Initial Development, including, but not limited to, the Studies, and non-GMP process development. Aevi will disclose to KKC any clinical trial data from the Adolescent Study received from the Children’s Hospital of Philadelphia (“**CHOP**”) promptly after Aevi receives such data. Aevi will maintain the Initial Development Data in its database and will upon KKC’s request, use good faith efforts to provide KKC with a copy or an electronic file of the Initial Development Data for KKC’s use within (***) of receipt of such request. Additionally, upon KKC’s reasonable request, Aevi will provide to KKC a copy or an electronic file of the topline data from the completed Studies in its possession within (***) following receipt of such request. The topline data will consist of the summary tables of efficacy and safety, as defined in the Adolescent Study Protocol or COVID Study Protocol, and will be compiled and prepared following database lock and all necessary QA/QC activities.

2.7.2 Adolescent Study Report and COVID Study Report. No later than (***) after the date of database lock for the Adolescent Study in accordance to TRaCk LIGHT, Aevi will provide KKC with a preliminary study report, including without limitation tables, figures, and listings (the “**Adolescent Study Report**”). Upon delivery of the Adolescent Study Report, Aevi will notify KKC whether Aevi will seek a meeting (such as an end of phase (“EOP”), EOP2a, EOP2 or Type C meeting, as applicable) with the FDA regarding the Adolescent Study and continued development of Anti-LIGHT mAb (“**FDA Meeting**”). Similarly, no later than (***) after the date of database lock for the COVID Study, Aevi will provide KKC with a preliminary study report, including without limitation tables, figures, and listings (the “**COVID Study Report**”).

2.8 Subcontracting; Affiliates. Aevi may transfer the Materials to its Affiliates, contract manufacturers, contract laboratories, contract research organizations and clinical sites as necessary or desirable to conduct the Initial Development on behalf of Aevi, subject to this Section 2.8. The Parties agree that CHOP and (***) performed the requalification activities for the Adolescent study set forth in Section 2.2. Aevi will not use any trial site for the COVID Study without obtaining KKC’s prior written consent, not to be unreasonably withheld, conditioned or delayed. In addition, Aevi will not use any contract research organization or contract manufacturing organization in connection with the Initial Development without obtaining KKC’s prior written consent, not to be unreasonably withheld, conditioned or delayed (any such approved contractor, a “**Authorized CRO and CMO**”). Aevi will only be permitted to transfer any of the Materials to its Affiliates and each Authorized CRO and CMO. Notwithstanding any such subcontracting, Aevi will remain at all times fully responsible for its obligations under this Agreement. Any agreement with a Third Party to perform Aevi’s responsibilities under this Agreement will include confidentiality and non-use provisions which are no less stringent than those set forth in Article 5.

2.9 Required Consents.

2.9.1 Following KKC’s receipt of Aevi’s proposed plan for the applicable Initial Development, including without limitation under Sections 2.3.2 and 2.4.1, and including the identity of any and all proposed subcontractors, KKC will use commercially reasonable efforts to obtain any additional consents or permissions, in form and substance reasonably acceptable to Aevi, from any Third Party with whom KKC has a contractual relationship that are reasonably necessary for Aevi to conduct such Initial Development.

2.9.2 Lonza Technology. Notwithstanding the foregoing, Aevi acknowledges that Lonza does not permit tiered sublicensing of its technology. With respect to the Lonza Technology and activities contemplated by Section 2.6, Aevi will negotiate with Lonza in an attempt to obtain Lonza’s agreement to (a) perform the activities contemplated by Section 2.6 on behalf of Aevi under terms acceptable to Aevi, it being understood that such terms include, but are not limited to, price, facility and resource availability and commitments for commercial scale manufacturing using Aevi’s preferred technology platform (the “**Aevi Lonza Supply Agreement**”) or (b) license the Lonza Technology directly to Aevi, including the right to sublicense to another contract manufacturer such that such contract manufacturer can perform

the activities contemplated by Section 2.6 on behalf of Aevi as well as commercial supply (the “**Aevi Lonza Plan A/B License Agreement**”). If such negotiations do not result in a mutually agreed upon Aevi Lonza Supply Agreement or Aevi Lonza Plan A/B License Agreement, then (***); provided that, if the terms of the proposed Aevi Lonza Plan A/B License Agreement do not require (i) upfront payments or milestone payments payable by Aevi to Lonza in excess of (***) and (ii) royalties and annual fees (for using a contract manufacturer that is not Lonza) payable by Aevi to Lonza in excess of the royalties and annual fees payable by KKC to Lonza under the Multi Product Licence Agreement between Lonza Sales AG and Kyowa Hakko Kirin Co., Ltd. (as successor to Kyowa Hakko Kogyo Co., Ltd. and Biowa, Inc.) dated July 15, 2008 (the “**KKC Lonza Plan A/B License Agreement**”), and the terms thereof are otherwise substantially similar in substance to the KKC Lonza Plan A/B License Agreement, Aevi will be required to enter into the Aevi Lonza Supply Agreement or Aevi Lonza Plan A/B License Agreement and KKC will not be required to sublicense the Lonza Technology to an Authorized CRO and CMO.

2.10 No Further Obligations. The Parties understand and agree that, except for the obligations, expressly set forth herein, KKC will have no other obligations or liability under this Agreement with respect to the conduct of the Initial Development. Aevi shall be responsible for all requirements and obligations under the contract between Aevi and BARDA (the “**BARDA Contract**”). KKC has no obligation for any research, Development, Manufacturing and/or Commercialization of Licensed Product under the BARDA Contract.

2.11 Defined Terms. Any capitalized terms that are not defined in this Agreement will have their respective meanings set forth in the license agreement attached hereto as Exhibit B.

Article 3

COSTS

3.1 Initial Development Costs. Aevi will bear all costs and expenses, including but not limited to FTE costs and out-of-pocket costs, incurred by or on behalf of Aevi or its Affiliates and their contractors relating to the conduct of the Initial Development. For the avoidance of doubt, neither KKC nor any of its Affiliates will be responsible for any cost incurred by or on behalf of Aevi in connection to its activities conducted under this Agreement or the Initial Development.

3.2 Lonza Costs. The Parties do not anticipate that any manufacture of Anti-LIGHT mAb will occur under this Agreement. However, if during the CDOA Term (as defined in Section 7.1) Aevi contracts with an Authorized CRO and CMO for the manufacture of Anti-LIGHT mAb or for the non-GMP process development work contemplated by Section 2.6, and the entry into such contract triggers any payment obligation by KKC to Lonza, then Aevi will reimburse KKC any and all such payments that KKC makes to Lonza, provided that any such reimbursement obligations of Aevi will not exceed (***). Alternatively, if Aevi enters into the Aevi Lonza Supply Agreement or Aevi Lonza Plan A/B License Agreement, Aevi may deduct (***%***) of the upfront payments and milestone payments (but not annual fees) made by Aevi to Lonza from the initial license fee and milestone payments to be paid to KKC by Aevi under the Plan A/B

License Agreement (as defined in Section 4.1.4(b)), such deduction not to exceed (a) if the Plan A Election (as defined in Section 4.1.4(b)) and only the Plan A Election is made, (***) or (b) if the Plan B Election (as defined in Section 4.1.4(b)) and/or the Plan C Option (as defined in Section 4.2.1) is exercised, (***). For clarity, if Lonza and Aevi enter into the Aevi Lonza Plan A/B License Agreement or Plan C License Agreement and Aevi has an obligation to pay an annual fee to Lonza pursuant to the Aevi Lonza Plan A/B License Agreement or Plan C License Agreement during the CDOA Term, as between the Parties, Aevi will solely bear such annual fee, and such payment will not be subject to the deduction set forth in this Section 3.2.

Article 4 **OPTIONS**

4.1 Plan A/B Option for Plan A License Agreement or Plan B License Agreement.

4.1.1 **Option Grant.** Subject to the terms and conditions of this Agreement, KKC hereby grants to Aevi an exclusive (even as to KKC and its Affiliates) option to obtain an exclusive (even as to KKC and its Affiliates) license to Develop, Manufacture and Commercialize Licensed Products in accordance with the terms and conditions specified in Exhibit B or Exhibit C attached hereto, as elected by KKC and as more fully described in Section 4.1.4 (the “***Plan A/B Option***”).

4.1.2 **Updates to Aevi’s Representations and Warranties in Plan A/B License Agreements; Notice of Changes to Aevi In-License.** On the date on which Aevi provides the Adolescent Study Report to KKC pursuant to Section 2.7.2, Aevi will provide KKC with written updates to Section 12.4 of the license agreement attached hereto as Exhibit B and Section 12.4 of the license agreement attached hereto as Exhibit C concerning any event, condition, fact or circumstance occurring after the CDOA Effective Date that would make Aevi’s representations and warranties set forth in Section 12.4 of the license agreement attached hereto as Exhibit B and Section 12.4 of the license agreement attached hereto as Exhibit C untrue or incorrect when made as of the date on which Aevi provides such update to KKC. All such written updates are collectively referred to as the “***Aevi Disclosure Schedule Updates***.” On the date on which Aevi provides the Adolescent Study Report to KKC pursuant to Section 2.7.2, Aevi will also provide KKC with written notice of any amendment to the Aevi In-License that would have a material impact on this Agreement, which notice will provide the substance of any such amendment.

4.1.3 **Updates to KKC’s Representations and Warranties in Plan A/B License Agreements; Notice of Changes to any KKC In-License.** No later than (**) after the date on which Aevi provides the Adolescent Study Report to KKC pursuant to Section 2.7.2, KKC will provide Aevi with written updates to Section 12.2 of the license agreement attached hereto as Exhibit B and Section 12.2 of the license agreement attached hereto as Exhibit C concerning any event, condition, fact or circumstance occurring after the CDOA Effective Date that would make KKC’s representations and warranties set forth in Section 12.2 of the license agreement attached hereto as Exhibit B and Section 12.2 of the license agreement attached hereto as Exhibit C untrue or incorrect when made as of the date on which KKC provides such update to Aevi. All such written updates are collectively referred to as the “***KKC Disclosure Schedule Updates***.” No later

than (***) after the date on which Aevi provides the Adolescent Study Report to KKC pursuant to Section 2.7.2, KKC will also provide KKC with written notice of any amendment to any KKC In-License that would have a material impact on this Agreement, which notice will provide the substance of any such amendment.

4.1.4 Plan A/B Option Exercise.

(a) Aevi may exercise the Plan A/B Option by giving KKC written notice of exercise of the Plan A/B Option (the “**Plan A/B Option Exercise Notice**”) at any time beginning (***) and ending (***):

(1) (***), or

(2) (***) (such period, the “**Plan A/B Option Period**”).

(b) If Aevi provides KKC with the Plan A/B Option Exercise Notice during the Plan A/B Option Period, then on or before (***), KKC will notify Aevi in writing as to whether it elects for the license agreement attached hereto as Exhibit B to become effective (the “**Plan A Election**”) or for the license agreement attached hereto as Exhibit C to become effective (the “**Plan B Election**”), with the election between the two being in KKC’s sole discretion. If KKC fails to notify Aevi as to whether it has elected the Plan A Election or the Plan B Election on or before (***), KKC will be deemed to have elected the Plan B Election as of the expiration of (***). As of the date KKC provides notice to Aevi as to whether KKC has elected the Plan A Election or the Plan B Election or KKC being deemed to have elected the Plan B Election (the “**Plan A/B License Agreement Effective Date**”), the applicable license agreement (i.e., the license agreement attached hereto as Exhibit B if KKC elects the Plan A Election or the license agreement attached hereto as Exhibit C if KKC elects or is deemed to have elected the Plan B Election) will become fully effective (such fully effective license agreement, the “**Plan A/B License Agreement**”) and the other license agreement will not become effective and will be null and void. For the avoidance of doubt, the Plan A Election and the Plan B Election will result in different rights and obligations accruing to the Parties.

4.1.5 License Terms. The Parties acknowledge and agree that the terms and conditions specified in the license agreements attached hereto as Exhibit B and Exhibit C, respectively, reflect the agreed upon terms of the Parties with respect to any potential license to Aevi under the Plan A Election or the Plan B Election, respectively. Exhibit B and Exhibit C will not, unless otherwise expressly agreed in writing by both Parties, be subject to further negotiation except that (a) Schedule 12.4 to the license agreement attached hereto as Exhibit B and Schedule 12.4 to the license agreement attached hereto as Exhibit C will be deemed updated by the Aevi Disclosure Schedule Updates and (b) Schedule 12.2 to the license agreement attached hereto as Exhibit B and Schedule 12.2 to the license agreement attached hereto as Exhibit C will be deemed updated by the KKC Disclosure Schedule Updates.

4.2 New Option for Plan C License Agreement.

4.2.1 Option Grant. Subject to the terms and conditions of this Agreement, KKC hereby grants to Aevi an exclusive (even as to KKC and its Affiliates) option to obtain an exclusive (even as to KKC and its Affiliates) license to develop, manufacture and commercialize Licensed Products in accordance with the terms and conditions specified in Exhibit G attached hereto (the “**Plan C Option**”).

4.2.2 Option Exercise. Aevi may exercise the Plan C Option by giving KKC written notice (the “**Plan C Option Exercise Notice**”) at any time beginning (***) and ending (***) (“**Plan C Option Exercise Period**”). With the Plan C Option Exercise Notice, Aevi will share with KKC the latest draft synopsis for the subsequent pivotal study which is available to Aevi at that time.

4.2.3 License Terms. Upon and as of the date of Aevi giving KKC the Plan C Option Exercise Notice (such date, the “**Plan C License Agreement Effective Date**”), the License Agreement attached to Exhibit G (the “**Plan C License Agreement**”) is automatically and fully effective as of the date of the Plan C Option Exercise Notice. The Parties acknowledge and agree that Plan C License Agreement reflects the agreed upon terms of the Parties with respect to any potential license to Aevi under the Plan C Option. The Plan C License Agreement is not subject to further negotiation and is automatically effective upon Aevi giving KKC the Plan C Option Exercise Notice.

4.3 Coordination of Options. The Parties acknowledge that: (a) the Plan A/B Option and Plan C Option are separate and independent options; and (b) the exercise of either of such options does not (i) result in exercise or termination of the other option or (ii) relieve either Party of their obligations or waive any of their rights under this Agreement in respect of the other study (i.e. the Adolescent Study or COVID Study) the option for which remains exercisable.

4.4 Exclusivity.

4.4.1 During the CDOA Term, neither KKC nor any of its agents will (a) continue or enter into discussions, negotiations or agreements with any entity or individual other than Aevi or its Affiliates for the purpose of discussing or evaluating a possible license, collaboration, joint venture, partnership, asset sale or other business relationship that would conflict with the Plan A/B Option or the Plan C Option or the rights to be granted under the Plan A/B License Agreement (if Aevi exercises the Plan A/B Option) or the Plan C License Agreement (if Aevi exercises the Plan C Option) or (b) furnish any information with respect to, assist or participate in, or in any other manner facilitate any effort or attempt by any Third Party to do or seek to do any of the foregoing. During the CDOA Term, KKC will not modify or amend any KKC In-License in any way that would materially adversely affect Aevi’s rights or economic interest under this Agreement or the license agreements attached to Exhibits B, C and G hereto without Aevi’s prior written consent.

4.4.2 During the CDOA Term, Aevi will not modify or amend any Aevi In-License in any way that would materially adversely affect KKC’s rights or economic interest under this Agreement or the license agreements attached to Exhibits B and C hereto without KKC’s prior written consent.

Article 5
DATA; CONFIDENTIAL INFORMATION

5.1 Initial Development Data.

5.1.1 The Parties will jointly own any and all Initial Development Data. KKC or Aevi, or their respective Affiliates, will use the Initial Development Data only to conduct Initial Development as contemplated hereunder or to analyze the results of the Initial Development. During the CDOA Term (as defined in Section 7.1) and except if permitted by a Plan A/B License Agreement or Plan C License Agreement then in effect, neither Party will, without the other Party's prior written consent, use or cause any Third Party to access or use the Initial Development Data for any other purpose.

5.1.2 The Parties will jointly own any intellectual property arising from the Initial Development or the Initial Development Data ("**Initial Development IP**"), except for patents and patent applications, where ownership will follow inventorship. For clarity, Aevi will own patents and patent applications solely invented by Aevi inventors, KKC will own patents and patent applications solely invented by KKC inventors, and Aevi and KKC will jointly own patents and patent applications invented by one or more Aevi inventor and one or more KKC inventor. Inventorship will be resolved in accordance with US patent laws. During the CDOA Term, each Party may practice the Initial Development IP with a right to sublicense only with the other Party's consent, for any purpose subject to such Party's obligations under this Agreement; provided that Aevi may sublicense the Initial Development IP as necessary or desirable to conduct the Initial Development including to its Affiliates, clinical sites and each Authorized CRO and CMO. During the CDOA Term, unless expressly provided herein, the intellectual property provisions in the license agreement attached to Exhibit B will apply to any Initial Development IP. Upon exercise of the Plan A/B Option or Plan C Option, the intellectual property provisions in the Plan A/B License Agreement or the Plan C License Agreement will apply to the Initial Development IP applicable to such license agreement and this Agreement will apply to the Initial Development IP that relates to the option that remains exercisable under this Agreement. If this Agreement expires or terminates prior to the exercise of the Plan A/B Option or Plan C Option, then all rights in the Initial Development Data and any Initial Development IP (including any patents or patent applications contained therein) will revert to KKC, and Aevi, at Aevi's cost and expense, will and hereby does assign to KKC, effective as of the effective date of such expiration or termination, Aevi's entire right title and interest in and to the Initial Development Data and any Initial Development IP (including without limitation any patents or patent applications contained therein).

5.1.3 During the CDOA Term, unless explicitly authorized in this Agreement or a Plan A/B License Agreement or Plan C License Agreement then in effect, Aevi and KKC will not, without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed, file any patent application, issue any scientific publications, or conduct further clinical studies with respect to the Initial Development Data, except that the foregoing will not be construed to prohibit the clinical investigators of the Studies (including, without limitation, CHOP) from making scholarly publications of the clinical data included in

the Initial Development Data (“**Publications**”); provided that Aevi will ensure that (a) any such clinical investigator must agree to submit to KKC for its review and comment, a copy of any proposed Publication, abstract or other disclosure resulting from such activities, simultaneous with submission of the same to Aevi and at least (***) prior to any such presentation or publication, (b) such publication will not contain any references to, or otherwise disclose any of, the Confidential Information (other than such clinical data included in the Initial Development Data) without KKC’s prior written consent, and (c) that at KKC’s request, such clinical investigator will, for a reasonable period of up to (***) from initial delivery to KKC, delay revealing any subject matter included in the Initial Development Data in any publication or disclosure in order to permit the filing of patent applications.

5.2 Confidential Information.

5.2.1 Definition of Confidential Information. “**Confidential Information**” means, any information that is disclosed by or on behalf of a Party (together with its Affiliates, the “**Disclosing Party**”) to the other Party (together with its Affiliates, the “**Receiving Party**”) that is (a) identified as confidential or some other similar designation either in writing or orally, provided that any orally disclosed information is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral disclosure requesting that such information be treated as ‘Confidential Information’ hereunder, (b) manifestly confidential, whether or not marked as such, and (c) proprietary data or information of such Disclosing Party or its sublicensees, including without limitation, (i) the existence and content of this Agreement (including the Exhibits attached hereto), (ii) the Initial Development Data, (iii) the information transferred under Section 1.1, (iv) any ‘KKC Confidential Information’ as defined by the “CONFIDENTIALITY AND NONDISCLOSURE AGREEMENT” made and entered into on May 22, 2015 among the Parties, (***) and CHOP, as amended through the date hereof, and (v) the confidential information disclosed under the Original CDOA, and, for clarity, KKC will be deemed to be the Disclosing Party for purposes of this Agreement with respect to such ‘KKC Confidential Information’. Notwithstanding anything to the contrary in this Article 5, the Initial Development Data will be deemed to be Confidential Information of both Parties during the CDOA Term, and if this Agreement expires or terminates prior to exercise of the Plan A/B Option or the Plan C Option, then the Initial Development Data will be deemed to be Confidential Information of KKC.

5.2.2 Use and Disclosure. Except as permitted by a Plan A/B License Agreement or Plan C License Agreement then in effect, all Confidential Information of the Disclosing Party will be used by the Receiving Party solely in connection with the activities contemplated by this Agreement, will be maintained in confidence by the Receiving Party and will not otherwise be disclosed by the Receiving Party to any Third Party, without the prior written consent of the Disclosing Party, except to the extent that the Confidential Information (as determined by competent documentation):

(a) was known or used by the Receiving Party without restriction as to its use or disclosure prior to its date of disclosure to the Receiving Party; or

(b) either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party without restriction as to its use or disclosure by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or

(c) either before or after the date of the disclosure to the Receiving Party becomes published or generally known to the public (including without limitation information known to the public through the sale of products in the ordinary course of business) through no fault or omission on the part of the Receiving Party; or

(d) is independently developed by or for the Receiving Party without reference to or reliance upon the Confidential Information.

5.2.3 Permitted Disclosures. Notwithstanding anything to the contrary in this Agreement, the provisions of this Article 5 will not preclude the Receiving Party from disclosing Confidential Information pursuant to Section 5.1.3 or to the extent such Confidential Information is required to be disclosed by the Receiving Party (i) in any filings made to the FDA or other similar regulatory authority in the United States or any other country, provided that such filings are directly related to the Initial Development, (ii) to defend or prosecute litigation or comply with governmental regulations, (iii) in connection with a valid order from a court or other governmental authority or (iv) in compliance with Section 5.3, provided that in each such case, the Party disclosing such information will disclose no more Confidential Information than is necessary and will provide the other Party with as much prior notice of the pendency of any such disclosure as is reasonably possible to allow such other Party sufficient opportunity to object to such disclosure or to exercise its rights to seek a protective order or request for confidential treatment for any such Confidential Information. KKC and Aevi each agree that they may provide Confidential Information received from the other Party only to their respective directors, officers, employees, or permitted subcontractors under and in accordance with Section 2.8, collaborators and advisors, and to those of such Party's Affiliates, who have a need to know for the purposes of the Initial Development and who are bound by confidentiality obligations at least as strict as this Article 5. In addition, each Party may disclose the terms of this Agreement (to the extent such terms are confidential) to its actual or prospective lenders, investors, acquirers, licensees/sublicensees or strategic partners or to a Party's accountants, attorneys and other professional advisors; provided that such disclosures will be subject to continued confidentiality obligations at least as strict as those contained in this Article 5.

5.2.4 Duration. If this Agreement expires pursuant to Section 7.1(i)(a), 7.1(ii)(a) or is terminated pursuant to Section 7.2, 7.3, 7.4 or 7.5, all obligations of confidentiality imposed under this Article 5 will expire five (5) years following such expiration or termination, except with respect to a trade secret, for which such obligations of confidentiality shall expire when such trade secret is no longer a trade secret. If this Agreement expires pursuant to Section 7.1(i)(b) or 7.1(ii)(b), then the Plan A/B License Agreement and Plan C License Agreement, each to the extent in effect, supersedes this Article 5 and will govern matters concerning Confidential Information, and any and all Confidential Information will be deemed to be "Confidential Information" as such term is defined in the Plan A/B License Agreement and Plan C License Agreement, each to the extent in effect.

5.3 Publicity. Except for public disclosures (a) permitted under Section 5.1.3 or 5.2.3 or (b) required by Applicable Law or by the rules and regulations of any securities exchange on which any of a Party's securities is listed, neither Party will disclose any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the execution of this Agreement, the subject matter of this Agreement, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party. If a public disclosure, other than public disclosures concerning either or both of the Studies and the development of the anti-LIGHT mAb, is required by any Applicable Law, including, without limitation, in a filing with the Securities and Exchange Commission or submission to an exchange on which any securities of a Party is listed, the disclosing Party shall provide copies of the disclosure (omitting portions of any filing, submission or disclosure not relevant to this provision) reasonably in advance of such filing or other disclosure, for the non-disclosing Party's prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The disclosing Party will negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.

5.4 Use of Names and Trademarks. Neither Party may use the name, trademark, trade name or logo of the other Party in any publicity, news release or public disclosure relating to this Agreement or its subject matter without the prior express written permission of the other Party, except as otherwise permitted under Sections 5.1.3 or 5.2.3.

Article 6

LICENSE

6.1 License Grant. Subject to the terms and conditions of this Agreement, KKC hereby grants Aevi an exclusive (even as to KKC and its Affiliates), sublicensable (to its Affiliates and, subject to Section 6.4, Third Parties approved by KKC), milestone-free and royalty-free right and license, under the KKC Technology, solely for the purpose of conducting the Initial Development during the CDOA Term.

6.2 Sanofi Technology. Subject to the terms and conditions of this Agreement, KKC hereby grants Aevi a non-exclusive, sublicensable (to its Affiliates and, subject to Section 6.4, Third Parties approved by KKC), milestone-free and royalty-free right and license to use the Sanofi Technology solely for the purpose of conducting the Initial Development in the European Union, Switzerland, the United States, Canada, Australia or South Korea during the CDOA Term. Aevi will use the Sanofi Technology only as described in the letters from Sanofi to KKC (***) .

6.3 Lonza Technology. Subject to the terms and conditions of this Agreement and subject to obtaining Lonza's written consent, KKC will grant to Aevi a non-exclusive, sublicensable (to its Affiliates and, subject to Section 6.4, Third Parties approved by KKC), milestone-free and royalty-free right and license to use the Lonza Technology solely for the purpose of conducting the Initial Development in the United States during the CDOA Term. The Parties understand

and agree that terms and conditions of such sublicense of the Lonza Technology to Aevi will be discussed and determined by the Parties separately from this Agreement.

6.4 No Sublicensing. Aevi will not sublicense any of the rights granted to it under Section 6.1, 6.2 or 6.3 to any Third Party except to the extent required in connection with subcontracting the Initial Development to its Affiliates, CHOP, or to another clinical site or to an Authorized CRO and CMO as set forth in Section 2.8 , and only upon KKC's prior written consent, which consent will not be unreasonably withheld, delayed or conditioned; provided, however, that KKC's denial of a consent will not be considered to be unreasonable if after compliance with Section 2.9, KKC is not able to obtain the applicable consent.

6.5 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party, as a result of this Agreement, obtain any ownership interest or other right in any intellectual property rights of the other Party, including without limitation items controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.

Article 7

TERM AND TERMINATION

7.1 Term. This Agreement will become effective on the CDOA Effective Date and, unless earlier terminated pursuant to Section 7.2, 7.3, 7.4 or 7.5, will expire on the later of (i) the earlier of (a) the expiration of the Plan A/B Option Period if Aevi does not exercise the Plan A/B Option or (b) the Plan A/B License Agreement Effective Date if Aevi does exercise the Plan A/B Option, and (ii) the earlier of (a) the expiration of the Plan C Option Exercise Period if Aevi does not exercise the Plan C Option or (b) the Plan C License Agreement Effective Date if Aevi does exercise the Plan C Option (the "**CDOA Term**"). For avoidance of doubt, this Agreement will not expire when only the Plan A/B Option or Plan C Option is exercised by Aevi.

7.2 Termination for Breach. If a Party (the "**Breaching Party**") is in breach of this Agreement, the other Party (the "**Non-Breaching Party**") will have the right to give the Breaching Party notice specifying the nature of such breach. The Breaching Party will have a period of thirty (30) calendar days after receipt of such notice to cure such breach (the "**Cure Period**") in a manner reasonably acceptable to the Non-Breaching Party. The Non-Breaching Party will have the right to terminate this Agreement, effective immediately upon delivery of written notice to the Breaching Party, in the event that the Breaching Party has not cured such breach within the Cure Period, provided that, if such breach is capable of cure but cannot be cured within the Cure Period, and the Breaching Party commences actions to cure such breach within the Cure Period and thereafter diligently continues such actions, the Non-Breaching Party may only terminate this Agreement if the Breaching Party stops using diligent efforts to cure such breach. For the avoidance of doubt, this Section 7.2 is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

7.3 Termination for Insolvency. To the extent permitted under Applicable Law, either Party will have the right to terminate this Agreement in its entirety, at its sole discretion, upon delivery

of written notice to the other Party upon the filing by such other Party in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction of a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such Party or its assets, upon the proposal by such Party of a written agreement of composition or extension of its debts, or if such Party is served by a Third Party (and not by the other Party) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by such other Party of an assignment for the benefit of its creditors.

7.4 Termination for Safety Reasons. If KKC and Aevi do not agree on whether the either or both of the Studies must be terminated because of a Material Safety Issue pursuant to Section 2.5.2, Aevi will have the right to terminate this Agreement as to the applicable study. In the event KKC wishes to terminate this Agreement because of a Material Safety Issue related to either or both of the Studies but Aevi does not agree, Aevi will have the right to continue the Studies, provided that it will assume all liability for any such decision and indemnify KKC for any liability resulting in such continuation, as set forth in Section 9.4.

7.5 Termination by KKC. If the Adolescent Study Report and COVID Study Report are not provided to KKC within (***) for reasons other than reasons that are outside of Aevi's control, then KKC will have the right to terminate this Agreement effective immediately upon written notice to Aevi. KKC may also terminate this Agreement effective immediately upon written notice to Aevi as set forth in Section 8.6.2.

7.6 Effects of Expiration or Termination.

7.6.1 Upon expiration (other than pursuant to clauses (i)(b) or (ii)(b) of Section 7.1) or termination of this Agreement or if requested by KKC, Aevi will return or destroy unused supplies of the Materials, including without limitation any Confidential Information of KKC, upon the direction of KKC and at Aevi's expense. In the event Aevi destroys the unused Materials, Aevi will provide KKC with a certificate regarding compliance with this provision.

7.6.2 Upon expiration of this Agreement pursuant to Section 7.1(i)(a) or 7.1(ii)(a) or termination of this Agreement pursuant to Section 7.2, 7.3, 7.4 or 7.5, the license agreements attached hereto as Exhibits B, C and G, if not already effective at such time, will not become effective and will be null and void. Upon expiration of this Agreement pursuant to Section 7.1(i)(b) or 7.1(ii)(b), the license agreements attached hereto as Exhibits B, C and G that became effective shall remain fully effective notwithstanding that it is not separately executed by the Parties and notwithstanding expiration of this Agreement.

7.6.3 In any termination or expiration of this Agreement, KKC has no obligation for further Development, Manufacture and/or Commercialization of the Licensed Product. Aevi shall be responsible for all negotiations with BARDA for the abandonment, and KKC will not take over from Aevi any Development, Manufacture and/or Commercialization for Licensed Product requested by BARDA.

7.7 Survival. Claims accrued prior to expiration or termination of this Agreement for any reason will survive expiration or termination of this Agreement. Sections 1.1.2 (last two sentences only), 1.1.3 (second sentence only upon (a) expiration of this Agreement pursuant to Section 7.1(i)(a) or (ii)(a) or termination of this Agreement pursuant to Section 7.2, 7.3, 7.4 or 7.5, in each case only if none of the license agreements attached hereto as Exhibits B, C or G shall have become effective), 1.2, 2.10, 3.1, 3.2, 5.1.2, 5.1.3 (with respect to publication review rights), 5.2, 5.3, 5.4, 6.5, 7.6 and this 7.7 and Article 9 and Article 10 will survive any expiration or termination of this Agreement for any reason in accordance with their respective terms; provided that if the Plan A/B License Agreement becomes fully effective in accordance with Section 4.1.4(b) and/or if the Plan C License Agreement becomes fully effective in accordance with Section 4.2, to the extent there is any inconsistency between such surviving terms and the terms of the Plan A/B License Agreement and/or the terms of the Plan C License Agreement, the terms of the Plan A/B License Agreement and/or the terms of the Plan C License Agreement will control.

Article 8

REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Mutual Representations and Warranties. Each Party represents, warrants and covenants to the other Party that as of the CDOA Effective Date of this Agreement:

(a) Corporate Existence and Authority. It is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Authorized Execution; Binding Obligation.

(1) The execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized and approved by all necessary corporate action on its part.

(2) This Agreement has been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with this Agreement's terms, except as the same may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws relating to or affecting creditors' rights generally and by general equity principles, including judicial principles affecting the availability of injunction and specific performance.

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

(d) All Consents and Approvals Obtained. Except with respect to any consent required from Lonza or Sanofi, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all governmental authorities and other persons or entities required to be obtained or provided by such Party in connection with the execution,

delivery and performance of this Agreement have been obtained and provided, except for those government approvals, if any, not required at the time of execution of this Agreement.

(e) Compliance with Law. It will at all times comply with Applicable Laws in all material respects. Neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Licensed Products: (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred by the FDA (or subject to a similar sanction of a Regulatory Authority) or (ii) has ever been under indictment for a crime for which a person or entity could be so debarred.

8.2 Mutual Covenants. Each Party hereby covenants to the other Party that during the CDOA Term:

(a) all employees and officers of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their Inventions, whether or not patentable, if any, to such Party as the sole owner thereof, and under the obligation to maintain as confidential the Confidential Information of such Party;

(b) such Party will perform its activities pursuant to this Agreement in compliance with good clinical practices and good manufacturing practices, in each case as applicable under the Applicable Laws and regulations of the country and the state and local government wherein such activities are conducted, and also with the standards in the pharmaceutical industry for the development and commercialization of pharmaceutical products;

(c) neither Party will employ (or, to its knowledge, use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or, to its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority), in the conduct of its activities under this Agreement, and each contractor or consultant used by a Party in connection with the conduct of clinical trials under this Agreement will be subject to a covenant that is the same or substantially the same as the foregoing covenant;

(d) neither Party will, during the CDOA Term, practice or exploit the intellectual property licensed to such Party under this Agreement except to the extent expressly permitted under the terms and conditions of this Agreement; and

(e) neither Party will, during the CDOA Term, grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to the other Party hereunder.

8.3 KKC Representations and Warranties. KKC represents and warrants to Aevi that as of the CDOA Effective Date:

(a) KKC Controls the KKC Patent Rights existing as of the CDOA Effective Date and is entitled to grant the rights and licenses specified herein. The KKC Technology

existing as of the CDOA Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by KKC as of the CDOA Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. KKC has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to Aevi hereunder.

(b) To the knowledge of KKC, there is no actual or threatened infringement of the KKC Patent Rights in the Field by any Third Party that would adversely affect Aevi's rights under this Agreement.

(c) To the knowledge of KKC, the KKC Patent Rights existing as of the CDOA Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by KKC or any of its Affiliates relating to the KKC Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and KKC is not aware of any reasonable basis for a claim alleging that (i) the KKC Patent Rights are invalid or unenforceable, (ii) the KKC Patent Rights or the licensing or exploiting of the KKC Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party or (iii) any Third Party other than a KKC Licensor has any right, title, or interest in, to, and under any KKC Patent Rights.

(d) To the knowledge of KKC, KKC is not in default, and to KKC's knowledge, none of the KKC Licensors is in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, any KKC In-License, and KKC has not waived or allowed to lapse any of its rights under any KKC In-License, and no such rights have lapsed or otherwise expired or been terminated.

(e) There are no claims, judgments or settlements against or owed by KKC or its Affiliates or pending or threatened claims or litigation relating to the KKC Technology.

8.4 KKC Covenants. KKC covenants that during the CDOA Term:

(a) KKC will use Commercially Reasonable Efforts to fulfill its obligations under the KKC In-Licenses to the extent such obligations have not been delegated to Aevi and to the extent that failure to do so would materially adversely affect Aevi or its rights hereunder.

(b) KKC will not assign, transfer, convey or otherwise encumber its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to Aevi hereunder.

(c) KKC will not enter into any subsequent agreement with any KKC Licensor that modifies or amends any KKC In-License in any way that would materially adversely affect Aevi's rights or economic interest under this Agreement without Aevi's prior written consent.

(d) KKC will not terminate any KKC In-License in whole or in part, directly or indirectly, without Aevi's prior written consent if such termination would materially affect Aevi's license granted hereunder; for clarity KKC may (i) terminate any KKC In-License by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and KKC will promptly notify Aevi after the occurrence of each such event.

(e) KKC will furnish Aevi with copies of all notices received by KKC relating to any alleged breach or default by KKC under any KKC In-License within (***) after KKC's receipt thereof and, if KKC cannot or chooses not to cure or otherwise resolve any such alleged breach or default, KKC will so notify Aevi within (***) thereafter.

8.5 Aevi Representations and Warranties. Aevi represents and covenants to KKC that as of the CDOA Effective Date:

(a) It is not constrained by any existing agreements in providing complete disclosure to KKC concerning the Initial Development.

(b) Its facilities and those of its contractors, including without limitation any contract manufacturers, contract laboratories, contract research organizations and clinical sites, are adequate to perform the Initial Development.

(c) It will use commercially reasonable efforts to ensure that any contractors, including without limitation any contract manufacturers, contract laboratories, contract research organizations, clinical sites, and clinical investigators, conducting the Studies will be, at all times during the CDOA Term, (i) in good professional standing; (ii) in possession of all requisite professional licenses; (iii) fully qualified to conduct the Studies; and (iv) fully experienced and knowledgeable with respect to all matters pertaining to the Studies.

(d) Aevi Controls the Aevi Patent Rights existing as of the CDOA Effective Date and is entitled to grant the rights and licenses specified herein. The Aevi Technology existing as of the CDOA Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by Aevi as of the CDOA Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. Aevi has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Aevi Technology in a manner that conflicts with any rights granted to KKC hereunder.

(e) To the knowledge of Aevi, there is no actual or threatened infringement of the Aevi Patent Rights in the Field by any Third Party that would adversely affect KKC's rights under this Agreement.

(f) To the knowledge of Aevi, the Aevi Patent Rights existing as of the CDOA Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by Aevi or any of its Affiliates relating to the Aevi Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and Aevi is not aware of any reasonable basis

for a claim alleging that (i) the Aevis Patent Rights are invalid or unenforceable or (ii) the Aevis Patent Rights or the licensing or exploiting of the Aevis Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party, or (iii) any Third Party other than the Aevis Licensor has any right, title, or interest in, to, and under any Aevis Patent Rights.

(g) To the knowledge of Aevis, the Development activities set forth in the initial Development Plan do not infringe any third party intellectual property rights.

(h) To the knowledge of Aevis, Aevis is not in default, and to Aevis's knowledge, the Aevis Licensor is not in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the Aevis In-License, and Aevis has not waived or allowed to lapse any of its rights under any Aevis In-License, and no such rights have lapsed or otherwise expired or been terminated.

(i) There are no claims, judgments or settlements against or owed by Aevis or its Affiliates or pending or threatened claims or litigation relating to the Aevis Technology.

8.6 Aevis Covenants

8.6.1 General. Aevis covenants that during the CDOA Term:

(a) Aevis will not engage in any activities that use the KKC Technology in a manner that is outside the scope of the rights granted to it hereunder.

(b) All of Aevis's activities related to its use of the KKC Technology pursuant to this Agreement will comply with all Applicable Laws.

(c) Aevis will use Commercially Reasonable Efforts to fulfill its obligations under the Aevis In-License to the extent such obligations have not been delegated to KKC and to the extent that failure to do so would materially adversely affect KKC or its rights hereunder.

(d) Aevis will not assign, transfer, convey or otherwise encumber its right, title and interest in the Aevis Technology in a manner that conflicts with any rights granted to KKC hereunder.

(e) Aevis will not enter into any subsequent agreement with CHOP that modifies or amends the Aevis In-License in any way that would materially adversely affect KKC's rights or economic interest under this Agreement without KKC's prior written consent.

(f) Aevis will not terminate the Aevis In-License in whole or in part, directly or indirectly, without KKC's prior written consent if such termination would materially affect KKC's license granted hereunder; for clarity Aevis may (i) terminate the Aevis In-License by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to

make royalty and milestone payments by making a lump-sum payment, and Aevi will promptly notify KKC after the occurrence of each such event.

(g) Aevi will furnish KKC with copies of all notices received by Aevi relating to any alleged breach or default by Aevi under the Aevi In-License within (***) after Aevi's receipt thereof and, if Aevi cannot or chooses not to cure or otherwise resolve any such alleged breach or default, Aevi will so notify KKC within (***) thereafter.

8.6.2 Debarment. Neither Aevi nor its Affiliates will employ (or, to its knowledge, use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of a regulatory authority), or, to its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of a regulatory authority), in the conduct of its activities under this Agreement, and each contractor or consultant used by a Party in connection with the conduct of clinical trials under this Agreement will be subject to a covenant that is the same or substantially the same as the foregoing covenant. If, during the CDOA Term, Aevi or any person employed or retained by it to perform the Initial Development: (i) comes under investigation by the FDA for a debarment action or disqualification; (ii) is debarred or disqualified; or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, Aevi will immediately notify KKC of same and address the issue as mutually agreed upon by the Parties, provided that, if, following good faith discussions, the Parties are unable to mutually agree on a resolution to address an issue described in subsections (i)-(iii) above so that the Licensed Products are not adversely affected by such issue, then KKC may immediately terminate this Agreement on written notice to Aevi.

Article 9

LIMITATION ON LIABILITY; INDEMNIFICATION

9.1 NO WARRANTY. The Parties acknowledge and agree that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) will be construed as representing an estimate or projection of either (a) the extent to which Licensed Products will be successfully Developed or Commercialized or (b) the anticipated sales or the actual value of any Licensed Product. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT IT WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT(S). EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED

PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL. AEVI ACKNOWLEDGES THAT THE MATERIALS ARE IN THE EXPERIMENTAL STAGE AND MAY HAVE HAZARDOUS PROPERTIES AND ARE PROVIDED BY KKC “AS IS”. KKC MAKES NO REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND FOR THE MATERIALS, EITHER EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE AND KKC SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

9.2 LIMITATION ON LIABILITY. EXCEPT FOR BREACHES OF A PARTY’S CONFIDENTIALITY OBLIGATIONS HEREUNDER, OR WITH RESPECT TO ANY CLAIMS SUBJECT TO INDEMNIFICATION HEREUNDER NEITHER PARTY WILL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, OR LOSS OF BUSINESS).

9.3 Aevi Indemnity. Aevi will indemnify, defend and hold harmless KKC and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives (the “**KKC Indemnitees**”), from and against any and all damages, losses, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney’s fees) or judgments of any kind (collectively “**Losses**”), arising out of any Third Party claim, suit or proceeding, whether for money or equitable relief, (each a “**Third Party Claim**”) to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness or wrongful intentional acts or omissions of Aevi or its Affiliates or their respective directors, officers, employees, contractors, and agents, in connection with Aevi’s performance of its obligations or exercise of its rights under this Agreement during the CDOA Term; (b) any breach by Aevi of this Agreement, including without limitation any representation, warranty, or covenant set forth in this Agreement, during the CDOA Term; or (c) the use, transfer, importation or exportation, manufacture, labeling, handling or storage, or use or disposal of, or exposure to the Materials, or the conduct of the Initial Development, including without limitation for each of clauses (a), (b) and (c) above, claims and threatened claims based on (i) product liability, bodily injury, risk of bodily injury, death or property damage and (ii) the failure to comply with Applicable Law except in any such case for Losses and Third Party Claims to the extent reasonably attributable to any KKC Indemnatee having committed an act or acts of negligence, recklessness or willful misconduct. In addition, Aevi will indemnify, hold harmless, and defend the KKC Indemnitees against any and all Losses to the extent arising out of Third Party Claims related to, directly or indirectly, any activities performed by or on behalf of Aevi or an Authorized CRO and CMO, if, pursuant to Section 2.9, KKC sublicenses its rights under such KKC Technology to Aevi or an Authorized CRO and CMO.

9.4 Indemnity for Material Safety Issue. Without limiting any remedy otherwise available, or the indemnity obligations contained in Section 9.3 (but only to the extent not otherwise covered by Section 9.3), if, pursuant to Section 7.4, KKC believes that there is a Material Safety Issue and wishes to terminate this Agreement as a result, but Aevi does not agree and elects instead to continue the Studies, then Aevi will defend, indemnify and hold harmless the KKC Indemnitees against any and all any Losses arising from any claim, suit or proceeding brought either directly by KKC or its Affiliates or by any Third Party, in each case, to the extent that such claim, suit or proceeding or related Losses arise out of or relate to, directly or indirectly, any activities performed by or on behalf of Aevi in connection with the Studies following Aevi's decision to continue the Studies after KKC notifies Aevi pursuant to Section 2.5.2 that KKC believes the Studies should be terminated.

9.5 KKC Indemnity. KKC will indemnify, defend and hold harmless Aevi and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives (the "**Aevi Indemnitees**"), from and against any and all Losses arising out of any Third Party Claim to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness or wrongful intentional acts or omissions of KKC or its Affiliates or their respective directors, officers, employees, contractors and agents, in connection with KKC's performance of its obligations or exercise of its rights under this Agreement during the CDOA Term; or (b) any breach by KKC of this Agreement, including without limitation any representation, warranty, or covenant set forth in this Agreement, during the CDOA Term, including without limitation for each of clauses (a) and (b) above, claims and threatened claims based on the failure to comply with Applicable Law; except in any such case for Losses and Third Party Claims to the extent reasonably attributable to any Aevi Indemnatee having committed an act or acts of negligence, recklessness or willful misconduct.

9.6 Indemnification Procedure. A claim to which indemnification applies under Section 9.3, 9.4 or 9.5 will be referred to herein as an "**Indemnification Claim**". If any KKC Indemnatee or Aevi Indemnatee (either, an "**Indemnatee**") intends to claim indemnification under this Article 9, the Indemnatee will notify the other Party (the "**Indemnitor**") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnatee to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor will have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnatee; provided, however, that an Indemnatee will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnatee, if representation of such Indemnatee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnatee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this Section 9.6, the Indemnatee may defend the Indemnification Claim, but will have no obligation to do so. The Indemnatee will not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor will not settle or compromise the Indemnification Claim in any manner which would have an adverse effect on the Indemnatee's

interests (including without limitation any rights under this Agreement or the scope or enforceability of the either Party's intellectual property, or Confidential Information or patent or other rights licensed to Aevi by KKC hereunder), without the prior written consent of the Indemnitee, which consent, in each case, will not be unreasonably withheld, conditioned or delayed. The Indemnitee will reasonably cooperate with the Indemnitor at the Indemnitor's expense and will make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information will be considered Confidential Information and subject to Article 5.

9.7 Insurance. Aevi will maintain insurance with respect to its activities to be performed in connection with the Initial Development. Such insurance will be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time.

Article 10

MISCELLANEOUS

10.1 Entire Agreement. This Agreement, together with the Exhibits attached hereto constitutes the entire agreement between the Parties relating to the Materials, and supersedes all prior and contemporaneous negotiations and discussions between the Parties concerning its subject matter, including, without limitation, the Material Transfer Agreement and the Original CDOA. The Exhibits hereto are an integral part of this Agreement and are deemed incorporated by reference herein.

10.2 Modification and Waiver. This Agreement may be amended or waived only in a writing signed by an authorized representative of the Party against whom enforcement of the Agreement is sought.

10.3 Notices. Any consent or notice required to be given or made under this Agreement by one of the Parties to the other will be in writing and (a) delivered by hand, (b) sent by internationally recognized overnight delivery service or (c) sent by facsimile transmission and confirmed by sender by prepaid, registered or certified mail letter, and will be deemed to have been properly served to the addressee upon delivery, in any event to the following addresses:

For Aevi:
Aevi Genomic Medicine, LLC
435 Devon Park Drive - Bldg 700
Wayne, PA 19087, USA
Attention: Chief Executive Officer

For KKC:
KYOWA KIRIN CO., LTD.
1-9-2, Otemachi Chiyoda-ku
Tokyo 100-0004, Japan
Attention: Director of Business Development Department

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) if personally delivered, when delivered; (b) if sent by internationally-recognized overnight courier, on the Business Day of the sender during which the sender delivers the notice to the courier; or (c) if sent by facsimile, when all pages of the notice are successfully transmitted (as shown by a report generated by the sender's facsimile machine) during a Business Day of the sender.

10.4 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one (1) or several provisions of this Agreement will 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.

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

10.6 No Third Party Beneficiaries. No person or entity other than Aevi, KKC and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

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

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

10.9 Headings. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and will have no effect on the meaning of the provisions hereof.

10.10 No Implied Waivers; Rights Cumulative. No failure on the part of KKC or Aevi to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

10.11 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Delivery of executed copies (including by PDF) of this Agreement or counterparts thereof by facsimile, email or other electronic means will have the same legal validity as delivery of ink-signed copies.

10.12 Governing Law. This Agreement will be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York, New York, U.S.A., notwithstanding the provisions governing conflict of laws of any jurisdiction to the contrary.

10.13 Dispute Resolution.

10.13.1 Escalation. With respect to any disputes between the Parties concerning this Agreement, the dispute will be submitted to escalating levels of Aevi and KKC senior management for review. If the dispute cannot be resolved despite such escalation, then the matter will be referred to the Chief Executive Officer of Aevi (or an executive of Aevi designated by such Chief Executive Officer) and the Chief Executive Officer of KKC (or an executive of KKC designated by such Chief Executive Officer) (the “**Executive Officers**”) to be resolved by negotiation in good faith as soon as practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers will be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party may submit such dispute for arbitration pursuant to Section 10.13.2.

10.13.2 Arbitration.

(a) If any dispute will arise between KKC and Aevi in connection with or relating to this Agreement and is referred for arbitration pursuant to Section 10.13.1, then such dispute will be resolved exclusively by and through an arbitration proceeding to be conducted under the auspices of, and pursuant to, the Commercial Rules of the International Chamber of Commerce (together with any successor organization thereto, the “**ICC**”) in New York, New York, U.S.A.. Such arbitration proceeding will be conducted in the English language applying the law provided in Section 10.12 and in such an expedited manner as is then permitted by the ICC’s commercial arbitration rules. The Parties also agree to take reasonable discovery, with reasonableness to be determined by the arbitrators. Each of the foregoing agreements to arbitrate all disputes and the results, determinations, findings, judgments and awards rendered through such arbitration will be final, non-appealable and legally binding on KKC and Aevi and may be entered and enforced by any court or tribunal of competent jurisdiction. Notwithstanding

anything to the contrary in this Section 10.13, a Party may seek injunctive relief in any court of competent jurisdiction.

(b) Any arbitration proceeding will be initiated by written notice from either KKC or Aevi to the other Party. The arbitration will be conducted before a panel of three (3) arbitrators. Each of KKC and Aevi will have the right to select one (1) arbitrator. The third arbitrator will be selected by the mutual agreement of the arbitrators appointed by the Parties. The Party initiating the arbitration proceeding will appoint its arbitrator within ten (10) days following service of the demand for arbitration to the other Party, who will in turn appoint its arbitrator within thirty (30) days of receiving service of the demand. The two appointed arbitrators will agree upon an arbitrator within thirty (30) days of the date of the appointment by the Parties of the second arbitrator. If either Party or their appointees fail to appoint an arbitrator within the specified time period, the ICC will exercise its powers pursuant to Article 9 of the ICC Rules of Arbitration to appoint such arbitrator. The ICC's appointment will be binding on the Parties. Each arbitrator will be an attorney in good standing in the Bar of New York and experienced in commercial disputes involving pharmaceutical companies. Time is of the essence as regards this arbitration procedure, and KKC and Aevi will instruct the arbitrators to render their decision within ninety (90) days of the arbitration's completion. The cost of the arbitration (including, without limitation, reasonable attorneys' fees, expenses and disbursements) will be borne as the arbitrators will decide; otherwise such costs (including, without limitation, the prevailing Party's reasonable attorneys' and accountants' fees, expenses and disbursements) will be borne by the Party against which the judgment of the arbitrator is to be enforced.

10.14 Assignment. Each Party may, without the consent of the other Party, assign or transfer all of its rights and obligations hereunder to an Affiliate, or to its successor in interest by reason of merger or consolidation or sale of all or substantially all of the assets of such Party relating to the subject matter of this Agreement. Any assignment or transfer in violation of the foregoing will be null and void and wholly invalid. This Agreement will inure to the benefit of and be binding on the Parties' successors and assigns.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the CDOA Effective Date.

Kyowa Kirin Co., Ltd.

Aevi Genomic Medicine, LLC

By: /s/ Yasuo Fujii

Name: Yasuo Fujii

Title: Executive Officer

Global Business Development Head Director, Business
Development

By: /s/ Michael F. Cola

Name: Michael F. Cola

Title: President and CEO

[Signature Page to Amended and Restated Clinical Development and Option Agreement]

EXHIBIT A
ADOLESCENT STUDY PROTOCOL

See Attached

(***)

EXHIBIT B
PLAN A LICENSE AGREEMENT

See Attached

LICENSE AGREEMENT

by and between

KYOWA KIRIN CO., LTD.

and

AEVI GENOMIC MEDICINE, LLC

<u>Article 1. DEFINITIONS</u>	1
<u>Article 2. EFFECTIVENESS OF THIS AGREEMENT</u>	16
<u>Article 3. GOVERNANCE</u>	17
<u>Article 4. DEVELOPMENT</u>	22
<u>Article 5. COMMERCIALIZATION</u>	28
<u>Article 6. DILIGENCE</u>	31
<u>Article 7. LICENSES</u>	32
<u>Article 8. FINANCIAL PROVISIONS</u>	35
<u>Article 9. INTELLECTUAL PROPERTY</u>	44
<u>Article 10. CONFIDENTIALITY</u>	53
<u>Article 11. TERM AND TERMINATION</u>	56
<u>Article 12. REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION</u>	63
<u>Article 13. MISCELLANEOUS PROVISIONS</u>	70

Schedules

Schedule 1.5 – AEVI In-License
Schedule 1.10 – AEVI Patent Rights
Schedule 1.15 – Amino Acid Sequence of Anti-LIGHT mAb
Schedule 1.24 – Commercialization Costs
Schedule 1.46 – FTE Rates
Schedule 1.51 – KKC In-Licenses
Schedule 1.55 – KKC Patent Rights

LICENSE AGREEMENT

This License Agreement (this “**Agreement**”), effective as of the Effective Date (as defined in Section 2.1), is by and between Kyowa Kirin Co., Ltd., a company organized and existing under the laws of the Japan and having its principal office at 1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan and formerly known as Kyowa Hakko Kirin Co., Ltd. (“**KKC**”), and Aevi Genomic Medicine, LLC, a Delaware limited liability company and successor to Medgenics, Inc., a Delaware corporation (“**AEVI**”). KKC and AEVI may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

INTRODUCTION

WHEREAS, the Parties have entered into the Amended and Restated Clinical Development and Option Agreement, effective as of May 28, 2020 (the “**Clinical Development and Option Agreement**”); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct the Initial Development (as defined in the Clinical Development and Option Agreement) with respect to Anti-LIGHT mAb (as defined in Section 1.15); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct one or more signal finding studies in the Field (as defined in Section 1.42) and an option to obtain an exclusive license to Develop, Manufacture and Commercialize products containing Anti-LIGHT mAb at KKC’s election either under the terms and conditions of this Agreement (the “**Plan A Election**”) or under the terms and conditions of the license agreement attached to Exhibit C to the Clinical Development and Option Agreement (the “**Plan B Election**”); and

WHEREAS, this Agreement will become fully effective in accordance with Section 2.1 of this Agreement only upon KKC making the Plan A Election pursuant to the terms and conditions of the Clinical Development and Option Agreement; and

WHEREAS, this Agreement will not become effective and be rendered null and void in accordance with Section 2.2 of this Agreement.

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

Article 1. DEFINITIONS

When used in this Agreement, each of the following terms will have the meanings set forth in this Article 1:

1.1 “**Accounting Standards**” means with respect to a Party, as applicable, (a) United States generally accepted accounting principles (“**GAAP**”), (b) Japanese generally accepted accounting standards, or (c) International Financial Reporting Standards, in each case consistently applied.

1.2 “**Acquirer Intellectual Property**” means the Patent Rights and Know-How owned or controlled by a Third Party acquirer of AEVI or KKC, as the case may be, immediately prior to a

Change of Control transaction, and Inventions thereto following the effective date of such Change of Control.

1.3 “**Administrative Contact**” means any contact to or from a Regulatory Authority that is general or administrative in nature (e.g., notification by a Regulatory Authority of the assignment of a new reviewer or a notification of a new address or new contact information).

1.4 “**AEVI Business Day**” means a day on which banking institutions in New York, New York are open for business other than Saturday or Sunday.

1.5 “**AEVI In-License**” means each Third Party agreement listed on Schedule 1.5.

1.6 “**AEVI Inventions**” means any and all Inventions made or generated hereunder solely by employees or contractors of AEVI (or its Affiliates), as determined by United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.7 “**AEVI Know-How**” means Know-How that is (a) Controlled by AEVI or any of its Affiliates on the Effective Date or during the Term (other than KKC Know-How pursuant to the licenses granted hereunder) and (b) reasonably necessary or useful in connection with Development, Manufacture, use or Commercialization of Licensed Products.

1.8 “**AEVI Licensor**” means The Children’s Hospital of Philadelphia (“**CHOP**”).

1.9 “**AEVI Lonza License Agreement**” means an agreement between AEVI and Lonza that licenses to AEVI the intellectual property rights subject to the (***) Agreement between Lonza and KKC (***), to the extent related to the Licensed Product in the Field in the Territory and the European Union, including the right to sublicense to another contract manufacturer such that such contract manufacturer can perform process development and supply of anti-LIGHT-mAb.

1.10 “**AEVI Patent Rights**” means (a) the United States and foreign patents and patent applications listed on Schedule 1.10 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (b) any Patent Rights included within AEVI Inventions prior to the completion of the Term that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products and (c) any Patents Rights included in Third Party Technology prior to the completion of the Term (i) in respect of which AEVI obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products.

1.11 “**AEVI Technology**” means AEVI Know-How, AEVI Patent Rights and AEVI Inventions other than Acquirer Intellectual Property.

1.12 “**Affiliate**” means, with respect to any person or entity, any other person or entity which controls, is controlled by, or is under common control with such person or entity. A person or entity will be regarded as in control of another entity if it owns or controls more than

fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.13 “**Allowable Expenses**” means, with respect to Profit-Share Products and each Contract Quarter, all FTE Costs and Out-of-Pocket Costs incurred by AEVI or its Related Parties that are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory, and Manufacture of such Profit-Share Products for Commercialization, during the applicable Contract Quarter, including such FTE Costs and Out-of-Pocket Costs which are: (a) Manufacturing Costs; (b) Commercialization Costs; and (c) Third Party Technology Costs, in each case determined from the books and records of AEVI or its Related Parties maintained in accordance with Accounting Standards and in each case of (a)-(c) as are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory during the applicable Contract Quarter. For clarity, no milestone payment made to KKC or its Affiliates pursuant to Section 8.3 will be an Allowable Expense. For purposes of clarity, it is understood that there will be no double-counting of expenses within the definition of Allowable Expenses.

1.14 “**Applicable Law**” means the laws, rules and regulations, including without limitation any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, Manufacturing or Commercialization of Licensed Products or other activities conducted by the Parties under this Agreement, that may be in effect from time to time in the applicable territory.

1.15 “**Anti-LIGHT mAb**” means the fully human monoclonal antibody targeting LIGHT (TNFSF14) consisting of the amino acid sequence set forth on Schedule 1.15.

1.16 “**Bankruptcy Code**” means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.17 “**Biosimilar**” means, with respect to a reference brand biologic product and a particular jurisdiction, a biologic product: (a) that is highly similar to such reference brand biologic product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences from such reference brand biologic product in terms of safety, purity and potency; and (c) for which a Biosimilar Application is approved by the relevant Regulatory Authority of such jurisdiction. Notwithstanding anything to the contrary in this Agreement, a “Biosimilar” does not include any biologic product sold under a BLA or approved Biosimilar Application of any Party or any of its Related Parties or manufactured or produced by or on behalf of a Party or any of its Related Parties.

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

1.19 “**BLA**” means a Biologics License Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.

1.20 “**BMS**” means Bristol-Myers Squibb Company.

1.21 “**Business Day**” means, with respect to KKC, a KKC Business Day, and, with respect to AEVI, an AEVI Business Day.

1.22 “**Change of Control**” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates.

1.23 “**Commercialization**” means importing, exporting, marketing, promoting, distributing, offering for sale and selling a Licensed Product and, solely with respect to Section 7.5, a Competing Product in the Field and will include activities required to fulfill ongoing post-approval regulatory obligations, including adverse event reporting and sales force training but excluding any Phase 4 Clinical Trial (as defined in Section 1.34). When used as a verb, “**Commercialize**” will mean to engage in Commercialization.

1.24 “**Commercialization Costs**” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of AEVI or its Related Parties in accordance with this Agreement and attributable to, or reasonably allocable to, the Commercialization of the Licensed Products in the Field in the Territory, including marketing costs, sales costs, distribution costs, importing and exporting costs, Phase 5 Clinical Trial costs, insurance costs incurred in connection with Commercialization activities, medical affairs costs and certain general and administrative costs (but excluding Development Costs) as further defined in Schedule 1.24. In this Agreement, “**Phase 5 Clinical Trial**” means a post-registration clinical trial that is not required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.25 “**Commercialization Party**” means the Party responsible for Commercialization of a Licensed Product in a jurisdiction under this Agreement.

1.26 “**Commercially Reasonable Efforts**” means, with respect to a Party, the carrying out of obligations in a diligent and sustained manner using such effort and employing such resources as would normally be exerted or employed by a similarly situated biopharmaceutical company for a product of similar commercial or strategic importance, and at a similar stage of its product life, based on conditions then prevailing, taking into consideration safety and efficacy, development costs, the anticipated prescription label, the nature of the Licensed Product, the

clinical setting in which it is expected to be used and all other relevant factors. Commercially Reasonable Efforts will be determined on a country-by-country basis.

1.27 “**Competing Product**” means (***), other than a Licensed Product, (***).

1.28 “**Confidential Information**” means, with respect to each Party, proprietary data or information of such Party or its Affiliates or sublicensees, including, without limitation, (a) with respect to KKC, all KKC Technology, and, with respect to AEVI, all AEVI Technology, (b) any information designated as Confidential Information of such Party hereunder, in all cases that is identified as confidential either in writing or orally, provided that any orally disclosed information is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral disclosure requesting that such information be treated as Confidential Information hereunder, and (c) all information that is manifestly confidential, whether or not marked as such.

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

1.30 “**Contract Year**” means the twelve (12) month period beginning on January 1 and ending on December 31 of each calendar year, provided, however, that the first Contract Year will be the period of time beginning on the Effective Date and ending on December 31, 2016. Each Contract Year, except the first Contract Year, will be divided into four (4) Contract Quarters.

1.31 “**Control**” or “**Controlled**” means with respect to any (a) material, item of information, method, data or other Know-How, or (b) intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by the referenced Party or its Affiliates of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.

1.32 “**Data Exclusivity Period**” means, with respect to a particular jurisdiction, the time period of legal protection and confidential treatment provided for clinical test data required to be submitted to a Regulatory Authority for such jurisdiction in order to demonstrate safety and efficacy of a new drug or biologic, and all similar protections on such clinical test data intended to prevent generic drug manufacturers or biosimilar manufacturers from relying on this data in their own Biosimilar applications.

1.33 “**Development**” means, with respect to a Licensed Product and, solely with respect to Section 7.5, a Competing Product in the Field, non-clinical and clinical drug development activities performed on or after the Effective Date, including without limitation the conduct of clinical trials, test method development, toxicology, pharmacology, pharmacokinetics formulation, data management, statistical analysis and report writing and clinical studies, and regulatory affairs and all activities associated with obtaining and maintaining Regulatory Approvals. When used as a verb, “Develop” means to engage in Development.

1.34 “**Development Costs**” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of a Party in accordance with this Agreement and attributable to, or reasonably allocable to, the Development of the Licensed Products in the Field in the Territory and European Union and that are materially consistent, as applicable, with the Development Plan, including costs and expenses for Regulatory Approvals and pricing and/or reimbursement approvals, and costs incurred after Regulatory Approval, including Phase 4 Clinical Trial costs, costs of non-clinical studies, costs of clinical studies for additional Indications in the Field, insurance costs incurred in connection with Development activities (but excluding costs that are allocable to Commercialization Costs and the costs of general company management, financial, legal or business development personnel). Development Costs will not include any costs incurred by either Party prior to the Effective Date, including, without limitation, costs for purchasing raw materials, for manufacturing clinical supplies of Licensed Product or for any labeling or packaging materials, whether or not such raw materials, clinical supplies or labeling or packaging materials are used by the Parties for Development activities after the Effective Date. In this Agreement, “**Phase 4 Clinical Trial**” means a post-registration clinical trial or post-marketing surveillance study performed in accordance with Applicable Laws and required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.35 “**Development Plan**” means (a) the written comprehensive plan for (i) the Development of any Licensed Product in the Field in the Territory and the European Union, including, but not limited to, activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing Regulatory Approval Applications in the Territory and the European Union and (ii) the preparation and submission of related Regulatory Approval Applications in the Territory and the European Union and (b) an annual budget for Development Costs setting forth both internal and external resources and expenses for the then-current Contract Year.

1.36 “**EMA**” means the European Medicines Agency and any successor agency having substantially the same functions.

1.37 “**European Union**” means all countries over which EMA has jurisdiction from time to time and all countries that exit the jurisdiction of the EMA from time to time.

1.38 “**Executive Officers**” means the Chief Executive Officer of AEVI (or an executive of AEVI designated by such Chief Executive Officer) and the Chief Executive Officer of KKC (or an executive of KKC designated by such Chief Executive Officer).

1.39 “**Fair Market Value**” means (a) with respect to investment by a Third Party in exchange for equity securities of AEVI, (i) for so long as AEVI’s common stock is publicly traded on a securities exchange, the volume weighted average closing price of a share of AEVI’s common stock on the principal exchange on which such stock is then trading for the ten (10) trading days ending on the date that is twenty (20) trading days on such exchange prior to the first public announcement of such equity investment, and (ii) if AEVI’s common stock is no longer publicly traded on a securities exchange, the fair market value of a share of common stock of AEVI as of the date of closing such investment as determined in good faith by the board of

directors of AEVI, taking into account such factors and for such time period as the board of directors of AEVI reasonably deems is appropriate, and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned, and (b) with respect to any non-cash consideration (other than equity securities), the fair market value of such consideration as determined in good faith by the board of directors of AEVI and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned.

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

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

1.42 “**Field**” means treatment, prevention, and diagnosis (***) of pediatric (18 and below) onset rare and orphan disease (***) Crohn Disease, Ulcerative Colitis, (***), Juvenile Idiopathic Arthritis, Psoriasis (***). Pediatric onset patients who survive into adulthood will be included in the scope of the Field.

1.43 “**First Commercial Sale**” means, with respect to a given Licensed Product in a country, the first commercial sale in an arms-length transaction of such Licensed Product to a Third Party by or on behalf of a Party, its Affiliate or its sublicensee in such country following receipt of applicable Regulatory Approval of such Licensed Product in such country.

1.44 “**FTE**” means a full time equivalent person year (consisting of a total of two thousand (2,000) hours per Contract Year, subject to a proportionate reduction in the first Contract Year) of scientific, technical, marketing, sales, distribution and certain general and administrative activities related to the Development of Licensed Products and/or the Commercialization of the Licensed Products in the Field in accordance with this Agreement. For the avoidance of doubt, no individual will count as more than one (1) FTE, and any individual who works less than two thousand (2,000) hours in a given Contract Year performing activities under this Agreement will be counted as a fraction of one (1) FTE, the numerator of which is the number of hours such individual performs activities under this Agreement and the denominator of which is two thousand (2,000) hours.

1.45 “**FTE Costs**” means all costs for FTEs calculated by multiplying (a) the actual number of FTEs utilized by KKC or AEVI in performing activities in accordance with any Development Plan and/or Commercialization Plan by (b) the applicable FTE Rate, provided that, to the extent either Party is unable to fully track the number of FTEs utilized, the Parties will agree on a mechanism for estimating such number.

1.46 “**FTE Rate**” means, with respect to an FTE, the applicable amount set forth on Schedule 1.46, as such amount may be adjusted pursuant to Section 8.7.

1.47 “**IND**” means an Investigational New Drug Application, as defined in the FD&C Act, or similar application or submission that is required to be filed with any Regulatory Authority before beginning clinical testing of a Licensed Product in human subjects.

1.48 “**Inventions**” means any and all ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable or copyrightable, and all Patent Rights and other intellectual property rights in any of the foregoing.

1.49 “**Joint Inventions**” means any and all Inventions made or generated hereunder jointly by at least one employee or contractor of each Party (or its respective Affiliates), as determined by United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.50 “**KKC Business Day**” means a day on which banking institutions in Tokyo, Japan are open for business other than a Saturday or Sunday.

1.51 “**KKC In-Licenses**” means the Third Party agreements listed on Schedule 1.51.

1.52 “**KKC Inventions**” means any and all Inventions made or generated hereunder solely by employees or contractors of KKC (or its Affiliates), as determined by the United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.53 “**KKC Know-How**” means Know-How that is (a) Controlled by KKC on the Effective Date or during the Term (other than AEVI Know How pursuant to the licenses granted hereunder) and (b) is reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory or the European Union.

1.54 “**KKC Licensor**” means LJI, BMS, Lonza, and Sanofi, respectively defined in this Article 1, and its respective successor and assigns, which has licensed rights to KKC pursuant to the KKC In-Licenses.

1.55 “**KKC Patent Rights**” means (a) the United States and foreign patents and patent applications listed on Schedule 1.55 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (b) the United States and foreign patents and patent applications licensed to KKC under the KKC In-Licenses but not listed on Schedule 1.55 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (c) any Patent Rights included within KKC Inventions prior to the completion of the Term that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory or the European Union and (d) any Patents Rights included in Third Party Technology prior to the completion of the Term (i) in respect of which KKC obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory or the European Union.

1.56 “**KKC Technology**” means KKC Patent Rights, KKC Know-How and KKC Inventions other than Acquirer Intellectual Property.

1.57 “**Know-How**” means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, material, technology or other know-how, whether or not patentable or copyrightable.

1.58 “**Licensed Product**” means any product containing as an active ingredient the Anti-LIGHT mAb.

1.59 “**LIGHT**” means TNFSF14 (Unigene cluster number: Hs. 129708).

1.60 “**LJI**” means La Jolla Institute for Allergy and Immunology and its respective successor and assigns, which has licensed rights to KKC pursuant to the LJI Agreement.

1.61 “**LJI Agreement**” means License Agreement between La Jolla Institute for Allergy and Immunology and Kyowa Hakko Kirin Co., Ltd. (***)

1.62 “**Lonza**” means Lonza Sales AG and its Affiliates.

1.63 “**Manufacturing**” means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of Licensed Products and, solely with respect to Section 7.5, a Competing Product, including without limitation process and formulation development, process validation, stability testing, process development, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, “**Manufacture**” will mean to engage in Manufacturing.

1.64 “**Manufacturing Costs**” means:

(a) With respect to Licensed Product manufactured by AEVI, its fully-burdened costs (including the costs associated with product testing and release activities) of producing (including startup and validation but excluding what will be covered under Section 4.3.3) and packaging Licensed Product for sale in a given country, determined in accordance with the applicable Accounting Standard, based on the sum of the following components: (i) direct costs, including manufacturing labor and materials directly incurred in producing and packaging such Licensed Product; (ii) manufacturing and accounting personnel costs incurred by AEVI and attributable and reasonably allocable to the manufacture of Licensed Product, including quality labor and manufacturing and quality supervisory services, depreciation, and other operating and administrative costs which of the manufacturing, quality and accounting departments and associated occupancy costs which are allocable to such company departments based on space occupied or headcount, or other activity based method of allocation; (iii) any other reasonable and customary Out-of-Pocket Costs incurred by AEVI for the testing, transport, customs clearance, duty, insurance and/or storage of such Licensed Products, including payments made

by AEVI to Third Parties for filing, finishing, packaging, labeling, testing, storage and shipment of such Licensed Product and AEVI's handling cost with respect thereto, as applicable; and (iv) AEVI's reasonably allocated share of cost of Licensed Product process improvements developed by AEVI or a Third Party on behalf of AEVI. For Licensed Products manufactured by AEVI, Manufacturing Cost will not include any general corporate overhead, any excess capacity cost or charges or cost for process development (except to the extent expressly provided above).

(b) With respect to Licensed Product manufactured for a Party by one or more Third Parties and supplied to the other Party hereunder amounts actually paid (net of any discounts, credits or refunds) by such Party to such Third Parties for the manufacture and supply of such Licensed Product.

(c) With respect to Licensed Product manufactured by KKC in Japan and exported to the Territory pursuant to Section 4.3.3, one hundred ten percent (110%) of KKC's fully burdened manufacturing cost (including the costs associated with product testing and release activities) of producing (including startup and validation) and packaging Licensed Product for sale in a given country, determined in accordance with the applicable Accounting Standard, based on the sum of the following components: (i) direct costs, including manufacturing labor and materials directly incurred in producing and packaging such Licensed Product; (ii) manufacturing and accounting personnel costs incurred by KKC and attributable and reasonably allocable to the manufacture of Licensed Product, including quality labor and manufacturing and quality supervisory services, depreciation, and other operating and administrative costs which of the manufacturing, quality and accounting departments and associated occupancy costs which are allocable to such company departments based on space occupied or headcount, or other activity based method of allocation; (iii) any other reasonable and customary Out-of-Pocket Costs incurred by KKC for the testing, transport, customs clearance, duty, insurance and/or storage of such Licensed Products, including payments made by KKC to Third Parties for filing, finishing, packaging, labeling, testing, storage and shipment of such Licensed Product and KKC's handling cost with respect thereto, as applicable; and (iv) KKC's reasonably allocated share of cost of Licensed Product process improvements developed by KKC or a Third Party on behalf of KKC. For Licensed Products manufactured by KKC, Manufacturing Cost will not include any general corporate overhead, any excess capacity cost or charges or cost for process development (except to the extent expressly provided above).

Notwithstanding the foregoing, if the Licensed Product is Manufactured by a Third Party other than Lonza, then the portion of the annual fee payable to Lonza payable by AEVI pursuant to Section 8.6.4(c) will be excluded from Manufacturing Costs.

1.65 "***Medical Affairs Activities***" means, with respect to a Licensed Product, activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, such Licensed Product, including, with respect to such Licensed Product: (a) conducting service based medical activities including providing input and assistance with consultancy meetings, recommending investigators for clinical trials and providing input in the design of such trials and other research related activities, and delivering non-promotional communications and conduct non-promotional activities including presenting new clinical trial

data and other scientific information; (b) grants to support continuing medical education, symposia, or Third Party research specifically related to such Licensed Product; (c) development, publication and dissemination of publications relating to such Licensed Product and relevant disease states; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call or email; (e) conducting advisory board meetings or other consultant programs; (f) support of investigator-initiated clinical trials; (g) managing relationships with cooperative groups, physician/hospital networks and advocacy groups; and (h) establishing and implementing risk, evaluation and mitigation strategies.

1.66 “**Net Sales**” means the gross invoiced sales by a Party and/or its Related Parties to Third Parties for Licensed Products sold, less deductions, consistent with applicable Accounting Standards used in the applicable reporting period for such Party’s consolidated financial reporting purposes, which will be limited to: (a) price adjustments, chargeback payments, credits, or rebates (or the equivalent thereof), allowances allowed and taken, quantity or other trade discounts and other amounts paid on sale of Licensed Products, including those granted to and actually used by group purchasing organizations or other buying groups, managed healthcare organizations, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other healthcare institutions (including hospitals), Third Party health care administrators or patient assistance or other similar program, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors and other trade customers; (b) sales, use, tariffs, value-add, and/or excise taxes, or other governmental charges and tariffs incurred in connection with exportation or importation directly imposed and with reference to particular sales; (c) reasonable and customary freight, postage, shipping, insurance and other transportation expenses and delayed ship order credits reflected in the applicable invoice and paid by the customer; and (d) amounts allowed, repaid or credited due to defects, returns, rejections, recalls, rebates and replacements and allowances of goods or because of retroactive price reductions; (e) normal and customary rebates, trade, cash or quantity discounts; billing errors; coupons for price reductions; (f) required distribution commissions/fees payable to Third Party wholesalers for distribution of the Licensed Products; (g) allowance and write-offs for bad debt made in accordance with generally accepted accounting principles, consistently applied to all of such Party’s products; (h) discounts pursuant to indigent patient programs and patient discount programs including coupon discounts; and (i) any item, substantially similar in character or substance to any of the foregoing permitted by the applicable Accounting Standards and customary in the pharmaceutical industry. Net Sales also includes the Fair Market Value of any non-cash consideration received in connection with the sale of the Licensed Products. In the case of any sale of Licensed Product for value other than in an arm’s length transaction exclusively for cash, Net Sales will be determined by referencing Net Sales at which substantially similar quantities of such Licensed Product are sold in an arm’s length transaction for cash. For purposes of calculating Net Sales, transfers of Licensed Product between a Party and its Related Parties, whether or not value is exchanged therefor, will not be booked as sales.

1.67 “**Out-of-Pocket Costs**” means, with respect to specified activities hereunder, direct expenses paid or payable by a Party or its Related Parties to Third Parties (other than employees

of such Party or its Related Parties) that are specifically identifiable and incurred to conduct such activities.

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

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

1.70 “**Planned Agency Contact**” means (a) all communications (whether an Administrative Contact or Substantive Contact) initiated from either Party to a Regulatory Authority or (b) pre-arranged contacts from a Regulatory Authority to a Party, in each case that reasonably relate to or may impact the Manufacture, Development or Commercialization of Licensed Products.

1.71 “**Product Labels and Inserts**” means (a) all labels and other written, printed or graphic matter affixed to any container, packaging or wrapper utilized with Licensed Product, or (b) any written material physically accompanying Licensed Product, including product package inserts.

1.72 “**Product Trademarks**” means the trademark(s), service mark(s), accompanying logos, trade dress and/or indicia of origin used in connection with the Commercialization of each Licensed Product in the Territory. For purposes of clarity, the term Product Trademark(s) will not include, without limitation, the corporate names and logos of either Party, and will include any internet domain names incorporating such Product Trademarks.

1.73 “**Profit**” means with respect to all Profit-Share Products with respect to a Contract Quarter and a country in the Territory: (a) Net Sales of such Profit-Share Products in the Field in the Territory by AEVI and its Affiliates, plus (b) Profit-Share Product Proceeds, minus (c) Allowable Expenses, to the extent such deductions have not already or otherwise been deducted in calculating the amounts described in (a) and (b) above. If a calculation of Profit for a given Contract Quarter pursuant to the preceding sentence would result in a negative number, the amount of such Profit for such Contract Quarter will be zero (0).

1.74 “**Profit-Share Product**” means a Licensed Product Commercialized by AEVI or its Related Parties in the Territory.

1.75 “**Profit-Share Product Proceeds**” means, with respect to Profit-Share Products, any proceeds received by AEVI or its Affiliates from Third Parties with respect to the Development, Manufacture, supply, or Commercialization of such Profit-Share Products in the Field in the Territory, including proceeds attributable to a grant of a license or sublicense, or a grant of distribution rights, to permitted sublicensees and distributors under this Agreement, to Develop, Manufacture or Commercialize such Profit-Share Products (or, if rights in addition to such rights

to such Profit-Share Products are granted to such Third Party, then reasonably allocated to the rights granted to such Third Party with respect to such Profit-Share Products). In the event any Third Party sublicensee makes a bona fide investment in any equity securities issued by AEVI or any of its Affiliates, the cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in exchange therefor will be excluded from the calculation of Profit-Share Product Proceeds, up to the Fair Market Value of such equity securities, and the sum of any cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in excess of the Fair Market Value of such equity securities will be included in the calculation of Profit-Share Product Proceeds.

1.76 “**Regulatory Approval**” means the approval of the applicable Regulatory Authority necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Licensed Product in a regulatory jurisdiction, including, where required, separate pricing and/or reimbursement approvals.

1.77 “**Regulatory Approval Application**” means an application submitted to the appropriate Regulatory Authority seeking Regulatory Approval of a Licensed Product in a regulatory jurisdiction, including without limitation a BLA.

1.78 “**Regulatory Authority**” means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity involved in granting of Regulatory Approval for a Licensed Product in a regulatory jurisdiction, including without limitation the FDA and the EMA.

1.79 “**Regulatory Materials**” means any regulatory submissions, notifications, registrations, approvals and/or other filings and correspondence made to or with a Regulatory Authority, and any other records required to be maintained for possible audit by a Regulatory Authority, that may be necessary or reasonably desirable to Develop, Manufacture, or Commercialize Licensed Products in the Territory and/or the European Union.

1.80 “**Related Party**” means, with respect to a Party, such Party’s Affiliates and permitted licensees and sublicensees, which term does not include wholesale distributors of such Party or its Affiliates, which distributors purchase a Licensed Product from such Party or its Affiliates in an arm’s-length transaction.

1.81 “**Royalty-Bearing Sales**” means Net Sales by KKC and its Affiliates of Licensed Products worldwide.

1.82 “**Sanofi**” means Sanofi, successor in interest to Sanofi-Aventis.

1.83 “**Significant Impact**” means a decrease in AEVI’s and its Related Parties’ Net Sales of Licensed Products (***).

1.84 “**Substantive Contact**” means any contact to or from a Regulatory Authority that is not an Administrative Contact.

1.85 “**Sublicensing Royalties**” means royalties and sales milestones received by KKC from its licensees or sublicensees on Net Sales by such licensees or sublicensees of Licensed Products worldwide.

1.86 “**Territory**” means the United States and its territories and possessions and Canada.

1.87 “**Third Party**” means any person or entity other than a Party or any of its Affiliates.

1.88 “**Third Party Technology**” means any Patent Rights, Know-How, inventions, or other intellectual property owned, in whole or in part, by or licensed to a Third Party.

1.89 “**Third Party Technology Costs**” means, with respect to a Profit-Share Product, royalties, license fees or other payments, as applicable, that are made to any Third Party for the use of any Third Party Technology and are reasonably allocable to and reasonably necessary or useful for, the Development, Manufacturing or Commercialization of such Licensed Product in the Field in the Territory. For the avoidance of doubt:

(a) the amounts payable to the KKC Licensors under the KKC In-Licenses are Third Party Technology Costs, provided however that:

(i) with respect to payments paid by KKC to LJL (**), only payments stipulated in paragraphs (1) and (3) of Section 12 of such addendum will be included in the Third Party Technology Costs and all other costs such as milestone payments will be solely borne by KKC and not included in Third Party Technology Costs;

(ii) with respect to payments paid by KKC to Lonza (**), only payments stipulated in Section 5.2 of such agreement will be included in the Third Party Technology Costs and all other costs except for annual maintenance fee which is stipulated in Section 8.6.4(c) in this Agreement, will be solely borne by KKC and not included in Third Party Technology Costs;

(iii) with respect to payments paid by KKC to BMS (**), only payments stipulated in Section 10.6.1(a)(i) of such agreement will be included in the Third Party Technology Costs and all other costs will be solely borne by KKC and not included in Third Party Technology Costs;

(b) the amounts payable by AEVI:

(i) to the AEVI Licensor pursuant to Section 6.4.1 and, with respect to amounts payable after receipt of the first Regulatory Approval for a Licensed Product in the Field in the Territory or the European Union, pursuant to Section 6.2 under the AEVI In-License will be included in the Third Party Technology Costs, and payments paid by AEVI to CHOP with respect of all other costs under the AEVI In-License, including but not limited to milestone payments, will be solely borne by AEVI and not included in Third Party Technology Costs; and

(ii) as royalties under the AEVI Lonza License Agreement shall be treated as Third Party Technology Costs; and

(c) the amounts payable for obtaining rights to Third Party Technology for the Territory under Section 9.5 are Third Party Technology Costs.

1.90 “**Unplanned Agency Contact**” means all communications (whether an Administrative Contact or Substantive Contact) from a Regulatory Authority to a Party without advance notice that reasonably relate to or may impact the manufacture, development of commercialization of Licensed Products, including without limitation e-mails, faxes, telephone calls or unplanned face-to-face meetings.

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

Term	Section
“ AEVT ”	Preamble
“ AEVI Indemnitees ”	12.10.2
“ Agreement ”	Preamble
“ Audited Party ”	8.6.6
“ BPCIA ”	9.6.2
“ Challenge ”	11.2.4
“ CHOP ”	1.8
“ Clinical Development and Option Agreement ”	Introduction
“ Commercialization Plan ”	5.2
“ Commercial Team Leader ”	3.3.1(a)
“ Co-Chairperson ”	3.1.1(b)
“ Controlling Party ”	9.3.3
“ Cooperating Party ”	9.3.3
“ Defending Party ”	9.4.2(a)
“ Defensive Actions ”	9.3.2
“ Development Team Leader ”	3.2.1(a)
“ Disclosing Party ”	10.1.1
“ Effective Date ”	2.1
“ Enforcement Expense ”	9.3.3
“ EU Royalty Rate ”	8.5.1
“ EU5 Countries ”	6.2
“ GAAP ”	1.1
“ Global Clinical Study ”	4.2.4
“ ICC ”	13.2.2(a)
“ Indemnitee ”	12.10.3
“ Infringement Claim ”	9.4.1
“ Inspecting Party ”	5.3.4
“ IP ”	11.7
“ Joint Commercialization Committee ” or “ JCC ”	3.3.1

“ <i>Joint Development Committee</i> ” or “ <i>JDC</i> ”	3.2.1
“ <i>Joint Patent</i> ”	9.2.2
“ <i>Joint Steering Committee</i> ” or “ <i>JSC</i> ”	3.1.1
“ <i>KKC</i> ”	Preamble
“ <i>KKC Indemnities</i> ”	12.10.1
“ <i>KKC Managed Patent Rights</i> ”	9.2.1
“ <i>KKC Manufacture Option</i> ”	5.3.3
“ <i>KKC Territory Royalty Rate</i> ”	8.5.1
“ <i>Losses</i> ”	12.10.1
“ <i>Manufacturing Responsibility Transition Plan</i> ”	5.3.3
“ <i>Other Royalty Rate</i> ”	8.5.1
“ <i>Party</i> ” or “ <i>Parties</i> ”	Preamble
“ <i>Phase 3 Clinical Trial</i> ”	4.2.4
“ <i>Phase 4 Clinical Trial</i> ”	1.34
“ <i>Phase 5 Clinical Trial</i> ”	1.24
“ <i>Plan A Election</i> ”	Introduction
“ <i>Plan B Election</i> ”	Introduction
“ <i>Prosecuting Party</i> ”	9.2.2
“ <i>Publications</i> ”	10.2.2
“ <i>Receiving Party</i> ”	10.1.1
“ <i>Recoveries</i> ”	9.3.3
“ <i>Reference Product Sponsor</i> ”	9.6.2
“ <i>Requesting Party</i> ”	8.6.6
“ <i>Section 351(k) Applicant</i> ”	9.6.1
“ <i>SPC</i> ”	9.8
“ <i>Supply Agreement</i> ”	5.3.2
“ <i>Term</i> ”	11.1
“ <i>Territory Royalty Rate</i> ”	8.5.1
“ <i>Third Party Claim</i> ”	12.10.1
“ <i>True-up Payment</i> ”	8.2.3

Article 2. EFFECTIVENESS OF THIS AGREEMENT

2.1 Effectiveness of this Agreement upon the Plan A Election. This Agreement is not and will not become effective except as set forth in this Section 2.1. As of the date on which KKC provides notice to AEVI that KKC has elected the Plan A Election in accordance with Section 4.1.4 of the Clinical Development and Option Agreement, this Agreement shall automatically become effective. Such date is referred to in this Agreement as the “*Effective Date*.”

2.2 Non-Effectiveness of this Agreement. Upon the earliest to occur of (a) the termination of the Clinical Development and Option Agreement pursuant to any of Section 7.2, 7.3, 7.4 or 7.5 thereof, (b) KKC making or being deemed to make the Plan B Election in accordance with Section 4.1.4 of the Clinical Development and Option Agreement or (c) the expiration of the Clinical Development and Option Agreement pursuant to Section 7.1(i)(a) or 7.1(ii)(a) thereof, this Agreement will not become effective and be rendered null and void. For the avoidance of doubt, upon this Agreement becoming effective, this Agreement shall survive the expiration or termination of the Clinical Development and Option Agreement for any reason.

Article 3. **GOVERNANCE**

3.1 Joint Steering Committee.

3.1.1 Establishment of JSC. As soon as practicable and no later than (***) after the Effective Date, the Parties will establish a committee to facilitate the Development and Commercialization of Licensed Products under this Agreement (the “*Joint Steering Committee*” or “*JSC*”) as follows:

(a) Composition of the Joint Steering Committee. The JSC will be comprised of two (2) representatives designated by each of the Parties. Each representative will be an individual of suitable authority and seniority with significant experience or expertise in biopharmaceutical drug development. Each Party will appoint its respective initial representatives to the JSC (***) after the Effective Date, and may from time to time substitute its representatives, in its sole discretion, effective upon notice to the other Party of such change. Additional representatives or consultants may from time to time be invited to attend JSC meetings, subject to such representatives’ and consultants’ written agreement to comply with the requirements of Article 10. Each Party will bear its own expenses relating to attendance at such meetings by its representatives and consultants.

(b) Chairperson. Each Party will designate one (1) of its representatives to be a co-chairperson (“*Co-Chairperson*”). Each Co-Chairperson or its designee will conduct the following activities of the Joint Steering Committee cooperatively: (i) scheduling meetings at least once per Contract Quarter, but more frequently if the JSC determines it necessary; (ii) setting agendas for meetings with solicited input from representatives of each Party; (iii) preparing and confirming minutes of the meetings, which will provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations made by the JSC, and delivering minutes to each Party’s senior management for review and final approval; and (iv) conducting effective meetings, including ensuring that objectives for each meeting are set and achieved.

(c) Meetings. The JSC will meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Contract Quarter. The JSC may meet by means of teleconference, videoconference or other similar communications equipment; provided that there will be at least one (1) in-person meeting in each

Contract Year. In-person meetings will alternate between a KKC facility in Japan and a AEVI facility in the United States.

(d) Responsibilities. Subject to Section 3.1.3, the JSC will have the following responsibilities:

(i) reviewing and approving all Development Plans (including Development budgets contained therein) and amendments and updates thereto, in each case within thirty (30) days after submission to the JSC;

(ii) reviewing and approving the regulatory strategy, clinical development strategy, and clinical supply strategy developed by the JDC for the Territory and the European Union for the initial indication and additional indications in the Field;

(iii) reviewing and approving a recommendation from the JDC to Develop any additional indications in the Field in the Territory and the European Union;

(iv) monitoring Development activities for Licensed Products undertaken by each Party in the Territory and the European Union, including, without limitation, monitoring the progress of each Party in its conduct of each Development Plan against the timelines and budgets contained therein; reviewing relevant data; and considering issues of priority;

(v) resolving any disputes that cannot be resolved by the JDC, including, but not limited to the disputes relating to Development budgets and Development Costs; and

(vi) performing such other activities as are contemplated under this Agreement and that the Parties mutually agree will be the responsibility of the JSC.

3.1.2 Appointment of Subcommittees and Project Teams. The JSC will be empowered to create such subcommittees of itself and other additional project teams as it may deem appropriate or necessary (e.g., CMC, technology transfer, preclinical, clinical) and may elect to delegate responsibilities to such subcommittees or additional project teams as it may from time to time deem appropriate. Each such subcommittee and project team will report to the JSC and the JSC will approve or reject recommendations or actions proposed thereby, subject to the terms of this Agreement. Notwithstanding the foregoing, no subcommittee or project team will have authority to make any decision binding upon the JSC, other committee, or the Parties.

3.1.3 Decision-Making. With respect to any matter over which the JSC has authority pursuant to Section 3.1.1(d), the JSC will use reasonable best efforts to reach unanimous agreement on a proposed action, approval or resolution with each Party (regardless of the number of attendees from the Party at a given meeting) having only one (1) vote, which vote will be cast by the Party's Co-Chairperson or its designee. If the JSC is unable to reach unanimous agreement, such matter will be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, then:

(a) AEVI will have final decision-making authority with respect to all matters concerning Development of the Licensed Product for the initial indication in the Field in the Territory and the European Union, subject to Section 8.2.1; provided that the performance of such activities under the Development Plan (or portions thereof) for the initial indication in the Field in the Territory or European Union cannot be assigned to KKC except with KKC's consent;

(b) Development of indications in the Field for the Licensed Product in the Territory and/or European Union beyond the initial indication will require the unanimous consent of the JSC on all matters relating to Development Plans and Development budgets; and

(c) final decision-making authority with respect to Commercialization of Licensed Products in a given territory, including but not limited to Commercialization Plans, Commercialization budgets, manufacturing of commercial supply and decisions on pricing and reimbursement, will not be subject to approval by the JSC (or any other committee created pursuant to this Agreement) and will be subject to the final decision-making authority of the Party who holds the Commercialization rights in such territory.

3.2 Joint Development Committee.

3.2.1 Establishment of JDC. As soon as practicable and no later than (***) after the establishment of the JSC, the JSC will establish a committee to facilitate Development of Licensed Products (the "**Joint Development Committee**" or "**JDC**") as follows:

(a) Composition of the JDC. The JDC will be comprised of not less than two (2) and not more than five (5) representatives from each Party. One (1) such representative from each Party will be designated as that Party's "**Development Team Leader**" to act as the primary JDC contact for that Party. AEVI's Development Team Leader will be the chairperson of the JDC. Each Development Team Leader will be responsible for ensuring that his/her Party's JDC members carry out the activities assigned to them under any Development Plan. Each Party will appoint its respective representatives to the JDC within (***) after the establishment of the JSC and may from time to time substitute its representatives, in its sole discretion, effective upon notice to the other Party of such change. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. Additional representatives or consultants may from time to time be invited to attend JDC meetings, subject to such representatives' and consultants' written agreement to comply with the requirements of Article 10. Each Party will bear its own expenses relating to attendance at such meetings by its representatives and consultants.

(b) Meetings. The JDC will meet monthly, or at such other frequency as is necessary, as agreed by the JDC based on the volume of Development activity. The JDC may meet by means of teleconference, videoconference or other similar communications equipment unless the Development Team Leaders agree to an in-person meeting. In-person meetings will alternate between a KKC facility in Japan and a AEVI facility in the United States.

(c) Secretary. AEVI's Development Team Leader will appoint a secretary from among the AEVI representatives on the JDC to act as secretary of the JDC meeting. The secretary will record in sufficient detail the discussion and decisions of the JDC. Such minutes will be circulated to the Parties promptly following the meeting for review, comment and distribution. Such minutes will then be distributed to the JSC for information only. The Parties will endeavor to manage the business and meetings of the JDC in the most cost-effective way possible.

(d) Responsibilities. The JDC will have the following responsibilities:

(i) preparing Development Plans and Development budgets set forth therein, including amendments and updates thereto, and submitting such Development Plans and Development budgets to the JSC for approval; provided that (1) the AEVI representatives on the JDC will be primarily responsible for preparing the portions of the Development Plan containing the operational activities of AEVI and all amendments and updates thereto and (2) the KKC representatives on the JDC will be primarily responsible for preparing the portions of the Development Plan containing the operational activities of KKC and all amendments and updates thereto;

(ii) developing a regulatory strategy, clinical development strategy and clinical supply strategy for the Territory and the European Union and submitting such strategies to the JSC for approval;

(iii) reviewing Development progress and a comparison of actual Development Costs to the applicable annual Development budget for the Contract Year-to-date;

(iv) making Development recommendations to the JSC for approval;

(v) facilitating the transfer of Know-How and Confidential Information between the Parties for purposes of facilitating the Development activities of the Parties under this Agreement

(vi) reviewing requests from clinical investigators on investigators' sponsored trials and making recommendations to the JSC for approval; and

(vii) performing such other activities as are contemplated under this Agreement and that the Parties mutually agree will be the responsibility of the JDC.

(e) JDC Decision-Making. With respect to any matter over which the JDC has authority pursuant to Section 3.2.1(d), the JDC will use reasonable best efforts to reach unanimous agreement on a proposed action, approval or resolution with each Party (regardless of the number of attendees from the Party at a given meeting) having only one (1) vote, which vote will be cast by the Party's Development Team Leader or its designee. If the JDC is unable to reach unanimous agreement, such matter will be referred to the JSC for resolution in accordance with Sections 3.1.1(d)(v) and 3.1.3.

3.3 Joint Commercialization Committee.

3.3.1 Establishment of JCC. As soon as practicable and no later than (***) prior to the projected First Commercial Sale of a Licensed Product in the Territory or the European Union, the JSC will establish a committee to facilitate Commercialization of Licensed Products (the “**Joint Commercialization Committee**” or “**JCC**”) as follows:

(a) Composition of the JCC. The JCC will be comprised of not less than two (2) and not more than five (5) representatives from each Party. One (1) such representative from each Party will be designated as that Party’s “**Commercial Team Leader**” to act as the primary JCC contact for that Party. Each Commercial Team Leader will be responsible for ensuring that his/her Party’s JCC members carry out the activities assigned to them under any Commercialization Plan. Each Party will appoint its respective representatives to the JCC within (***) after the establishment of the JCC and may from time to time substitute its representatives, in its sole discretion, effective upon notice to the other Party of such change. Any member of the JCC may designate a substitute to attend and perform the functions of that member at any meeting of the JCC. Additional representatives or consultants may from time to time be invited to attend JCC meetings, subject to such representatives’ and consultants’ written agreement to comply with the requirements of Article 10. Each Party will bear its own expenses relating to attendance at such meetings by its representatives and consultants.

(b) Meetings. The JCC will meet monthly, or at such other frequency as is necessary, as agreed by the JCC based on the volume of Commercialization activity. The JCC may meet by means of teleconference, videoconference or other similar communications equipment unless the Commercial Team Leaders agree to an in-person meeting. In-person meetings will alternate between a KKC facility in Japan and a AEVI facility in the United States.

(c) Secretary. AEVI’s Commercial Team Leader will appoint a secretary from among the AEVI representatives on the JCC to act as secretary of the JCC meeting. The secretary will record in sufficient detail the discussion and decisions of the JCC. Such minutes will be circulated to the Parties promptly following the meeting for review, comment and distribution. Such minutes will then be distributed to the JSC for information only. The Parties will endeavor to manage the business and meetings of the JCC in the most cost-effective way possible.

(d) Responsibilities. The JCC will have the following responsibilities:

(i) overseeing the Commercialization of the Licensed Products;

(ii) setting overall strategic objectives and plans (including pricing and reimbursements) relating to Commercialization of the Licensed Products in the Field in the Territory and the European Union;

(iii) reviewing the Commercialization Plans and Commercialization budgets for the Territory and proposed material amendments or updates thereto submitted to the JCC by AEVI;

(iv) reviewing the Commercialization Plan and Commercialization budgets for the European Union and proposed material amendments or updates thereto submitted to the JCC by KKC;

(v) monitoring Commercialization activities for Licensed Products undertaken by the Parties in the Territory and the European Union;

(vi) reviewing Commercialization issues in the Field in the Territory and the European Union;

(vii) providing a forum for the Parties to discuss the Commercialization of the Licensed Products in the Field in the Territory and the European Union;

(viii) facilitating the transfer of Confidential Information between the Parties for purposes of facilitating the Commercialization activities of the Parties hereunder; and

(ix) performing such other activities as are contemplated under this Agreement and that the Parties mutually agree will be the responsibility of the JCC.

(e) JCC Decision-Making. The JCC is a consultative body only and has no decision making power.

Article 4. **DEVELOPMENT**

4.1 Overview. AEVI will take the lead for (a) all Development of the Licensed Product in the Field in the Territory (subject to Section 6.1.2 in the case of Canada) for the initial indication and, if additional Development is approved by the JSC, additional indications in the Field beyond the initial indication, and (b) all Development of the Licensed Product in the Field in the European Union (subject to Section 6.1.1 in the case of terminated countries in the European Union) for the initial indication before the first Regulatory Approval for a Licensed Product in the European Union is transferred from AEVI to KKC, in each of (a) and (b) as more fully set forth in this Article 4. After receipt of the first Regulatory Approval for a Licensed Product in the Field in the United States and after the transfer of the first Regulatory Approval to KKC, pursuant to Section 4.3.1(c), further Development in the given jurisdiction is subject to Section 4.2.2.

4.2 Development Plans.

4.2.1 Development Plans. AEVI has delivered to KKC the most current version of the clinical protocol for the Adolescent Study (as defined in the Clinical Development and Option Agreement).

4.2.2 Additional Indications. At any time, either Party may propose to Develop in the Territory and/or the European Union Licensed Products for additional indications in the Field (i.e., in addition to the first indication) by submitting to the JDC a written proposal for the

Development thereof, including a proposed work plan, budget and timeline. Upon unanimous agreement by the JDC members to Develop Licensed Products for such additional indication(s), the JDC will update the Development Plan to include such Development and submit the updated Development Plan for approval by the JSC. Neither Party will initiate such Development activities in the Territory and/or the European Union with respect to any additional indication in the Field without the unanimous approval by JSC.

4.2.3 Updates. As early as necessary and no later than (***) prior to the beginning of the next Contract Year, the JDC will update each Development Plan and submit such updated Development Plans to the JSC for approval, which approval will occur no later than (***) prior to the beginning of the next Contract Year. Each Development Plan will contain the specific Development objectives to be achieved by each Party during the then-current Contract Year and the annual budget for such Contract Year, the specific Development activities to be performed by each Party and the timeline for performing such Development activities. Each Party will use its Commercially Reasonable Efforts to perform the activities designated to be performed by such Party pursuant to each Development Plan.

4.2.4 Global Clinical Study. If AEVI conducts a Global Clinical Study in the Field in any country in the Territory, at KKC's request AEVI will in good faith discuss with KKC including sites in countries outside of the Territory for such Global Clinical Study in order for KKC to join such Global Clinical Study. In order for AEVI to include such sites in the Global Clinical Trial, such discussions must result in a mutually satisfactory amendment to this Agreement that addresses all relevant matters including operational matters (such as allocation of responsibilities between the Parties), regulatory matters (such as preparation of any required IND, management of communications with Regulatory Authorities and which Party will be the holder of the IND/sponsor of the trial), risk matters (including KKC indemnifying AEVI for Losses resulting from Third Party Claims arising from the trial at such sites including product liability and from AEVI's performance of its allocated responsibilities) and KKC bearing all costs associated with all of the foregoing. In this Agreement, "**Global Clinical Study**" means, with respect to Development of Licensed Products, a study with a unique protocol, the results of which are designed to be submitted to Regulatory Authorities of the United States and European Union and other countries as mandatory for obtaining Regulatory Approval of such Licensed Products in the respective countries.

4.2.5 Development Event Notices. AEVI will inform KKC of the occurrence of each of the following events in writing within (***) after such occurrence: (a) commencement of the first Phase 3 Clinical Trial for any Licensed Product in the Territory and/or the European Union; and (b) receipt of the first Regulatory Approval for any Licensed Product in the Territory. In this Agreement, "**Phase 3 Clinical Trial**" means a registration or pivotal clinical trial performed in accordance with applicable laws and conducted in subjects with a particular disease or condition which is designed to establish the efficacy and safety of a Licensed Product given its intended use and to define warnings, precautions and adverse events that are associated with such Licensed Product in the dosage range intended to be prescribed.

4.3 Development Responsibilities for Licensed Products. The Parties will share responsibility for Development activities for Licensed Product for the Field for Territory and the European Union as follows:

4.3.1 Regulatory Matters.

(a) Strategy. The JDC will develop, and the JSC will review and approve, a regulatory strategy for the Field for the United States, the European Union and Canada (subject to Section 6.1.2), that is consistent with the terms of this Agreement. Pursuant to and in accordance with such regulatory strategy, AEVI will use Commercially Reasonable Efforts to prepare Regulatory Approval Applications or other submissions to Regulatory Authorities that AEVI is responsible for preparing under this Agreement that are suitable in content and format for use in all geographies in the applicable Territory and the European Union (e.g., use of ICH eCTD format).

(b) Communications with Regulatory Authorities.

(i) The Parties will jointly participate in the following, as set forth in Section 4.3.1(b)(ii): (w) all material communications with any Regulatory Authority in the Territory and the European Union; (x) label development, including negotiations with any Regulatory Authority in the Territory and the European Union; (y) advisory committee meetings in the Territory and the European Union; and (z) negotiation with any Regulatory Authority in the Territory and the European Union regarding post-approval commitments.

(ii) The Parties will comply with the following procedures for effecting joint participation in communications with Regulatory Authorities with respect to Licensed Products in the Field in the Territory and the European Union as follows:

(1) AEVI will lead communications with Regulatory Authorities in the Territory. AEVI will lead communications with Regulatory Authorities in the European Union until the first Regulatory Approval for a Licensed Product in the Field in the European Union is transferred from AEVI to KKC. KKC will lead communications with Regulatory Authorities in the European Union after the first Regulatory Approval for a Licensed Product in the Field in the European Union is transferred from AEVI to KKC. AEVI will assist KKC in communications with Regulatory Authorities in the European Union.

(2) In this regard, in the event of a Planned Agency Contact from a Regulatory Authority in the Territory or the European Union to AEVI that is a Substantive Contact, AEVI will notify KKC in advance of the contact in order to allow adequate time for KKC's participation or review. If the Substantive Contact is required urgently and is imminent, every reasonable attempt should still be made to notify KKC to enable comment or participation;

(3) In the event of an Unplanned Agency Contact from a Regulatory Authority in the Territory or the European Union to a Party that is a Substantive Contact, such Party will communicate the substance of such Substantive Contact to the other Party as soon as possible. In the rare case that an immediate response is required by the

Regulatory Authority, the responding Party will capture the response provided to the Regulatory Authority in writing and communicate the response to the other Party within twenty-four (24) hours;

(4) In the event of Planned Agency Contacts or Unplanned Agency Contacts that are Administrative Contacts, AEVI, KKC or the contacted Party, as applicable, will communicate such contact with the other Party no later than forty-eight (48) hours after such contact is made;

(5) Each Party will provide to the other Party, as soon as reasonably practicable, copies of any documents or other correspondence received from such Regulatory Authorities in the Territory or the European Union (including without limitation any meeting minutes); and

(c) Regulatory Approvals.

(i) AEVI will be responsible for preparing and filing Regulatory Approval Applications for the Licensed Products in the Field for the United States and Canada (subject to Section 6.1.2). Regulatory Approval Applications for which AEVI is responsible and any resulting Regulatory Approvals of the Licensed Products in the Field in the Territory will be made and issued in the name of AEVI or its Related Parties. AEVI will provide KKC with drafts of any Regulatory Approval Applications for which AEVI is responsible to be submitted to the applicable Regulatory Authorities in the Territory sufficiently in advance of submission to allow KKC to exercise its right to review and comment on such documents.

(ii) AEVI will be responsible for preparing and filing the first Regulatory Approval Application for the Licensed Products in the Field for the European Union. AEVI will apply for such first Regulatory Approval for the Licensed Products in the Field in the European Union by submitting the Regulatory Approval Applications with AEVI (or its local agent) as the applicant and KKC or KKC's designee as the proposed Regulatory Approval holder to EMA. AEVI will provide KKC with drafts of any Regulatory Approval Applications to be submitted to EMA sufficiently in advance of submission to allow KKC to exercise its right to review and comment on such documents. After receipt of the Regulatory Approval for the Licensed Product in the first indication in the Field in the European Union, the JSC will determine which Party shall be responsible for preparing and filing Regulatory Approval Applications for (a) the Licensed Products in the Field in any country in the European Union in which AEVI fails to obtain Regulatory Approval in the first indication, if any, and (b) the Licensed Products in the second indication in the Field in the European Union. All Regulatory Approval Applications and any resulting Regulatory Approvals of the Licensed Products for the European Union after the Regulatory Approval for the first indication will be issued in the name of KKC or its Related Parties. In countries/regions in the European Union where a Regulatory Approval is only given to a party who has filed the Regulatory Approval Application therefor, the Parties will discuss in good faith and decide on the method how to file the Regulatory Approval Applications and the timing to transfer the title to the Regulatory Approval Applications and/or Regulatory Approval from AEVI to KKC such that KKC will hold title to such Regulatory Approval as soon as practicable after such Regulatory Approval is obtained.

(iii) AEVI grants KKC a right of reference to Regulatory Approval Applications filed by AEVI in the Territory for purposes of KKC obtaining Regulatory Approval (a) outside the Field in the Territory and (b) outside the Territory and will provide the FDA with any required document to effect such right of reference. In addition, AEVI will provide KKC manufacturing information for the CMC section of KKC's Regulatory Approval Applications for the Licensed Product outside the Territory where applicable.

(d) Assistance. Each Party will cooperate with the other Party to provide all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law, including, but not limited to, reporting adverse drug experiences (and serious adverse drug experiences) to the applicable Regulatory Authorities.

4.3.2 Clinical Development. Subject to Sections 3.1.3 and 4.2.2, the JDC will develop, and the JSC will review and approve, a clinical development strategy for the Field for the Territory and the European Union. Each Development Plan will be consistent with such clinical development strategy. AEVI will lead the day-to-day clinical Development for Licensed Product in the Field for the Territory as necessary for preparing and submitting Regulatory Approval Applications in the Territory and, subject to the following sentence, with EMA. After the first Regulatory Approval for a Licensed Product in the Field in the European Union is obtained by KKC, any such Development will be performed by the Parties as determined by the JSC, subject to Sections 3.1.3(b) and 4.2.2. AEVI will take the lead for any Phase 4 Clinical Trial, and will provide assistance with respect to any other activity, that is required by the applicable Regulatory Authority to be conducted in the Territory and/or European Union for the initial indication in the Field. AEVI will provide reasonable consultation to KKC upon KKC's request in connection with Development of the Licensed Product outside the Territory.

4.3.3 CMC. AEVI will be solely responsible for all chemistry, manufacturing and control activities for the Licensed Product to support Regulatory Approval for the initial indication in the Field in the Territory and the European Union, which, for clarity includes all CMC activities up to and including manufacturing process development, commercial scale-up and validation. AEVI will bear all costs and expenses incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development for the initial indication in the Field in the Territory and the European Union (including failed batches and any batches, or parts thereof, that are Manufactured after the Effective Date, in anticipation of clinical studies but which are not actually used), and disposal of clinical samples, and, for clarity, none of such costs will be included in Allowable Expenses.

4.3.4 Preclinical Development. If the JSC so tasks the JDC, the JDC will develop, and the JSC will review and approve, a preclinical strategy for the Territory and the European Union, which strategy will provide for the roles and responsibilities of the Parties in (a) preparing and reviewing the preclinical sections of all Regulatory Approval Applications and other submissions to any Regulatory Authorities for the Territory and the European Union, and (b) providing pharmacokinetic, pathology, toxicology and bioanalytical support for the clinical program.

4.4 Drug Safety.

4.4.1 Responsibility Before First Commercial Sale. Prior to the First Commercial Sale of a Licensed Product in the Field in the Territory or the European Union, AEVI will hold and manage the safety database and will lead safety monitoring and reporting in the Territory and the European Union, and KKC will hold and manage the safety database during clinical development and will lead safety monitoring and reporting outside the Territory and outside the European Union. Each Party will allow the other Party and its Affiliates and sublicensees or Third Parties acting on their respective behalf, to:

- (a) review all serious adverse events within time frames that comply with 21 CFR 312.32;
- (b) review IND safety reports, investigator brochure amendments, patient consent forms and clinical protocols;
- (c) review monthly line listings;
- (d) read and write to the database;
- (e) participate in signaling discussions; and
- (f) review all periodic reporting required by Regulatory Authorities (e.g., IND Annual Reports, EU Annual Safety Reports, etc.).

The Parties agree to jointly develop and enter into a global safety data exchange and pharmacovigilance agreement to facilitate this exchange of information no later than (***) prior to the date of initiation of the first clinical study sponsored by KKC if and when KKC decides to Develop the Licensed Product in its jurisdiction. In such case, AEVI will be responsible for holding and maintaining the global safety database for the Licensed Product.

4.4.2 After First Commercial Sale. In case the Parties have not entered in to a global safety data exchange and pharmacovigilance agreement according to Section 4.4.1, not later than (***) prior to the anticipated First Commercial Sale of a Licensed Product in the Territory or the European Union, AEVI and KKC will jointly develop and enter into a global safety data exchange and pharmacovigilance agreement. In such case, AEVI will be responsible for holding and maintaining the global safety database for the Licensed Product.

4.5 Records. Each Party will maintain scientific records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of Development under this Agreement by such Party. Each Party will have the right, during normal business hours and upon reasonable notice, to inspect and copy (or request the other Party to copy) all records of the other Party maintained in connection with the work done and results achieved in the performance of Development under this Agreement. All such records and the information disclosed therein will be maintained in confidence by the recipient in accordance with Article 10.

4.6 Know-How Transfer. In order to facilitate Development of Licensed Products, from time to time during the Term, each Party will disclose or transfer to the other Party any applicable KKC Know-How or AEVI Know-How, as the case may be, existing as of the Effective Date or developed after the Effective Date that is reasonably necessary or useful for the Development or Manufacture of the Licensed Products. Except as otherwise provided under this Agreement or explicitly authorized in writing by a Party, all Know-How delivered by such Party to the other Party will remain the sole property of such Party.

Article 5.

COMMERCIALIZATION

5.1 Commercialization. AEVI will be solely responsible for all Commercialization activities relating to the Licensed Products in the Field in the Territory, and as between AEVI and KKC, AEVI will record all revenues in connection with the Commercialization of Licensed Products in the Field in the Territory. KKC will be solely responsible for all Commercialization activities relating to the Licensed Products (a) outside the Field in the Territory and (b) outside the Territory, and as between AEVI and KKC, KKC will record all revenues in connection with the Commercialization of Licensed Products (i) outside the Field in the Territory and (ii) outside the Territory. AEVI will provide reasonable consultation to KKC upon KKC's request in connection with Commercialization of the Licensed Product outside the Territory.

5.2 Commercialization Plans and Budgets. Commencing at least (***) prior to the projected First Commercial Sale of a Licensed Product in the Field in the Territory or the European Union, as applicable, the Commercialization Party will commence preparing a commercialization plan (each, a "**Commercialization Plan**") for such Licensed Product in the Field in the Commercialization Party's territory (i.e., AEVI is the Commercialization Party with respect to the Territory and KKC is the Commercialization Party with respect to the European Union), including but not limited to marketing strategies and materials, and patient advocacy, and a proposed annual budget estimating with reasonable detail Allowable Expenses expected to be incurred by AEVI in connection with the Commercialization of Profit-Share Products. No later than (***) prior to the projected First Commercial Sale of such Licensed Product in the Commercialization Party's territory, the Commercialization Party will submit a Commercialization Plan to the JCC for information only. After the launch of such Licensed Product, no later than (***) prior to the beginning of the next Contract Year, the Commercialization Party will update the Commercialization Plan for the Field in the Commercialization Party's territory for such Licensed Product and submit such proposed updates to the JCC for information only. During the course of the Commercialization Party's initial preparation of the Commercialization Plan and any subsequent updates, the other Party may, through its representatives on the JCC, provide input on Commercialization strategies for the Field for the Territory and the European Union. The Commercialization Party will give reasonable consideration to the other Party's input, but the other Party acknowledges that the Commercialization Party has the final decision-making authority over Commercialization activities in the Field in the Commercialization Party's territory.

5.3 Manufacturing and Supply.

5.3.1 Responsibility. The JCC will develop a manufacturing and supply strategy for the Territory. Pursuant to this strategy, AEVI will be solely responsible for and will lead day-to-day operational management of Manufacturing and supplying any Licensed Product for Commercialization in the Field in the Territory.

5.3.2 Supply by AEVI. Subject to Section 5.3.3, AEVI will Manufacture and supply all of KKC's requirements of Licensed Product for Commercialization and/or Development outside the Field in the Territory and outside the Territory. AEVI will supply KKC with unlabeled vialled Licensed Product for clinical trials conducted (a) outside the Territory, and (b) outside of the Field in the Territory and unlabeled vialled Licensed Product for Commercialization (i) outside the Territory or (ii) outside the Field in the Territory, in each case at (**). AEVI's distribution of Licensed Product will be to a single distributor or Affiliate of KKC, as directed by KKC. AEVI will ship all Licensed Product FCA (INCOTERMS 2020) AEVI's point of destination. The Parties will use Commercially Reasonable Efforts to complete within (**) after the Effective Date a supply agreement governing the terms of such supply by AEVI to KKC containing reasonable and customary terms contained herein and those additional terms typically associated with supply of pharmaceutical products (the "**Supply Agreement**").

5.3.3 KKC Manufacture Option. KKC will have the right to assume the right and responsibility to Manufacture or have Manufactured the Licensed Product for the jurisdictions designated in writing by KKC by notifying AEVI ("**KKC Manufacture Option**"). KKC may exercise the KKC Manufacture Option at any time on or before (**). Within (**) after such notice, the JCC will begin working on a transition plan for transferring responsibility for such Manufacturing from AEVI to KKC within a commercially reasonable timeframe, which transition plan will ensure the continuous, uninterrupted supply of the Licensed Product in the Territory, a process for ensuring that the transfer of the Manufacturing process and KKC's Manufacturing activities will comply with all Applicable Law (including without limitation obtaining all required permits and licenses from FDA) and the assignment to, and assumption by, KKC of any manufacturing agreement entered into between AEVI or any of its Related Parties and any Third Party for the Manufacture of the Licensed Product (the "**Manufacturing Responsibility Transition Plan**"). In the event that KKC determines not to assume any contract for the Manufacture of the Licensed Product, AEVI and KKC will each be responsible for the payment of fifty percent (50%) of any fees and expenses attributable to the early termination of such agreement. The Manufacturing Responsibility Transition Plan will be subject to the unanimous approval of the JSC. Each Party will use Commercially Reasonable Efforts to perform its responsibilities under the Manufacturing Responsibility Transition Plan. Under the Manufacturing Responsibility Transition Plan, AEVI will transfer to KKC all AEVI Know-How that is reasonably necessary or useful for Manufacturing of the Licensed Product. Upon transfer of Manufacturing to KKC in accordance with the Manufacturing Responsibility Transition Plan, as between the Parties, KKC will assume the right and responsibility to Manufacture Licensed Products for the jurisdictions designated by KKC, itself or through Third Parties. For the avoidance of doubt, none of AEVI or any of its Related Parties will be required to cease Manufacturing of the Licensed Product or to terminate any manufacturing agreement entered into between AEVI or any of its Related Parties and any Third Party for the Manufacture of the Licensed Product, in each case, until (a) KKC enters into a supply agreement with AEVI or its

Related Parties (as designated by AEVI) governing the terms of supply by KKC to AEVI containing reasonable and customary terms contained herein and those terms typically associated with supply of pharmaceutical product and (b) the transition of Manufacturing to KKC has been successfully completed including KKC receiving all required permits and licenses from FDA and KKC demonstrating its ability to Manufacture Licensed Product for the Field in the Territory that meets all relevant quality standards and specifications and in quantities sufficient to meet AEVI's and its Related Parties requirements. The Out-of-Pocket Costs for the transfer will be shared equally by both Parties. After the transition is completed, AEVI will have the right to purchase the unlabeled viald Licensed Product from KKC at (**).

5.3.4 Inspection Rights. Not more than once per year, if either Party (the "**Inspecting Party**") has any reasonable concerns regarding the other Party's or its Related Parties' Manufacturing of any Licensed Products or any other reasonable necessities for inspection or audit, the Inspecting Party will have the right, at the Inspecting Party's expense and on not less than (**) prior notice, to inspect the facilities where the other Party or its Related Parties Manufacture, or have Manufactured, any Licensed Products and to audit the procedures of such other Party or its Related Parties for the Manufacturing of Licensed Products for purposes of quality control.

5.4 Medical Affairs Activities. AEVI will be solely responsible for Medical Affairs Activities with the Licensed Products in the Field in the Territory, and KKC will be solely responsible for Medical Affairs Activities with the Licensed Products outside the Territory. The Commercialization Party will have the exclusive right to respond to all questions or requests for information about the Licensed Products made by any medical professionals or any other Person in its respective territory and field that are beyond the scope of the Product Labels and Inserts.

5.5 Cross Territory Sales.

5.5.1 KKC Restrictions. KKC will not Commercialize or authorize the Commercialization of any Licensed Product in the Field in the Territory. KKC will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Licensed Products in the Field in the Territory; provided that KKC may ship, consign, or otherwise transfer any Licensed Product inside Territory for purposes of Manufacturing the Licensed Products for Development and Commercialization of the Licensed Products outside Territory or outside the Field in the Territory. KKC will use Commercially Reasonable Efforts to ensure that Licensed Products sold by or on behalf of KKC outside the Territory are not Commercialized in the Field in the Territory, including use via re-importation from a country or jurisdiction outside the Territory. Without limiting the generality of the foregoing, KKC will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product in the Field in the Territory. KKC will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of KKC's contracts with any of the foregoing.

5.5.2 AEVI Restrictions. AEVI will not Commercialize or authorize the Commercialization of any Licensed Product outside the Territory or outside the Field in the

Territory. AEVI will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Licensed Product outside the Territory or outside the Field in the Territory; provided that AEVI may ship, consign, or otherwise transfer any Licensed Product outside the Territory for purposes of Manufacturing the Licensed Products and/or Developing the Licensed Products for Commercialization in the Field in the Territory. AEVI will use Commercially Reasonable Efforts to ensure that Licensed Products sold by or on behalf of AEVI in the Territory are not Commercialized outside the Territory. Without limiting the generality of the foregoing, AEVI will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product outside the Field in the Territory or facilitate the use of such Licensed Product outside the Territory. AEVI will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of AEVI's contracts with any of the foregoing.

Article 6. **DILIGENCE**

6.1 Diligence in Development.

6.1.1 Generally. AEVI will use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in the Territory (subject, with respect to Canada, to Section 6.1.2) and the European Union and to obtain Regulatory Approvals for the Licensed Product in the Field in the Territory (subject, with respect to Canada, to Section 6.1.2) and the European Union. For clarity, in the European Union, AEVI will apply to obtain the Regulatory Approval for a Licensed Product for the initial indication in the Field, provided that such Regulatory Approval will be owned by KKC or KKC's designee and will designate KKC or KKC's designee as the marketing authorization holder as described in Section 4.3.1(c)(ii). For clarity, AEVI will take the lead for the Phase 4 Clinical Trial in the European Union and provide KKC or KKC's designee all the Regulatory Materials with respect to such Phase 4 Clinical Trial for the initial indication. Subject to Section 6.1.2, if, with respect to any country in the Territory or the European Union, AEVI (a) does not (**), or (b) (**) files a Regulatory Approval Application but does not obtain Regulatory Approval and no additional clinical Development or Manufacturing activities are being conducted (**) in such country for such Licensed Product, then KKC will have the right to terminate this Agreement with respect to such country. For the avoidance of doubt, the filing of a Regulatory Approval Application with the EMA is considered a filing of a Regulatory Approval Application in all countries of the European Union.

6.1.2 Canada. With respect to Canada, the Parties acknowledge that Development of a Licensed Product in the Field in Canada is a matter for discussion in the JDC and the JSC at an appropriate time after Development of the Licensed Product for the initial indication in the Field in the Territory and the European Union is substantially advanced. Such discussion should take place no later than when the JSC decides to file the first Regulatory Approval Application for the Licensed Products in the Field in the United States, following the data readout of the Phase 3 Clinical Trial. If the JSC unanimously agrees not to proceed with the Development of a

Licensed Product in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, then AEVI will not be required to use Commercially Reasonable Efforts to Develop a Licensed Product and to obtain Regulatory Approvals for the Licensed Product in the Field in Canada. If AEVI elects not to proceed with the Development of a Licensed Product in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, and the JSC does not unanimously agree to the foregoing, then KKC may terminate this Agreement pursuant to Section 11.2.3 solely with respect to Canada, and AEVI will not be required to use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in Canada and to obtain Regulatory Approvals for the Licensed Product in the Field in Canada.

6.2 Diligence in Commercialization. AEVI will use Commercially Reasonable Efforts to Commercialize each Licensed Product in each country of the Territory in which Regulatory Approval is obtained, including identifying and committing sufficient resources for pre-launch, launch and subsequent Commercialization activities. KKC will use Commercially Reasonable Efforts to Commercialize each Licensed Product in the United Kingdom, France, Germany, Spain, and Italy ("**EU5 Countries**"); provided that Regulatory Approval is obtained for such country, including identifying and committing sufficient resources for pre-launch, launch and subsequent Commercialization activities. Both Parties acknowledge and agree that there may be cases that KKC may use Commercially Reasonable Efforts and choose not to Commercialize the Licensed Product in some of the EU5 Countries due to reimbursement pricing or for some other reasons, and in such cases KKC will not be liable for a breach of the diligence obligation set forth in this Section 6.2 in respect of such country.

6.3 Reports. On a semiannual basis but not later than June 30 and December 31 of each Contract Year, (a) each Party will provide to the JSC a written report summarizing its Development (including the status of any Regulatory Approval process) activities in the Territory and the European Union and (b) each Commercialization Party will provide other Party with a written report summarizing its Commercialization activities with respect to the Licensed Products in its territory on a Licensed Product-by-Licensed Product and country-by-country basis during the just-ended semiannual period.

Article 7.

LICENSES

7.1 License Grants to AEVI.

(a) Subject to the terms and conditions of this Agreement, KKC grants to AEVI, under the KKC Technology, an exclusive, non-transferable (except in accordance with Section 13.3) license, with the right to grant sublicenses solely as provided in Section 7.4, to:

(i) Develop Licensed Products (1) in the Field in the Territory, and (2) in the Field in the European Union, in the case of this clause (2) on behalf of KKC;

(ii) Manufacture or have Manufactured (subject to Sections 7.4.4 and 7.6) Licensed Products, unless and until KKC assumes Manufacturing after KKC exercises the KKC Manufacture Option; and

(iii) use, offer for sale, sell, have sold and otherwise Commercialize Licensed Products in the Field in the Territory; in each of clause (i), (ii), and (iii) in accordance with this Agreement.

(b) KKC hereby grants AEVI a non-exclusive, royalty-free, perpetual, worldwide, fully paid-up license, with the right to sublicense as provided in Section 7.4 without a duty of accounting or the obligation to obtain consent, under the KKC Inventions for which the costs of generating such KKC Invention was borne by both Parties pursuant to Section 8.2 and/or accounted as an Allowable Expense pursuant to Section 8.4, for any and all purposes.

7.2 License Grants to KKC.

(a) Subject to the terms and conditions of this Agreement, AEVI grants KKC, under the AEVI Technology, a non-exclusive license, royalty-free (except as to the AEVI In-License as set forth in Section 8.6.4(b)) license, with the right to sublicense solely as provided in Section 7.4, to:

(i) Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized Licensed Products outside the Field in the Territory and in any and all fields outside the Territory; and

(ii) Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized any diagnostic product that is reasonably necessary or useful in connection with the Manufacture, use, offer for sale, and/or sale of the Licensed Product outside the Field in the Territory and in any and all fields outside the Territory.

(b) AEVI hereby grants KKC a non-exclusive, royalty-free, perpetual, worldwide, fully paid-up license, with the right to sublicense as provided in Section 7.4 without a duty of accounting or the obligation to obtain consent, under any AEVI Inventions for which the costs of generating such KKC Invention was borne by both Parties pursuant to Section 8.2 and/or accounted as an Allowable Expense pursuant to Section 8.4, for any and all purposes.

7.3 Rights of Reference. Each Party hereby grants to the other Party the right to reference any and all Regulatory Approval Applications and Regulatory Approvals filed or obtained by the other Party in respect of a Licensed Product solely for use in connection with exercising such Party's rights under Section 7.1 or 7.2, as applicable.

7.4 Sublicenses.

7.4.1 Right to Sublicense. AEVI may not sublicense the rights granted to it under Section 7.1 to its Related Parties or Third Parties without the prior written consent of KKC,

which consent will not be unreasonably withheld, conditioned or delayed. KKC may not sublicense the rights granted to it under Section 7.2 to its Related Parties or Third Parties without the prior written consent of AEVI, which consent will not be unreasonably withheld, conditioned or delayed. The sublicensing Party will remain responsible for the performance of its sublicensees under this Agreement, including for all payments due hereunder. The sublicensing Party will provide the other Party with notice of each sublicense granting rights to Commercialize Licensed Products promptly after execution of such sublicense. In addition, each Party will provide a copy of any such sublicense to the other Party after execution of such sublicense. All such notices of sublicenses provided by the sublicensing Party under this Section 7.4.1 will be deemed to be Confidential Information of the sublicensing Party subject to the provisions of Article 10 whether or not so marked. (***) for nominal consideration to the extent reasonably necessary or useful for the Manufacture of Licensed Products (***)

7.4.2 Terms. Each sublicense granted by a Party pursuant to Section 7.4.1 will be subject and subordinate to the terms and conditions of this Agreement and will contain terms and conditions consistent with those in this Agreement. Agreements with any sublicensee that include the right to Commercialize any Licensed Product(s) will contain the following provisions: (a) the requirement set forth in Section 8.6.4(c); and (b) a requirement that such sublicensee comply with the confidentiality and non-use provisions of Article 10 with respect to both Parties' Confidential Information.

7.4.3 Effect of Termination on Sublicenses. If this Agreement terminates for any reason, each Party agrees to use Commercially Reasonable Efforts to enter into direct licenses with the other Party's sublicensees; provided that the sublicensee is not in breach of its sublicense agreement and such sublicensee agrees to comply with all of the terms of this Agreement to the extent applicable from the rights originally sublicensed to it by the sublicensing Party.

7.4.4 Subcontracting. The Parties will be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development activities; provided that each Party will remain at all times fully liable for its respective responsibilities under each Development Plan and this Agreement. Any agreement with a Third Party to perform a Party's responsibilities under this Agreement will include confidentiality and non-use provisions which are no less stringent than those set forth in Article 10 and intellectual property provisions that will allow such Party to comply with Article 9. Notwithstanding the foregoing, AEVI will not have the right to have the Licensed Product Manufactured by any Third Party without the prior written consent of KKC, which consent will not be unreasonably withheld, conditioned or delayed.

7.5 Exclusivity. Until expiration of all Data Exclusivity Periods for the Licensed Product in a jurisdiction in the Territory, AEVI and its Affiliates will not Commercialize, directly or indirectly, or in-license or otherwise acquire any product that is a Competing Product in the Field in such jurisdiction; provided, however, if AEVI or its Affiliates obtains such a Competing Product through a Change of Control or other acquisition or merger with, a Third Party, then

AEVI or its Affiliate (***) KKC has the right to Develop, Manufacture or Commercialize, directly or indirectly, or in-license or otherwise acquire any product that is a Competing Product.

7.6 In-Licenses.

7.6.1 KKC In-Licenses. All licenses and other rights granted to AEVI by KKC under this Article 7 are subject to the rights and obligations of KKC under the KKC In-Licenses. For the avoidance of doubt, if KKC Controls only a non-exclusive license under a KKC In-License, KKC's grant of exclusive license rights pursuant to Section 7.1 means that KKC and its Affiliates will not exercise and will not sublicense such rights with respect to Licensed Products in the Field in the Territory. AEVI and its Related Parties, and the applicable rights and licenses granted to AEVI hereunder, shall be subject to the rights retained, and obligations imposed, by the US government pursuant to the Bayh-Dole Act, Chapter 18 of Title 35 of the United States Code, Sections 200-212 with respect to the KKC Patent Rights solely owned by LJI. AEVI agrees to be bound by the pertinent sections of Section 1 of, and Sections 2.2, 2.3, 2.4, 2.5, 3.1, 5.3, 7.3, 7.4, 7.6, 7.9, 8.4, 8.5, 8.6, 10.4, 10.5, 10.6, 11.1, 12.6, 12.7 and 12.10 of, the LJI Agreement to the same extent that KKC is bound thereby.

7.6.2 AEVI In-Licenses. All licenses and other rights granted to KKC by AEVI under this Article 7 are subject to the rights and obligations under the AEVI In-License. KKC and its Related Parties, and the applicable rights and licenses granted to KKC hereunder, shall be subject to the rights retained, and obligations imposed, by the US government pursuant to the Bayh-Dole Act, Chapter 18 of Title 35 of the United States Code, Sections 200-212 with respect to the AEVI Patent Rights described in clause (a) of Section 1.10. KKC agrees to be bound by the pertinent sections of Sections 2, 3.6, 8.1, 9.2 and 12.3 of the AEVI In-License to the same extent that AEVI is bound thereby. In addition, the sublicense to KKC of the AEVI Technology licensed to AEVI under the AEVI In-License automatically terminates if and to the extent of termination of the AEVI In-License, subject to the right of KKC to request a direct license from CHOP.

7.7 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party, as a result of this Agreement, obtain any ownership interest or other right in any intellectual property rights of the other Party, including items Controlled or developed by the other Party, or provided by the other Party to such Party at any time pursuant to this Agreement. Unless expressly provided otherwise in this Agreement, KKC will retain all rights (including but not limited to Development and Commercialization rights) to the Licensed Products outside the Territory and outside the Field in the Territory.

Article 8.

FINANCIAL PROVISIONS

8.1 Initial License Fee. Within (***) after the Effective Date, AEVI will pay to KKC an initial license fee of (***)

8.2 Sharing of Development Costs.

8.2.1 Development Costs.

(a) The responsibility for payment of the Development Costs incurred during the Term will be shared between AEVI and KKC as set forth below:

(i) with respect to the Development of the initial indication for the Licensed Product in the Field in the Territory and in the European Union, the Parties will equally split the Development Costs incurred in accordance with a JSC-approved Development Plan up to aggregate Development Costs of (***) provided, that the Parties acknowledge that the initial Development Plan currently budgets (***) and further provided, for clarity, that increasing the Development budget for the initial indication in the Field in the Territory and the European Union requires compliance with the JDC, JSC, escalation and decision-making process set forth in Article 3;

(ii) except for Development Costs incurred for Phase 4 Clinical Trials, if Development Costs for the initial indication in the Territory and the European Union exceeds (***) for any reason, then AEVI will be solely responsible to fund such excess;

(iii) the Parties will equally split the Development Costs incurred for Phase 4 Clinical Trials; and

(iv) the allocation of Development Costs between the Parties with respect to Development of the Licensed Product for indications beyond the initial indication in the Field in the Territory and the European Union will be a matter for written agreement of the Parties if the JSC approves Development of such additional indication(s).

(b) Development Costs will not include any Manufacturing-related development costs, including but not limited to the process and analytical method developments, the comparability studies, stability program, process characterization and validation, method qualifications and validations, or the cost incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development in the Territory and the European Union, which costs will be borne solely by AEVI pursuant to Section 4.3.3. All payments made by a Party to a Third Party in connection with the performance of its activities under the applicable Development Plan will be charged as Development Costs at such Party's actual Out-of-Pocket Costs. For the avoidance of doubt, the cost for Phase 4 Clinical Trial conducted in Territory and/or European Union will be included in Development Costs.

8.2.2 Reporting of Development Costs. Within (**) after the end of each Contract Quarter, each Party will submit to the other Party a reasonably detailed report of all actual Development Costs incurred by such Party during the prior Contract Quarter. The payee, description of the services to which the payment relates and amount paid will be included in the report. Each Party will capture Development Costs in its respective accounting systems.

8.2.3 Payment of Development Costs. Within (**) after the delivery of both reports described in the preceding sentence, the Parties or their respective Affiliates will make payments to each other to the extent necessary to effect the division of the Development Costs

described in Section 8.2.1 (the “**True-up Payment**”). An illustrative, non-binding example of the payment required by this Section 8.2.3 is as follows: if the aggregate Development Costs incurred by both Parties in a Contract Quarter is \$5,000,000, with AEVI having paid \$3,000,000 and KKC having paid \$2,000,000, then KKC will pay to AEVI a \$500,000 True-up Payment so that AEVI will have paid \$2,500,000 in Development Costs and KKC will have paid \$2,500,000 in the Development Costs for such Contract Quarter. Notwithstanding the foregoing, in no event will a Party incur Development Costs greater than the amounts set forth in the applicable Development Plan, without the prior approval of the JSC. AEVI consents to the payment by an Affiliate of KKC of any and all payments payable by KKC under this Section 8.2.3.

8.2.4 Other Development Costs. Except for Development Costs allocated to AEVI in respect of the initial indication in the Field for the Licensed Product in the European Union or that AEVI and KKC agree to incur in respect of additional indications as set forth in Section 8.2.1(a)(iii), KKC will be solely responsible for Development Costs incurred in Developing any Licensed Product (a) outside the Field in the Territory and (b) outside the Territory.

8.3 Milestones.

8.3.1 Milestone Payments. AEVI will pay to KKC the amounts set forth below no later than (***) after the earliest date on which AEVI or any of its Related Parties receives written notification that the corresponding milestone event has first been achieved with respect to a Licensed Product:

<u>Milestone Event</u>	<u>Payment</u>
(***) for a Licensed Product by AEVI or its Related Party	(***\$***)
(***) for a Licensed Product by AEVI or its Related Party	(***\$***)
(***) for a Licensed Product filed with FDA by AEVI or its Related Party	(***\$***)
(***) for a Licensed Product filed with EMA by AEVI or its Related Party	(***\$***)

8.3.2 One Time Milestone Payments. Once AEVI has made any particular milestone payment under Section 8.3.1, AEVI will not be obligated to make any payment under Section 8.3.1 with respect to the re-occurrence of the same milestone, whether or not such re-occurrence is with respect to a different or the same Licensed Product.

8.4 Sharing of Profit.

8.4.1 Allocation. Profit will be allocated to (***) AEVI and KKC, such that (***)

8.4.2 Reconciliation. From and after the First Commercial Sale of a Licensed Product in the Field in the Territory, the Parties will conduct a quarterly reconciliation of Profit as follows:

(a) Within (***) after the end of each Contract Quarter, AEVI will submit to KKC a preliminary written report setting forth the following information, estimated where necessary,

revenues and expenses included in Profit for Profit-Share Products for the first two (2) months of such Contract Quarter, including, as applicable:

(i) all sales in units and in Net Sales value of such Profit-Share Products in the Territory made by AEVI and its Related Parties during such two (2) month period, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such two (2) month period;

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to such Profit-Share Products during such two (2) month period; and

(iv) good faith estimate of revenues and expenses included in Profit for Profit-Share Products for the last month of such Contract Quarter, for financial reporting purposes.

(b) Within (***) after the end of each Contract Quarter, AEVI will submit to KKC a final written report setting forth, as applicable:

(i) all sales in units and in Net Sales value of Profit-Share Products in the Territory made by AEVI and its Related Parties during such Contract Quarter, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such Contract Quarter, and

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to Profit-Share Products during such Contract Quarter.

8.4.3 Tax Reporting. Together with the report submitted by AEVI pursuant to Section 8.4.2(b), AEVI will submit to KKC the calculation of Profit, the amount of any taxes required to be withheld and the calculation of the net amount owed by AEVI to KKC in order to ensure the sharing of Profit set forth in Section 8.4.1 and the proper allocation of withholding taxes pursuant to Section 8.6.1. The net amount payable with respect to Profit, after appropriate adjustment for any withholding taxes, will be paid by AEVI within (***) following receipt of invoice for such amount.

8.4.4 Supporting Documents. In addition to providing the information set forth in Section 8.4.2, AEVI will provide reasonable supporting documentation of Allowable Expenses included in the calculation of Profit.

8.5 KKC Royalties.

8.5.1 Royalty Percentages. During the Term, but subject to any applicable offsets contained herein, KKC will pay to AEVI royalties on Royalty-Bearing Sales or Sublicensing Royalties, as applicable, on a country-by-country basis, subject to any applicable offsets or

reductions pursuant to Section 8.5.2, 8.5.3, and/or 8.5.4, at the rate of: (a) (***) (the “**EU Royalty Rate**”) of (i) Royalty-Bearing Sales by KKC and its Affiliates in the Field in the European Union and (ii) Sublicensing Royalties resulting from sales in the Field in the European Union; (b) (***) (the “**KKC Territory Royalty Rate**”) of (i) Royalty-Bearing Sales by KKC and its Affiliates in the Field outside of the Territory and outside of the European Union and (ii) Sublicensing Royalties resulting from sales in the Field outside of the Territory and outside of the European Union; (c) (***) (the “**Other Royalty Rate**”) of (i) Royalty-Bearing Sales by KKC and its Affiliates outside of the Field outside of the Territory and (ii) Sublicensing Royalties resulting from sales outside of the Field outside of the Territory; and (d) (***) (as adjusted, if applicable, pursuant to the following sentence, the “**Territory Royalty Rate**”) of Royalty-Bearing Sales by KKC and/or its Affiliates in the Territory and Sublicensing Royalties resulting from sales in the Territory. In the event that AEVI’s Net Sales of Licensed Products in a country in the Territory experience a Significant Impact as a result of KKC or any of its Related Parties commercializing Licensed Product in the Territory, the Parties will negotiate in good faith to increase the Territory Royalty Rate for such country to offset the Significant Impact, which Territory Royalty Rate will not exceed (***) in any country.

8.5.2 Third Party License Offsets. If KKC enters into an agreement with a Third Party (other than a KKC Licensor) to obtain a license under Third Party Technology (including without limitation under Section 9.5) that KKC reasonably believes or expects to be necessary to Commercialize one or more Licensed Products outside the Territory or outside of the Field, then KKC may offset (***) of the amount of commercially reasonable royalties or other payments payable by KKC to such Third Party with respect to a particular Licensed Product against amounts KKC is obligated to pay AEVI under Section 8.5.1 for Royalty-Bearing Sales by KKC and/or its Affiliates and Sublicensing Royalties, provided that in no event will any such offset (a) with respect to sales in the Field in the European Union, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(a) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field in the European Union, (b) with respect to sales in the Field outside of the Territory and outside of the European Union, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(b) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field outside of the Territory and outside of the European Union, (c) with respect to sales outside of the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(c) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties outside of the Field outside of the Territory, and (d) with respect to sales in the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(d) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Territory; provided further that, if such (***) offset of such Third Party royalties or other payments exceeds the amount of payments withheld by KKC under this Section 8.5.2 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.3 Claimed Infringement of Third Party Rights Offsets. If costs and expenses and damages are incurred by the Parties in connection with the defense of an Infringement Claim outside the Field or outside the Territory pursuant to Section 9.4, then KKC may offset (***) of such costs and expenses and damages with respect to a particular Licensed Product against

amounts KKC is obligated to pay AEVI under Sections 8.5.1 and 8.5.2 on sales of such Licensed Product, provided that in no event will any such offset (a) with respect to sales in the Field in the European Union, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(a) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field in the European Union, (b) with respect to sales in the Field outside of the Territory and outside of the European Union, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(b) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field outside of the Territory and outside of the European Union, (c) with respect to sales outside of the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(c) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties outside of the Field outside of the Territory, and (d) with respect to sales in the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(d) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Territory; provided further that, if such (**) offset of such costs and expenses and damages incurred by the Parties exceeds the amount of payments withheld by KKC under this Section 8.5.3 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.4 Royalty Reduction for Biosimilars.

(a) If a Biosimilar version(s) of any Licensed Product is commercialized in any country in which there are Royalty-Bearing Sales, then the royalty rate payable to AEVI pursuant to Sections 8.5.1, 8.5.2 and 8.5.3 applicable for the sale of Licensed Products in such country will be reduced by (i) (**) applicable for the first Contract Quarter during which the market share of such Biosimilars is (**) in such country, (ii) (**) applicable for the first Contract Quarter during which the market share of such Biosimilars is (**) in such country, (iii) (**) applicable for the first Contract Quarter during which the market share of such Biosimilars is (**) in such country, (iv) (**) applicable for the first Contract Quarter during which the market share of such Biosimilars is (**) in such country; and (v) (**) applicable for the first Contract Quarter during which the market share of such Biosimilars is (**) in such country. For clarity, the reduction in royalty rates permitted pursuant to this Section 8.5.4 will be taken after any reduction taken pursuant to Section 8.5.2 and Section 8.5.3. For the avoidance of doubt, the minimum EU Royalty Rate will be (**), each of the minimum KKC Territory Royalty Rate and the minimum Other Royalty Rate will be (**) and the minimum Territory Royalty Rate (on a country-by-country basis) will be no less than (**) of the Territory Royalty Rate (on a country-by-country basis) then in-effect prior to the adjustments permitted by this Section 8.5.4; provided that, if such reduction permitted under this Section 8.5.4 exceeds the amount of payments withheld by KKC under this Section 8.5.4 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

(b) The Parties will utilize a mutually-agreed (such agreement not to be unreasonably withheld, delayed, or conditioned) measure of the market share of any relevant Biosimilars in each country where a Biosimilar version(s) of a Licensed Product is being commercialized and will adjust the royalty rate payable to AEVI for the sale of Licensed Products in such country every (**), to the extent permitted pursuant to Section 8.5.4(a). If the

royalty rate payable to AEVI for the sale of Licensed Products has been adjusted pursuant to Section 8.5.4(a), then such royalty rates in such country may not thereafter be adjusted upwards.

8.5.5 Reports and Royalty Payments. Within (***) after the end of each Contract Quarter during the Term, KKC will deliver to AEVI a report setting forth for the previous Contract Quarter the following information on a Licensed Product-by-Licensed Product and country-by-country basis: (a) the gross sales and Royalty-Bearing Sales of each Licensed Product, (b) the number of units sold by KKC or its Affiliate, (c) the Sublicensing Royalty received by KKC, (d) the basis for any adjustments to the royalty payable for the sale of each Licensed Product, (e) the royalty due hereunder for the sales of each Licensed Product, and (f) the applicable exchange rate as determined pursuant to Section 8.6.2. The total royalty due for the sale of Licensed Products during such Contract Quarter will be remitted at the time such report is made but no later than (***) after the end of each Contract Quarter during the Term. Along with such reports, KKC will also provide the Sales Tracking Methodologies used to determine Royalty-Bearing Sales outside the Field in the Territory.

8.6 Payment Provisions Generally.

8.6.1 Taxes and Withholding. If Applicable Laws require withholding of income taxes or other taxes imposed upon payments set forth in Article 8, the paying Party will make such withholding payments as required and subtract such withholding payments from the payments set forth in Article 8. The paying Party will submit appropriate proof of payment of the withholding taxes to the payee Party within a reasonable period of time. At the request of the payee Party, the paying Party will, at the payee Party's cost, give the payee Party such reasonable assistance, which will include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable the payee Party to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and will upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.

8.6.2 Payment and Currency Exchange. All amounts payable and calculations hereunder will be in United States dollars and will be paid by bank wire transfer in immediately available funds to such bank account as may be designated in writing by the payee Party from time to time. Whenever for the purposes of calculating the Profit or royalties payable under Section 8.4 or 8.5, conversion from any foreign currency will be required, all amounts will first be calculated in the currency in which the activity was paid or sale was recorded and then converted into United States dollars by applying the rate of exchange quoted in the New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter.

8.6.3 Overdue Payments. If any payment due under this Agreement (other than payments that are the subject of a good faith dispute between the Parties) is overdue by more than thirty (30) days, the paying Party will pay interest to the payee Party at a rate per annum equal to the lesser of the prime rate of interest, as reported by New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter, or

the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due.

8.6.4 Financial Matters Relating to Existing In-Licenses.

(a) All amounts payable in respect of Profit-Share Products under the KKC In-Licenses will be paid directly by KKC or its Related Parties to the KKC Licensor, AEVI will reimburse KKC such amounts as defined in Section 1.89(a), and any such amounts reimbursed by AEVI will be treated as Allowable Expenses.

(b) All amounts payable in respect of Profit-Share Products under AEVI In-Licenses will be paid directly by AEVI or its Related Parties to the applicable AEVI Licensor and such amounts as defined in Section 1.89(b) will be treated as Allowable Expenses to the extent paid by AEVI or any of its Related Parties. All amounts required to be paid pursuant to Section 6.4.1 of the AEVI In-License as a direct result of sales of any Licensed Product sold by KKC or its Related Parties will be paid and borne solely by KKC and its Related Parties. In addition, all amounts required to be paid pursuant to Section 6.4.2 of the AEVI In-License as a direct result of sales of any diagnostic sold by KKC or its Related Parties will be paid and borne solely by KKC and its Related Parties and will not be a part of Third Party Technology Costs described in Section 1.89(b). For avoidance of doubt, all amounts required to be paid pursuant to Section 6.4.2 of the AEVI In-License as a direct result of sales of any diagnostic sold by AEVI or its Related Parties will be paid and borne solely by AEVI and its Related Parties and will not be a part of Third Party Technology Costs described in Section 1.89(b).

(c) If AEVI or any of the Related Parties contracts with a Third Party other than Lonza, or if KKC grants a sublicense under the KKC Technology to AEVI's preferred contract manufacturer pursuant to Section 7.4.1, for the supply of the Licensed Product, and the entry into such contract triggers any payment obligation by KKC to Lonza, then AEVI will reimburse KKC (***), provided that any such reimbursement obligations of AEVI will not exceed (**) per calendar year. Such payment to Lonza will be first payable within (**) of signature of a manufacturing agreement with such Third Party or grant of sublicense to such contract manufacturer and will continue for the duration of such manufacture by such Third Party or sublicense. No payment made by AEVI under this Section 8.6.4(c) will be included in Allowable Expenses.

(d) Notwithstanding anything to the contrary in Section 8.6.4(c), if AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date, AEVI may deduct (**) from the initial license fee and milestone payments payable to KKC by AEVI under Sections 8.1 and 8.3, (**).

(e) If AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date and AEVI has an obligation to pay an annual fee to Lonza pursuant to such agreement for conducting the process development or Manufacture of the Licensed Product using a contract manufacturer that is not Lonza, KKC will reimburse AEVI an amount equal to (**). For clarity, no portion of (**) pursuant to this Section 8.6.4(e) will be subject to the deduction set forth in Section 8.6.4(d) or will be included in Allowable Expenses.

8.6.5 Record-Keeping. Each Party will keep, and will cause their respective Related Parties to keep, books and accounts of record in connection this Agreement in sufficient detail to permit accurate determination of all figures necessary for any and all financial calculations required by this Agreement, including without limitation all elements of Allowable Expense, Developments Costs, Net Sales, Royalty-Bearing Sales, and Profit. Each Party will maintain, and will cause their respective Related Parties to maintain, such records for a period of at least five (5) years after the end of the Contract Year in which they were generated.

8.6.6 Audits. Upon thirty (30) days' prior written notice from a Party (the "**Requesting Party**"), the Party receiving the written notice (the "**Audited Party**") will permit an independent certified public accounting firm of nationally recognized standing selected by the Requesting Party and reasonably acceptable to the Audited Party, to examine, at the Requesting Party's sole expense, the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the amounts reporting or payable by the Audited Party to the Requesting Party. An examination by a Requesting Party under this Section 8.6.6 will occur not more than once in any Contract Year and will be limited to the pertinent books and records for any Contract Year ended not more than five (5) years before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination will be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm will provide both the Audited Party and the Requesting Party a written report disclosing any discrepancies in the reports submitted by the Audited Party or, as applicable, the amounts payable under this Agreement, and in each case, the specific details concerning any discrepancies. No other information will be provided to the Requesting Party.

8.6.7 Underpayments/Overpayments. If such accounting firm concludes that additional amounts were due to the Requesting Party, the Audited Party will make such payments as is necessary for the Requesting Party to have been paid the correct amount due under this Agreement for the audited periods. If such underpayment exceeds five percent (5%) of the amounts that were to be paid, the Audited Party also will reimburse the Requesting Party for all Out-of-Pocket Costs incurred in conducting the audit. If such accounting firm correctly concludes that the Audited Party overpaid amounts due to the Requesting Party, the Requesting Party will refund such overpayments to the Audited Party within sixty (60) days of the date the Requesting Party receives such accountant's report so correctly concluding.

8.6.8 Confidentiality. All financial information of a Party that is subject to review under this Section 8.6 will be deemed to be Confidential Information of such Audited Party subject to the provisions of Article 10, and the Requesting Party will not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than verifying payments to be made by the Audited Party to the Requesting Party hereunder.

8.7 Adjustment of FTE Rates. Effective upon each anniversary of the Effective Date, the FTE Rates will increase by the percentage increase, if any, in the Consumer Price Index published by the United States Bureau of Labor Statistics during the most recent preceding one (1) year period for which final data is available, and such increase will be effective for the then-current and all subsequent FTE Costs hereunder unless and until further modified under this Section 8.7. In addition, within sixty (60) days after the third anniversary of the Effective Date and every three (3) years thereafter, each Party will have the right to require the other Party to conduct a salary survey in respect of FTEs and provide the result of such survey. In addition, a Party may conduct a salary survey at its own discretion in respect of FTEs and provide such survey to the other Party. Following receipt of such survey from each Party, the Parties may agree in writing to adjust one or more of the FTE Rates.

Article 9.

INTELLECTUAL PROPERTY

9.1 Ownership of and Rights to Intellectual Property.

9.1.1 AEVI Technology. As between the Parties, AEVI is and will remain the sole owner of the AEVI Technology. KKC acknowledges that certain of the AEVI Patent Rights have been licensed to AEVI from the AEVI Licensor pursuant to the AEVI In-License.

9.1.2 KKC Technology. As between the Parties, KKC is and will remain the sole owner of the KKC Technology. AEVI acknowledges that certain of the KKC Patent Rights have been licensed to KKC from the KKC Licensors pursuant to the KKC In-Licenses.

9.1.3 Joint Inventions. The Parties will jointly own all Joint Inventions, and each will have an undivided interest in the Joint Inventions subject to the licenses granted under this Agreement.

9.1.4 Inventorship. For purposes of determining whether an invention is solely invented by AEVI or solely invented by KKC, or a Joint Invention, questions of inventorship will be resolved in accordance with United States patent laws.

9.2 Filing, Prosecution and Maintenance of Patent Rights.

9.2.1 KKC Patent Rights. This Section 9.2 will not apply to the KKC Patent Rights over which KKC has no right to control the filing, prosecution or maintenance thereof, and, for purposes of this Section 9.2, the KKC Patent Rights over which KKC has the right to control the filing, prosecution and maintenance thereof, including those described in clauses (a) and (c) of Section 1.55, but excluding those described in clause (b) of Section 1.55, are referred to as the “***KKC Managed Patent Rights***.”

(a) As between KKC and AEVI, KKC, through counsel of its choosing, will control (but not be obligated to control) the prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of the KKC Patent Rights in the Territory. AEVI will provide all reasonable assistance required to prosecute the KKC Patent Rights in the

Territory. AEVI will have the right to review and comment upon any substantive communications received from the applicable patent offices with respect to the KKC Managed Patent Rights, including, but not limited to, official actions, examination reports, documents relating to patentability and/or amendment or cancellation of the claims, and documents related to patent term adjustment and patent term extension. KKC will consider all comments received from AEVI with respect to the KKC Managed Patent Rights and will comply with all reasonable requests. In addition, AEVI will have the right to review and comment upon any substantive communications that KKC plans to make to an applicable patent office in the Territory with respect to the KKC Managed Patent Rights, including, but not limited to, draft responses to official actions, draft responses to examination reports, drafts relating to amendment or cancellation of the claims, and drafts relating to patent term adjustment and/or extension. KKC will provide AEVI with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. KKC will consider all comments received from AEVI and will comply with all reasonable requests. In addition to the above, KKC will keep AEVI reasonably informed with respect to all such prosecution and maintenance activities to which KKC has access, including written communications with patent office officials, and consult with AEVI regarding such matters, including the planned abandonment of claims thereof.

(b) At AEVI's sole cost and expense, KKC will keep AEVI reasonably informed with respect to all prosecution and maintenance activities concerning Patent Rights outside the Territory that correspond to the KKC Patent Rights. AEVI will have the right to review any substantive communications received from the applicable patent offices with respect to the KKC Managed Patent Rights, including, but not limited to, official actions, examination reports, documents relating to patentability and/or amendment or cancellation of the claims, and documents related to patent term adjustment and patent term extension. In addition, AEVI will have the right to review any substantive communications that KKC plans to make to an applicable patent office outside of the Territory with respect to the KKC Managed Patent Rights, including, but not limited to, draft responses to official actions, draft responses to examination reports, drafts relating to amendment or cancellation of the claims, and drafts relating to patent term adjustment and/or extension.

(c) If KKC determines in its sole discretion to abandon or not maintain any KKC Managed Patent Rights, in one or more country(ies) or in the entire Territory, then KKC will provide AEVI with at least sixty (60) days prior written notice of such determination to abandon or cease maintenance (or such other longer period of time reasonably necessary to allow AEVI to assume such responsibilities). If KKC provides such a notification, then AEVI will have the right (but not the obligation), to control the prosecution and maintenance of any such KKC Managed Patent Rights in its sole discretion and at AEVI's sole cost and expense by providing KKC with notice thereof within such sixty (60) day period. In the event that AEVI so elects to control the prosecution and maintenance of any KKC Managed Patent Rights, then in the concerned country(ies) or in the entire Territory, as applicable, KKC will provide all reasonable assistance required to prosecute such KKC Managed Patent Rights in the concerned country(ies) or in the entire Territory, at AEVI's sole cost and expense, including allowing AEVI to exercise all rights of KKC under the KKC In-License with LJI relevant to prosecution and maintenance of the KKC

Managed Patent Rights. KKC will have the right to review and comment upon any substantive communications and filings made by AEVI with respect to the prosecution of such KKC Managed Patent Rights before they are sent to any patent offices in the entire Territory. AEVI will provide KKC with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. With respect to all such prosecution and maintenance AEVI will keep KKC reasonably informed with respect to such activities (including by providing KKC with access to all filings and correspondence with and from any patent offices or officials upon request by KKC), and consult with KKC regarding such matters, including the abandonment of claims thereof

(d) Notwithstanding anything to the contrary in this Agreement (including Section 9.3.1(a)), the following terms and conditions will apply with respect to the KKC Patent Rights: (i) with respect to those KKC Patent Rights solely owned by LJI, LJI and KKC will have the joint right to control the filing, prosecution and maintenance of such KKC Patent Rights, including the extension of the patent term(s) of such KKC Patent Rights, and if both LJI and KKC determine in their sole discretion to abandon or not maintain such KKC Patent Rights, then AEVI will have the right, subject to Section 9.3.1(a) and the other applicable terms and conditions of this Agreement, to control the prosecution and maintenance of any such KKC Patent(s) and KKC will request LJI to provide all reasonable assistance required to prosecute and maintain such KKC Patent Rights; and (ii) with respect to those KKC Patent Rights jointly owned by LJI, on the one hand, and KKC and/or its Affiliates, on the other hand, in the event that both KKC and AEVI determine in their sole discretion to abandon or not maintain any such KKC Patent(s), then (A) LJI will have the right to control the filing, prosecution and maintenance (including, without limitation, the extension of the patent term(s)) of such KKC Patents, and (B) all rights and licenses granted to KKC under the LJI Agreement (and therefore the sublicense to AEVI under this Agreement) in and to such KKC Patent(s) will immediately terminate.

(e) Notwithstanding anything to the contrary in this Agreement, to the extent that KKC does not have the right to control or participate in the prosecution or maintenance of Patent Rights under a KKC In-License, no right to prosecute or maintain such Patent Rights are granted to AEVI by this Agreement.

(f) All information, if any, exchanged between the Parties or between KKC's outside patent counsel and AEVI regarding preparation, filing, prosecution or maintenance of the KKC Patent Rights will be deemed Confidential Information of KKC. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution and maintenance of the KKC Patent Rights, the interests of the Parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the KKC Patent Rights including without limitation, privilege under the common interest doctrine and similar or related doctrines.

9.2.2 Joint Inventions. With respect to any potentially patentable Joint Invention, the Parties will meet and agree upon which Party will lead (in a joint effort with the other Party)

the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of patent applications covering such Joint Invention (any such patent application and any patents issuing therefrom a “**Joint Patent**”) in any jurisdiction. Joint Patents are included within both the KKC Technology and AEVI Technology and within the licenses granted to each Party hereunder. The Party that leads prosecution of a patent application in the Joint Patents (the “**Prosecuting Party**”) will provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patents in the particular jurisdictions, and such other Party will provide the Prosecuting Party reasonable assistance in such efforts, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. The Prosecuting Party will provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and will provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party will no longer be obligated to pay any costs for filing, prosecution or maintenance thereof; (ii) the disclaiming Party will, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration and (iii) if such assignment is effected, any such Joint Patent would thereafter be deemed a patent of AEVI in the case of assignment to AEVI, or a patent of KKC in the case of assignment to KKC.

9.2.3 New Inventions. AEVI will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all AEVI Inventions, and KKC will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all KKC Inventions. All the foregoing will be included in the license granted by each Party to the other Party in Article 7. Each Party will disclose any such inventions or improvements to the other Party within ninety (90) days of filing a patent application claiming the Invention.

9.2.4 Cooperation. Each Party hereby agrees: (a) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party’s authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution as contemplated by this Agreement; (b) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights that are subject to this Agreement; and (c) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the prosecution and maintenance of the other Party’s patent applications that are subject to this Agreement.

9.2.5 Patent Costs. The Parties will each be responsible for paying fifty percent (50%) of the costs and expenses of filing, prosecuting and maintaining the KKC Patent Rights, the AEVI Patent Rights described in clause (a) of Section 1.10, and the Joint Patents, in the Territory and in the European Union. During the Term, if KKC agrees in writing, the Parties

will add to Schedule 1.10 the patents described in clauses (b) and (c) of Section 1.10, and thereafter, the costs and expenses of filing, prosecuting and maintaining of each such patent will be shared by the Parties. For clarity, costs and expenses outside of the Territory and outside of the European Union will be borne solely by KKC for the KKC Patent Rights, solely by AEVI for the AEVI Patent Rights, and equally by each Party for the Joint Patents.

9.3 Enforcement of Patent Rights.

9.3.1 Notification. Each Party will promptly report in writing to the other Party during the Term any (a) known or suspected infringement by a Third Party of any KKC Patent Rights, AEVI Patent Rights or Patent Rights covering Joint Inventions or (b) unauthorized use or misappropriation by a Third Party of any Confidential Information, including KKC Know-How or AEVI Know-How, of which it becomes aware, and will provide the other Party with all available evidence supporting such infringement or unauthorized use or misappropriation.

9.3.2 Rights to Enforce. KKC will have the right, but not the obligation, to take any reasonable measures it deems appropriate to: (a) stop infringing activities described in Section 9.3.1 in respect of the KKC Technology in the Territory including initiating or prosecuting an infringement or other appropriate suit or action against the alleged infringer, but not granting adequate rights and licenses necessary for continuing such activities by the alleged infringer or (b) defend the KKC Technology in the Territory against any declaratory judgment, opposition, patentability or invalidity actions (“*Defensive Actions*”). KKC may request that AEVI grant such adequate rights and licenses; provided that AEVI will have no obligation to grant any such rights or licenses; and provided further that upon making such request, AEVI will have the right to participate in all negotiations with the alleged infringer concerning such adequate rights and licenses. Before KKC takes any action to stop the infringing activity against an alleged infringer of the KKC Technology in the Territory, KKC will consult in good faith with AEVI concerning the alleged infringement, including selection of counsel, litigation strategy, litigation risks, the damage being caused to KKC and/or AEVI and any other matter relevant to enforcement of the KKC Technology against the alleged infringer in the Territory. In particular, KKC will consider in good faith a request from AEVI to not take any actions to enforce the KKC Technology against the alleged infringer in the Territory and only take such actions, in light of such request from AEVI, if KKC is suffering material harm from the infringement in the Territory. Subject to the provisions of the LJI Agreement, in the event that KKC elects to not take action or cease action with respect to the KKC Managed Patent Rights pursuant to this Section 9.3.2 with respect to the Territory, including declining or ceasing to defend Defensive Actions, KKC will so notify AEVI in writing of its intention (***) prior to any deadlines by which an action must be taken to establish, preserve or maintain any enforcement rights or defend or continue to defend the Defensive Action, and, subject to Section 9.3.4, AEVI will have the right, but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer or defend the Defensive Action, in which event, upon AEVI’s request, KKC will exercise its rights under the LJI Agreement to the extent necessary for the enforcement or defense of KKC Managed Patent Rights that are subject to the LJI Agreement.

9.3.3 Procedures: Expenses and Recoveries. The Party having the right to initiate any infringement suit or defend a Defensive Action under Section 9.3.2 (the “**Controlling Party**”) will have the sole and exclusive right to select counsel for and control any such suit or Defensive Action. The expenses of the suit or the Defensive Action, including attorneys’ fees and court costs and reasonable Out-of-Pocket Costs of the other Party (the “**Cooperating Party**”) in rendering assistance requested by the Controlling Party (“**Enforcement Expense**”) will be (***). If required under Applicable Law in order for the Controlling Party to initiate and/or maintain such suit or to defend the Defensive Action, or if either Party is unable to initiate or prosecute such suit or defend the Defensive Action solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party will join as a party to the suit or Defensive Action and will execute and cause its Affiliates to execute all documents necessary for the Controlling Party to initiate litigation to prosecute and maintain such action or defend the Defensive Action. In addition, at the Controlling Party’s request, the Cooperating Party will provide reasonable assistance to the Controlling Party in connection with an infringement suit (***). The Cooperating Party will have the right to participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation) (“**Recoveries**”) in the Territory, such amounts will be (***). A Cooperating Party may choose not to share the Enforcement Expense, provided however that in such case such Cooperating Party will not be entitled to receive any of the Recoveries. For clarity, (a) KKC will offer AEVI the opportunity to fund its share of the Enforcement Expense with respect to any suit initiated by KKC in the European Union and, if AEVI elects to fund such Enforcement Expense, AEVI will be entitled to an equal share in the Recovery received in respect of any such suit, and (b) KKC will have the sole right to take action and earn all Recoveries outside of the Territory and the European Union.

9.3.4 LJI Enforcement Rights. The Parties acknowledge and agree that in the event that (***), LJI will have the right but not the obligation under the LJI Agreement to bring, defend, or maintain any appropriate suit or action involving such infringement or Defensive Action at its own cost and expense against alleged infringers and to defend such KKC Patent Rights from Defensive Actions. Subject to the foregoing, if LJI finds it necessary or reasonably desirable to join AEVI and/or KKC into such suit or action, AEVI and/or KKC will execute all papers and perform such other acts as may be reasonably required, and AEVI and/or KKC, at their respective options, may be represented by respective counsel(s) of their own choice, provided that (a) (***), and (b) if any amount is recovered on any such action or suit, whether by judgment or settlement (any such settlement requiring the consent of KKC), the balance of any such recovery will be paid to or retained (***) (including, for clarity, the LJI (***) set forth on Schedule 1.51) in respect of the applicable KKC Patent Right(s) and Licensed Product(s), after reimbursement for the reasonable attorneys’ fees incurred with respect to such suit or action by LJI, KKC and AEVI.

9.4 Claimed Infringement of Third Party Rights.

9.4.1 Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of such Party’s

respective Related Parties, claiming infringement of such Third Party's Patent Rights or unauthorized use or misappropriation of such Third Party's Know-How, based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of a Licensed Product (each, an "***Infringement Claim***"), such Party will promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served. Each Party agrees to make available to the other Party its advice and counsel regarding the technical merits of any such claim at no cost to the other Party and to offer reasonable assistance to the other Party at no cost to the other Party.

9.4.2 Right to Defend. AEVI will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product in the Field in the Territory. KKC will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product outside the Field and outside the Territory.

(a) Procedure. The Party having the obligation or first right to defend an Infringement Claim in which either Party is named as defendant will be referred to as the "***Defending Party***." The Defending Party will have the sole and exclusive right to select counsel for any Infringement Claim; provided that it will consult with the other Party with respect to selection of counsel for such defense. The Defending Party will keep the other Party informed, and will from time to time consult with the other Party regarding the status of any such claims and will provide the other Party with copies of all documents filed in, and all written communications relating to, any suit brought in connection with such claims. The other Party will also have the right to participate and be represented in any such claim or related suit, at its own expense. The other Party will have the sole and exclusive right to control the defense of an Infringement Claim in the event the Defending Party fails to exercise its right to assume such defense within (***) following written notice from the other Party of such Infringement Claim. No Party will settle any claims or suits involving rights of another Party without obtaining the prior written consent of such other Party, which consent will not be unreasonably withheld. Any recoveries by the Defending Party of attorneys' fees or costs in defense of a claim in the Territory under this Section 9.4, and any sanctions awarded to Defending Party and against a party asserting a claim in the Territory being defended under this Section 9.4, will be (***). The Parties will (***) be responsible for paying (***) of the costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim in the Territory. The costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim outside the Field or outside the Territory will be allocated between the Parties as follows: (***). AEVI and KKC will have the right to take action to invalidate Third Party's patents which would be infringed by the activity under this Agreement. The cost and expenses of such action will be shared in the same way as set forth above.

9.4.3 Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTION 12.10, THE FOREGOING STATES THE ENTIRE RESPONSIBILITY OF KKC AND MEDGENICS, AND THE SOLE AND EXCLUSIVE REMEDY OF KKC OR

MEDGENICS, AS THE CASE MAY BE, IN THE CASE OF ANY CLAIMED INFRINGEMENT OF ANY THIRD PARTY PATENT RIGHTS OR UNAUTHORIZED USE OR MISAPPROPRIATION OF ANY THIRD PARTY'S KNOW-HOW.

9.5 Third Party Technology. If either Party reasonably determines that any Third Party Technology is reasonably necessary for the Development, Manufacture, or Commercialization of a Licensed Product in the Field, then such Party will notify the JSC. If the JSC determines that it needs to obtain one or more licenses from one or more Third Parties for such activities, the JSC will determine which Party will negotiate the most favorable license. The chosen Party will obtain a license to such Third Party Technology, with the right to sublicense, in order to permit both Parties to conduct such activities. Subject to the foregoing, the terms and conditions involved in obtaining such rights will be determined at such chosen Party's sole discretion. If such chosen Party elects not to obtain rights to such Third Party Technology, or is unsuccessful in obtaining such Third Party Technology, then the other Party will have the right (but not the obligation) to negotiate and obtain rights from such Third Party at its sole discretion and expense. Notwithstanding anything to the contrary in this Section 9.5, AEVI will pay to a Third Party any and all royalties and other payments pursuant to any agreement under which a Party acquires rights to intellectual property that would otherwise block the Development and/or Commercialization of a Profit-Share Product in the Field in the Territory. Any such payments will be included in Third Party Technology Costs and, for clarity, will be included in Allowable Expenses for the applicable Profit-Share Product. The costs outside the Field will be borne solely by KKC, provided that such costs will be subject to royalties reduction to AEVI in accordance with Section 8.5.2. Notwithstanding the foregoing, with respect to any lump sum payment under any such agreement that is made with respect to a license covering countries or jurisdictions both inside and outside of the Territory, the Parties will negotiate and decide in good faith the allocation of the payment based on the scope and territory of the acquired rights.

9.6 Other Infringement Resolutions.

9.6.1 Notice of Third Party Applications. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the type described in Sections 9.3 or 9.4, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) will apply. Notwithstanding anything herein to the contrary, within (***) after Regulatory Approval is achieved with respect to a BLA for a Licensed Product in the Territory (or such shorter time as the Parties agree in the case of a Licensed Product in the Territory that does not earn reference product exclusivity under the PHS Act), the Parties will consult as to potential strategies with respect to unexpired Patent Rights Controlled by either Party that potentially could be asserted if an unlicensed person engaged in the making, using, offering to sell, selling, or importing into the United States of a product described in a Biosimilar Application filed by a Third Party applicant (a "***Section 351(k) Applicant***").

9.6.2 Cooperation and Enforcement. If either Party who is the reference product sponsor of the Licensed Product within the meaning of section 351(l)(1)(A) of the PHS Act

(“**Reference Product Sponsor**”) receives notice of a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product and related manufacturing information in accordance with section 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with section 351(l)(8)(A) of the PHS Act, then such Party will provide notice to the other Party, and the Parties will discuss and cooperate with each other in determining the Reference Product Sponsor’s course of action with regard to (a) engaging in the information exchange provisions of the Biologics Price Competition and Innovation Act of 2009, Section 351(k) of the Public Health Service Act, as may be amended, supplemented, or replaced (the “**BPCIA**”), including providing a list of patents that relate to the relevant Licensed Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under Section 351(l)(6) of the BPCIA. In the event that the Parties do not agree with respect to the exercise of any such rights, KKC will make the final determination with respect thereto, including without limitation with respect to (a), (b) and (c) above. If any patent litigation commences with respect to a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product, then the provisions of Section 9.3 will thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.

9.7 Product Trademarks.

9.7.1 Product Trademarks in the Territory. AEVI will own the Product Trademarks for each Licensed Product in the Territory and will be solely responsible for filing and maintaining the Product Trademarks in the Territory (including payment of costs associated therewith). AEVI hereby grants to KKC a non-exclusive, nontransferable (except as provided in Section 13.3) license, with the right to grant sublicenses solely in accordance with Section 7.4, under the Product Trademarks, to use and display the Product Trademarks in connection with Commercialization outside the Territory.

9.7.2 Product Trademarks Outside the Territory. KKC will own the Product Trademarks for each Licensed Product outside the Territory and will be solely responsible for filing and maintaining the Product Trademarks outside the Territory (including payment of costs associated therewith).

9.7.3 Each Party agrees to (a) conduct its business in a manner that will not damage the reputation or integrity of the Trademarks of the other Party, (b) conduct its business in a manner that will not damage in any way the goodwill associated with the Trademarks of the other Party, (c) use the Trademarks of the other Party in a manner that will not cause a negative impact upon the good name of such other Party, (d) conduct its business in compliance with all applicable trademark Laws and (e) use the other Party’s Trademarks only in accordance with this Agreement.

9.8 Patent Term Extensions. The Parties will use reasonable efforts to obtain all available supplementary protection certificates (“**SPC**”) and other extensions of Patent Rights. Each Party will execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties will cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable

to Patent Rights. The Party first eligible to seek patent term restoration or extension of any such Patent Rights or any SPC related thereto will have the right to do so; provided that if in any country the first Party has an option to extend the patent term for only one of several patents, the first Party will consult with the other Party before making the election. If more than one patent is eligible for extension or patent term restoration, KKC will select in good faith a strategy that will maximize patent protection and commercial value for each Licensed Product. All filings for such extensions and certificates will be made by the Party to whom responsibility for prosecution and maintenance of the Patent Rights are assigned, provided that in the event that the Party to whom such responsibility is assigned elects not to file for an extension or SPC, such Party will (a) inform the other Party of its intention not to file and (b) grant the other Party the right to file for such extension or SPC in the patentee's name, and (c) provide all necessary assistance in connection therewith.

9.9 Patent Marking. AEVI (and its Related Parties) will mark Licensed Products marketed and sold by AEVI (and/or its Related Parties, as applicable) with appropriate numbers of the KKC Patent Rights printed on the appropriate portion of the packaging. Without limiting the foregoing, AEVI shall mark each Licensed Product sold or offered for sale by or on behalf of AEVI with the patent number or numbers of any issued patents encompassed within the KKC Patent Rights solely owned by LJI, if applicable, and AEVI shall ensure that the content, form, location and language of such markings is in accordance with the applicable laws and practices of each jurisdiction in which the Licensed Products are made, used or sold.

Article 10.

CONFIDENTIALITY

10.1 Confidentiality.

10.1.1 Confidential Information. All Confidential Information disclosed by or on behalf of a Party (together with its Affiliates, the “**Disclosing Party**”) to the other Party (together with its Affiliates, the “**Receiving Party**”) during the Term will be used by the Receiving Party solely in connection with the activities contemplated by this Agreement, will be maintained in confidence by the Receiving Party and will not otherwise be disclosed by the Receiving Party to any other person, firm, or agency, governmental or private (other than a Party's Affiliates or as set forth in Section 10.1.2), without the prior written consent of the Disclosing Party, except to the extent that the Confidential Information (as determined by competent documentation):

(a) was known or used by the Receiving Party without restriction as to its use or disclosure prior to its date of disclosure to the receiving Party; or

(b) either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party without restriction as to its use or disclosure by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or

(c) either before or after the date of the disclosure to the Receiving Party becomes published or generally known to the public (including information known to the public through

the sale of products in the ordinary course of business) through no fault or omission on the part of the Receiving Party or its sublicensees; or

(d) is independently developed by or for the Receiving Party without reference to or reliance upon the Confidential Information.

All obligations of confidentiality imposed under this Article 10 will expire five (5) years following termination of this Agreement.

10.1.2 Required Disclosures. Section 10.1.1 will not preclude the Receiving Party from disclosing Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure. If a public disclosure is required by any Applicable Laws, including, without limitation, in a filing with the Securities and Exchange Commission or submission to an exchange on which any securities of a Party is listed, the disclosing Party will provide copies of the disclosure (but shall be permitted to redact or omit portions of any filing, submission or disclosure not relevant to this Agreement) reasonably in advance of such filing or other disclosure, for the non-disclosing Party's prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The disclosing Party will negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.

10.1.3 Permitted Disclosures. KKC and AEVI each agree that they will provide Confidential Information received from the other Party only to their respective directors, officers, employees, consultants, suppliers, sublicensees, collaborators and advisors, and to those of such Party's Related Parties, who have a need to know for such Party's development, manufacture, and commercialization of Licensed Products in accordance with this Agreement, including in connection with Regulatory Filings and obtaining Regulatory Approvals, provided that such Third Parties are bound by confidentiality obligations at least as strict as this Article 10. In addition, each Party may not disclose the terms of this Agreement (to the extent such terms are confidential) to any Third Party except to actual or prospective lenders, investors, acquirers, licensees/sublicensees or strategic partners (including the KKC Licensors and AEVI Licensors) or to a Party's accountants, attorneys and other professional advisors; provided that such disclosures will be subject to continued confidentiality obligations at least as strict as this Article 10.

10.2 Publication Review.

10.2.1 Publications by the Parties. Subject to Section 10.2.2 and except as required by Applicable Law, during the Term, each Party agrees that, unless explicitly authorized in this Agreement, it will not without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed, file patent application, issue any press

release, make any public announcement, or issue any scientific or other presentations or publications, with respect to the results of any Development work relating to this Agreement without the opportunity for prior review by the other Party. With respect to any such proposed publications or presentations by one of the Parties, each Party will provide to the other Party for information and review any (a) abstracts, posters and slide presentations that the Party proposes prior to any scientific meetings and the other Party will provide feedback to the publishing Party within ten (10) of its Business Days of its receipt of such abstracts, posters and slide presentations, and (b) primary and final manuscripts and review articles that the Party proposes prior to journal submission and the other Party will provide feedback within fifteen (15) of its Business Days of its receipt of such manuscript or article. Each Party agrees, upon request from the other Party, not to submit any abstract or manuscript for publication or to make any scientific presentation until the other Party is given up to forty-five (45) days from the date of such written request to seek appropriate patent protection for any material in such publication or presentation which it reasonably believes is patentable. Once such abstracts, manuscripts or presentations have been reviewed by the other Party and have been approved for publication, the same abstracts, manuscripts or presentations do not have to be provided again to the other Party for review for a later submission for publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Parties. The other Party also will have the right to require that its Confidential Information that may be disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation.

10.2.2 Publications by Third Parties. Notwithstanding Section 10.2.1, the Parties understand and agree that any restrictions on scientific or other presentations or publications will not be construed to prohibit the clinical investigators of any clinical trials conducted under this Agreement (including without limitation CHOP), from making scholarly publications, manuscripts, abstracts, oral presentations or other disclosures with respect to the results of any Development work, including without limitation clinical data resulting from such clinical trials (“**Publications**”); provided that AEVI will ensure that (a) any such clinical investigator must agree to submit to KKC for its review and comment, a copy of any proposed Publication, abstract or other disclosure resulting from such activities, simultaneous with submission of the same to AEVI and at least forty-five (45) days prior to any such presentation or publication, (b) such publication will not contain any references to, or otherwise disclose any of, the Confidential Information (other than clinical data) without KKC’s prior written consent, and (c) at KKC’s request, such clinical investigator will, for a reasonable period of up to ninety (90) days from initial delivery to KKC, delay revealing any subject matter included in the clinical data in any publication or disclosure in order to permit the filing of patent applications.

10.3 Public Announcements and Use of Names. Except for public disclosures (a) resulting from the issuance of one or more press releases to be mutually-agreed upon by the Parties, (b) otherwise permitted under this Article 10 or (c) required by Applicable Law or by the rules and regulations of any securities exchange on which a Party’s securities are traded, neither Party will disclose any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the execution of this Agreement, the subject matter of this Agreement, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party.

Article 11.
TERM AND TERMINATION

11.1 Term. This Agreement will commence on the Effective Date and will remain in full force and effect for as long as any Licensed Product(s) is Commercialized by either Party and/or its Related Parties, unless terminated earlier pursuant to Section 11.2 or 11.3 (the “**Term**”).

11.2 Termination by KKC.

11.2.1 Insolvency. To the extent permitted under Applicable Laws, KKC will have the right to terminate this Agreement in its entirety, at KKC’s sole discretion, upon delivery of written notice to AEVI upon the filing by AEVI in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of AEVI or its assets, upon the proposal by AEVI of a written agreement of composition or extension of its debts, or if AEVI is served by a Third Party (and not by KKC) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by AEVI of an assignment for the benefit of its creditors.

11.2.2 Breach. KKC will have the right to terminate this Agreement in its entirety, at KKC’s sole discretion, subject to Section 11.2.5, upon delivery of written notice to AEVI in the event of any material breach by AEVI of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and KKC’s intention to terminate is given by KKC to AEVI; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by KKC (except that in the case of a bona fide dispute over whether or to what extent a payment by AEVI to KKC is due, this Section 11.2.2 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Such termination will be effective upon expiration of the applicable time period set forth in this Section 11.2.2. Subject to Section 11.2.5, any such termination of this Agreement will become effective at the end of the applicable cure period, unless AEVI has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, KKC’s right of termination will be suspended only if and for so long as AEVI has provided to KKC a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to KKC (such acceptance not to be unreasonably withheld, conditioned, or delayed), and AEVI commits to and carries out such plan as provided to KKC.

11.2.3 Termination as to a Country.

(a) European Union. KKC will have the right to terminate this Agreement, solely as it relates to a particular country in the European Union if AEVI fails to satisfy its obligations set forth in Section 6.1.1 with respect to such country.

(b) Canada. KKC will have the right to terminate this Agreement, solely as it relates to Canada, if (a) the JSC unanimously decides to not proceed with Development in the

Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada or (b) AEVI declines to proceed with Development in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, and the JSC does not unanimously agree, in each case as set forth in Section 6.1.2.

11.2.4 Termination for Patent Challenge. If AEVI or any of its Affiliates directly claim, or cause a Third Party to claim, or knowingly supports (other than as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or in response to a subpoena or court or administrative law request or order), including by providing information, documents, and/or funding, a claim (a) to the validity, scope, enforceability or patentability of any of the KKC Patent Rights in any formal legal or administrative action or proceeding, or (b) that no Earned Royalties, Sublicense Royalties, Net Receipts, milestone payments, Patent Costs or other payments (as such capitalized terms are defined under the LJI Agreement) are due or required to be paid to LJI under the LJI Agreement because the applicable KKC Patents licensed by LJI to KKC under the LJI Agreement covering or claiming a Licensed Product are invalid or unenforceable except where such KKC Patent Rights have been found to be unpatentable, invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal is taken or can be taken, or have been admitted or determined to be invalid or unenforceable through reissue, re-examination, disclaimer or similar formal proceeding, or where a pending application within the KKC Patent Rights has been abandoned or finally rejected (in each case, other than pursuant to a claim by KKC, AEVI or their respective Affiliates or by a Third Party caused by any of the foregoing entities) in any Challenge, then (x) if and to the extent permitted by Applicable Law, (***) during and after the pendency of such Challenges from the date KKC, AEVI, or any of their respective Affiliates first institute or make such challenges. In such event, notwithstanding anything to the contrary in this Agreement, (i) AEVI will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of KKC or any of its Affiliates (in which case, KKC will be responsible for (***)), and (ii) KKC will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of AEVI or any of its Affiliates (in which case, AEVI will (***)). (***) under this Section 11.2.4 (x) may be exercised at any time after AEVI (or any of its Affiliates) may have Challenged or knowingly supports (other than in response to a subpoena or court order) a Challenge to the validity, enforceability or patentability of any of the KKC Patent Rights. If a sublicensee of AEVI Challenges the validity, scope or enforceability of or otherwise opposes any of the KKC Patent Rights under which such sublicensee is sublicensed, then AEVI will, upon written notice from KKC, promptly terminate such sublicense. “**Challenge**” under this Section 11.2.4 will refer to a legal action or filing with a patent authority or tribunal or a court that could, if successful, result in a holding of invalidity, unenforceability, or unpatentability of a patent or application within the KKC Patent Rights.

11.2.5 Dispute. If AEVI reasonably and in good faith disagrees as to whether KKC has a basis for terminating this Agreement pursuant to Section 11.2.2, AEVI may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by KKC pursuant to Section 11.2.2 will be effective unless and until

KKC's right to terminate this Agreement under Section 11.2.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.2.6 Abandonment. If AEVI, in its discretion, decides to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, AEVI will promptly notify KKC in writing of its intent to do so. KKC will have the right to terminate this Agreement immediately upon receipt of such notice.

11.3 Termination by AEVI.

11.3.1 Insolvency. To the extent permitted under Applicable Law, AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, upon delivery of written notice to KKC upon the filing by KKC in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of KKC or its assets, upon the proposal by KKC of a written agreement of composition or extension of its debts, or if KKC is served by a Third Party (and not by AEVI) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by KKC of an assignment for the benefit of its creditors.

11.3.2 Breach. AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, subject to Section 11.3.4, upon delivery of written notice to KKC in the event of a material breach by KKC of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and AEVI's intention to terminate is given by AEVI to KKC; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by AEVI (except that in the case of a bona fide dispute over whether or to what extent a payment by KKC to AEVI is due, this Section 11.3.2 will not be triggered provided that KKC will pay the amount in dispute into escrow until such dispute is resolved). Such termination will be effective upon expiration of the applicable time period set forth in this Section 11.3.2. Subject to Section 11.3.4, any such termination of this Agreement will become effective at the end of the applicable cure period, unless KKC has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, AEVI's right of termination will be suspended only if and for so long as KKC has provided to AEVI a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to AEVI (such acceptance not to be unreasonably withheld, conditioned, or delayed), and KKC commits to and carries out such plan as provided to AEVI.

11.3.3 Convenience. (***), such termination to be effective at the end of such notice period, AEVI may terminate this Agreement as to such Licensed Product and/or such jurisdiction for any reason or no reason, including if AEVI, in its reasonable discretion, decides

to cease all of its Development and/or Commercialization efforts with respect to such Licensed Product in such jurisdiction.

11.3.4 Dispute. If KKC reasonably and in good faith disagrees as to whether AEVI has a basis for terminating this Agreement pursuant to Section 11.3.2, KKC may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by AEVI pursuant to Section 11.3.2 will be effective unless and until KKC's right to terminate this Agreement under Section 11.3.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.4 Consequences of Termination. Upon termination of this Agreement in its entirety or with respect to a country in the Territory or the European Union pursuant to Section 11.2.3(a) and in case of Canada pursuant to Section 11.2.3(b) (in which event the following will apply only with respect to such country):

11.4.1 Reversion. All rights and licenses granted to AEVI in Article 7 will terminate, all rights of AEVI under the KKC Technology will revert to KKC, and AEVI and its Affiliates will cease all use of the KKC Technology. Except as set forth in Sections 11.4.2 through 11.4.9, all rights and licenses granted to KKC in Article 7 will terminate, all rights of KKC under the AEVI Technology will revert to AEVI, and KKC and its Affiliates will cease all use of the AEVI Technology.

11.4.2 Regulatory Filings. AEVI will assign, and hereby does assign effective as of the effective date of such termination, to KKC all Regulatory Filings (including all INDs and NDAs) and Regulatory Approvals and all other documents necessary to further Develop, Manufacture, and Commercialize the Licensed Products, as they exist as of the date of such termination, (and all of AEVI's right, title and interest therein and thereto). AEVI will provide to KKC one (1) copy of the foregoing documents and Regulatory Filings, all documents and filings contained in or referenced in any such Regulatory Filings, together with the raw and summarized data for any preclinical and clinical studies of the Licensed Product. For clarity, KKC will have the right to use the foregoing material information, materials and data developed by AEVI solely in connection with KKC's development, manufacture and commercialization of Licensed Products. KKC will have the right to seek specific performance of AEVI's obligations referenced in this Section 11.4.2 and/or in the event of failure to obtain assignment, AEVI hereby consents and grants to KKC the right to access and reference (without any further action required on the part of AEVI, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose. Without limiting the foregoing in this paragraph, to the extent applicable, AEVI's obligations under this Section 11.4.2 will continue with respect to all countries in the Territory and the

European Union for which there is a failure to obtain assignment of all regulatory filings and Regulatory Approvals.

11.4.3 Know-How Transfer. AEVI will provide to KKC all data and information generated during the Term necessary for the development and/or commercialization of the relevant Licensed Products and assign (or, if applicable, cause its Affiliate to assign) to KKC all of AEVI's (and such Affiliate's) entire right, title and interest in and to all such data and information. AEVI will provide to KKC the tangible embodiments of all other Know-How Controlled by AEVI and its Affiliates in existence as of the effective date of such termination relating to the Development, Manufacturing, and Commercialization of the Licensed Products, including without limitation AEVI's manufacturing processes, techniques and trade secrets necessary for and used in the manufacture of such Licensed Products as of the effective date of such termination and all Know-How specifically relating to any composition, formulation, method of use or manufacture of such Licensed Products. AEVI will grant, and hereby does grant effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide right and license under such Know-How for developing, making, using, importing, selling and offering for sale Licensed Products. AEVI will reasonably cooperate with KKC to assist KKC with understanding and using the Know How provided to KKC under this Section 11.4.3. If AEVI has decided to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, and this Agreement is terminated pursuant to Section 11.2.6, AEVI will provide to KKC all technology resulting from such abandoned Development and/or Commercialization efforts. KKC will have a royalty-free, irrevocable, world-wide, unlimited license to such abandoned Development and/or Commercialization efforts including the right to sublicense and to contract with Third Parties for further Development and/or Commercialization.

11.4.4 Trademarks. To the extent that AEVI owns any trademark(s) (including without limitation any Product Trademarks) and/or domain names that pertain specifically to an Licensed Product that KKC believes would be necessary for the Commercialization of a Licensed Product (as then currently marketed, but not including any marks that include, in whole or part, any corporate name or logo of AEVI), AEVI will assign (or, if applicable, cause its Affiliate to assign), and hereby does assign effective as of the effective date of such termination, to KKC all of AEVI's (and such Affiliate's) right, title and interest in and to any registered or unregistered trademark, trademark application, trade name or internet domain name in each country.

11.4.5 Termination License. AEVI will grant, and hereby grants effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license under any Patent Rights owned solely by AEVI or its Affiliates as of the effective date of termination to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products. AEVI will grant to KKC, under any Patent Rights that AEVI's Controls but does not own at the time of termination, to the full extent permitted under the agreement(s) of AEVI covering such Patent

Rights, a non-exclusive, irrevocable, royalty-free (as to AEVI), transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license, to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products; provided that KKC enters into a written agreement with AEVI with respect to each such Patent Right that (a) ensures compliance with the applicable contract between AEVI and its licensor including KKC agreeing to all provisions thereof that must be imposed on sublicensees, (b) requires KKC to pay all amounts payable by AEVI to its licensor related to KKC's exercise or enjoyment of such rights including milestones, royalties and patent expenses and (c) indemnifies AEVI for any breach of such agreement between KKC and AEVI.

11.4.6 Continued Supply. If AEVI has any inventory of any Licensed Products suitable for use in clinical trials, AEVI will offer to sell such Licensed Products to KKC at (***) (but KKC will be under no obligation to purchase the foregoing inventory of Licensed Products unless it agrees to do so in writing at such time); provided, however, that, in the event of a termination pursuant to Section 11.3.3, (***). If AEVI has the capability in place as of the effective date of such termination to commercially Manufacture and supply to KKC all or part of KKC's requirements of the applicable Licensed Products, if KKC so elects in its sole discretion, AEVI will use Commercially Reasonable Efforts to supply to KKC (**) as much of KKC's requirements of such Licensed Products (and to develop a reasonable inventory level) during such period, (**) for such Licensed Products, under terms and conditions as may be mutually agreed between the Parties. If KKC, despite its best efforts, is unable to Manufacture, or to secure a supply of, such Licensed Products in an amount sufficient to meet its requirements (**), AEVI will continue to supply such Licensed Products to KKC to the extent necessary to meet KKC's requirements, so long as KKC continues to use its best efforts to develop the capabilities necessary to Manufacture such Licensed Products and/or to secure a supply of such Licensed Products.

11.4.7 Transfer of Manufacturing Technology. In the event, at the time of such termination, (a) AEVI manufactures the Licensed Products at its own facility, AEVI will conduct manufacturing technology transfer to KKC, and (b) if AEVI engages a Third Party to manufacture and supply the Licensed Products, AEVI will, at KKC's election, either (i) have such Third Party conduct manufacturing technology transfer to KKC or (ii) will use reasonable efforts to assist in the transfer of such supply arrangements to KKC.

11.4.8 Continuing Obligations. Neither Party will be relieved of any obligation that accrued prior to the effective date of such termination. All amounts due or payable to KKC that were accrued prior to the effective date of termination will remain due and payable. Except as otherwise expressly provided herein, no additional amounts will be payable based on events occurring after the effective date of termination; provided that the foregoing will not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the effective date of such termination that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the effective date of such termination.

11.4.9 Retention of Payments. KKC will have the right to retain all amounts previously paid to KKC by AEVI.

11.4.10 No Compensation. KKC will not owe any compensation to AEVI for the research, development, manufacture, or commercialization of any Licensed Products in the event of any termination of the Agreement by KKC, without prejudice to any rights that either Party may have to bring a claim for damages arising out of this Agreement and the termination thereof or any other amounts payable with respect to activities conducted prior to the effective date of such termination.

11.4.11 Costs. Any costs and expenses incurred by AEVI in connection with the assignments and transfers made by AEVI under this Section 11.4 will be borne by AEVI.

11.5 Return of Confidential Information. Upon the termination of this Agreement, each Party will promptly return to the other Party, delete or destroy (with written notification of such destruction) all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only.

11.6 Effect of Termination; Survival. The termination of this Agreement will not relieve the Parties of any obligation accruing prior to such termination. The provisions of Article 10 (Confidentiality), Article 12 (Representations and Warranties; Indemnification) and Article 13 (Miscellaneous Provisions) and Sections 7.4.3 (Effect of Termination on Sublicenses) and 9.2.2 (Joint Inventions) will survive any termination of this Agreement. Except as set forth in this Article 11 or as otherwise set forth in this Agreement, upon termination of this Agreement all other rights and obligations cease. Any termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

11.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by either Party, including without limitation Article 7, are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "**IP**"). The Parties agree that each Party, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. In the event of termination of a Party pursuant to Section 11.2.1 or 11.3.1, the terminated Party hereby grants to the other Party and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of intellectual property, which, if not already in such other Party's possession, will be promptly delivered to it upon such other Party's written request therefor. The term "embodiments of intellectual property" includes all tangible, electronic or other embodiments of rights and licenses hereunder, including all Licensed Products, all Regulatory Approval Applications and Regulatory Approvals and rights of reference therein, and all Information related to Licensed Products, KKC Technology and

AEVI Technology, as applicable. The terminated Party will not interfere with the exercise by the other Party or its Affiliates of rights and licenses to IP and embodiments of intellectual property licensed hereunder in accordance with this Agreement and agrees to assist such other Party and Affiliates of such other Party to obtain the IP and embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for such other Party or Affiliates of such other Party to exercise such rights and licenses in accordance with this Agreement. The Parties acknowledge and agree that milestone payments made under Section 8.3 do not constitute royalties within the meaning of U.S. Bankruptcy Code §365(n) or relate to licenses of intellectual property hereunder.

11.8 No Limitation of Remedies. Except as herein expressly provided, notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination nor prejudice either Party's right to obtain performance of any obligation. Each Party will be free, pursuant to Section 13.2, to seek (without restriction as to the number of times it may seek) damages, costs and remedies that may be available under Applicable Law or in equity and will be entitled to offset the amount of any damages and costs obtained in a final determination under Section 13.2 of monetary damages or costs (as permitted by this Agreement) against the other Party against any amounts otherwise due to such other Party under this Agreement. It is understood and agreed that either Party will be entitled to seek specific performance as a remedy to enforce the provisions of this Article 11, in addition to any other remedy to which such Party may be entitled by Applicable Law. Nothing in this Article 11 will be deemed to limit any remedy to which either Party may be entitled by Applicable Law.

Article 12.

REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION

12.1 Mutual Representations and Warranties. Each Party represents, warrants and covenants to the other Party that as of the Effective Date of this Agreement:

(a) Corporate Existence and Authority. It is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Authorized Execution; Binding Obligation.

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

(ii) This Agreement has been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with this Agreement's terms, except as the same may be limited by applicable bankruptcy, insolvency,

reorganization, moratorium or other laws relating to or affecting creditors' rights generally and by general equity principles, including judicial principles affecting the availability of injunction and specific performance.

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

(d) All Consents and Approvals Obtained. Except with respect to any consent required from Lonza or Sanofi, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all governmental authorities and other persons or entities required to be obtained or provided by such Party in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those government approvals, if any, not required at the time of execution of this Agreement.

(e) Compliance with Law. It will at all times comply with Applicable Laws in all material respects. Neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Licensed Products: (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred by the FDA (or subject to a similar sanction of a Regulatory Authority) or (ii) has ever been under indictment for a crime for which a person or entity could be so debarred.

12.2 KKC Representations and Warranties. KKC represents and warrants to AEVI that as of the Effective Date:

(a) KKC Controls the KKC Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The KKC Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by KKC as of the Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. KKC has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(b) To the knowledge of KKC, there is no actual or threatened infringement of the KKC Patent Rights in the Field by any Third Party that would adversely affect AEVI's rights under this Agreement.

(c) To the knowledge of KKC, the KKC Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by KKC or any of its Affiliates relating to the KKC Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and KKC is not aware of any reasonable basis for a claim alleging that (i) the KKC Patent Rights are invalid or unenforceable, (ii) the KKC Patent Rights or the licensing or exploiting of the KKC Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party, or (iii) any

Third Party other than a KKC Licenser has any right, title, or interest in, to, and under any KKC Patent Rights.

(d) To the knowledge of KKC, KKC is not in default, and to KKC's knowledge, none of the KKC Licensors is in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, any KKC In-Licenses, and KKC has not waived or allowed to lapse any of its rights under any KKC In-Licenses, and no such rights have lapsed or otherwise expired or been terminated.

(e) There are no claims, judgments or settlements against or owed by KKC or its Affiliates or pending or threatened claims or litigation relating to the KKC Technology.

12.3 KKC Covenants. KKC covenants that during the Term:

(a) KKC will use Commercially Reasonable Efforts to fulfill its obligations under the KKC In-Licenses to the extent such obligations have not been delegated to AEVI and to the extent that failure to do so would materially adversely affect AEVI or its rights hereunder.

(b) KKC will not assign, transfer, convey or otherwise encumber its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(c) KKC will not enter into any subsequent agreement with any KKC Licenser that modifies or amends any KKC In-Licenses in any way that would materially adversely affect AEVI's rights or economic interest under this Agreement without AEVI's prior written consent.

(d) KKC will not terminate any KKC In-Licenses in whole or in part, directly or indirectly, without AEVI's prior written consent if such termination would materially affect AEVI's license granted hereunder; for clarity KKC may (i) terminate any KKC In-Licenses by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and KKC will promptly notify AEVI after the occurrence of each such event.

(e) KKC will furnish AEVI with copies of all notices received by KKC relating to any alleged breach or default by KKC under any KKC In-Licenses within (***) after KKC's receipt thereof and, if KKC cannot or chooses not to cure or otherwise resolve any such alleged breach or default, KKC will so notify AEVI within (***) thereafter.

12.4 AEVI Representations and Warranties. AEVI represents and warrants to KKC that as of the Effective Date:

(a) AEVI Controls the AEVI Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The AEVI Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by AEVI as of the Effective Date that are necessary or useful to Develop, Manufacture and

Commercialize the Licensed Product. AEVI has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

(b) To the knowledge of AEVI, there is no actual or threatened infringement of the AEVI Patent Rights in the Field by any Third Party that would adversely affect KKC's rights under this Agreement.

(c) To the knowledge of AEVI, the AEVI Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by AEVI or any of its Affiliates relating to the AEVI Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and AEVI is not aware of any reasonable basis for a claim alleging that (i) the AEVI Patent Rights are invalid or unenforceable, (ii) the AEVI Patent Rights or the licensing or exploiting of the AEVI Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party or (iii) any Third Party other than the AEVI Licensor has any right, title, or interest in, to, and under any AEVI Patent Rights.

(d) To the knowledge of AEVI, the Development activities set forth in the initial Development Plan do not infringe any third party intellectual property rights.

(e) To the knowledge of AEVI, AEVI is not in default, and to AEVI's knowledge, the AEVI Licensor is not in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the AEVI In-License, and AEVI has not waived or allowed to lapse any of its rights under any AEVI In-License, and no such rights have lapsed or otherwise expired or been terminated.

(f) There are no claims, judgments or settlements against or owed by AEVI or its Affiliates or pending or threatened claims or litigation relating to the AEVI Technology.

12.5 AEVI Covenants. AEVI covenants that during the Term:

(a) AEVI will not engage in any activities that use the KKC Technology in a manner that is outside the scope of the rights granted to it hereunder.

(b) All of AEVI's activities related to its use of the KKC Technology, and the research, Development and Commercialization of the Licensed Products, pursuant to this Agreement will comply with all Applicable Laws.

(c) AEVI will use Commercially Reasonable Efforts to fulfill its obligations under the AEVI In-License to the extent such obligations have not been delegated to KKC and to the extent that failure to do so would materially adversely affect KKC or its rights hereunder.

(d) AEVI will not assign, transfer, convey or otherwise encumber its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

(e) AEVI will not enter into any subsequent agreement with CHOP that modifies or amends the AEVI In-License in any way that would materially adversely affect KKC's rights or economic interest under this Agreement without KKC's prior written consent.

(f) AEVI will not terminate the AEVI In-License in whole or in part, directly or indirectly, without KKC's prior written consent if such termination would materially affect KKC's license granted hereunder; for clarity AEVI may (i) terminate the AEVI In-License by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and AEVI will promptly notify KKC after the occurrence of each such event.

(g) AEVI will furnish KKC with copies of all notices received by AEVI relating to any alleged breach or default by AEVI under the AEVI In-License within (***) after AEVI's receipt thereof and, if AEVI cannot or chooses not to cure or otherwise resolve any such alleged breach or default, AEVI will so notify KKC within (***) thereafter.

12.6 Mutual Covenants. Each Party hereby covenants to the other Party that during the Term:

(a) All employees and officers of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their Inventions, whether or not patentable, if any, to such Party as the sole owner thereof, and under the obligation to maintain as confidential the Confidential Information of such Party.

(b) Such Party will perform its activities pursuant to this Agreement in compliance with good clinical practices and good manufacturing practices, in each case as applicable under the Applicable Laws and regulations of the country and the state and local government wherein such activities are conducted, and also with the standards in the pharmaceutical industry for the development and commercialization of pharmaceutical products.

(c) Such Party will not employ (or, to its knowledge, use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or, to its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority), in the conduct of its activities under this Agreement, and each contractor or consultant used by such Party in connection with the conduct of clinical trials under this Agreement will be subject to a covenant that is the same or substantially the same as the foregoing covenant.

(d) Such Party will not practice or exploit the intellectual property licensed to such Party under this Agreement except to the extent expressly permitted under the terms and conditions of this Agreement.

(e) Such Party will not grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to the other Party hereunder.

12.7 Consequences of Partial Termination of an In-License. In the event that a portion, but not all of KKC's rights under the KKC In-Licenses terminate, then AEVI will owe no further obligations to KKC under this Agreement with respect to such terminated rights. In the event that a portion, but not all of AEVI's rights under the AEVI In-License terminate, then KKC will owe no further obligations to AEVI under this Agreement with respect to such terminated rights.

12.8 Warranty Disclaimer. The Parties acknowledge and agree that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) will be construed as representing an estimate or projection of either (a) the extent to which Licensed Products will be successfully Developed or Commercialized or (b) the anticipated sales or the actual value of any Licensed Product. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT IT WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT(S). EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

12.9 No Consequential Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.9 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY'S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING CONFIDENTIALITY UNDER ARTICLE 10.

12.10 Indemnification and Insurance.

12.10.1 Indemnification by AEVI. AEVI will indemnify, hold harmless, and defend KKC, its Affiliates, and their respective directors, officers, employees and agents ("***KKC Indemnitees***") from and against any and all damages, losses, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments of any kind (collectively, "***Losses***") arising out of any Third Party claim, suit or

proceeding, whether for money or equitable relief (each, a “**Third Party Claim**”), arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by AEVI in this Agreement, or any breach or violation of any covenant or agreement of AEVI or a Related Party in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of AEVI or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by AEVI or its Affiliate or sublicensee (including a sublicensed contract manufacturer) of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by AEVI or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from AEVI’s exercise in accordance with the terms of this Agreement of any intellectual property rights granted by KKC hereunder. Furthermore, AEVI will have no obligation to indemnify the KKC Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any matter for which KKC must indemnify AEVI under this Agreement. In addition, AEVI will indemnify, hold harmless, and defend (i) LJI and its directors, officers, employees, and agents from and against any and all Losses (including costs of investigation and court costs) arising at any time from or in any manner connected with, directly or indirectly, any activity of AEVI involving the KKC Patent Rights solely owned by LJI or any information furnished under the LJI Agreement, including the use, handling, storage, distribution, containment, sale and/or disposition of any product (whether or not a Licensed Product), or provision of any service, related to or derived directly or indirectly from or using any KKC Patent Rights solely owned by LJI; and (ii) the KKC Indemnitees from and against any and all Losses arising out of any Third Party Claims related to, directly or indirectly, any activities performed by or on behalf of AEVI or AEVI’s Third Party contract manufacturer in connection with the exercise of rights under the KKC Technology licensed under the KKC In-License with Lonza, if, pursuant to Section 7.4.1, KKC sublicenses its rights under such KKC Technology to AEVI or AEVI’s Third Party contract manufacturer for the Manufacture of Licensed Products by AEVI or such contract manufacturer.

12.10.2 Indemnification by KKC. KKC will indemnify, hold harmless, and defend AEVI, its Affiliates and their respective directors, officers, employees and agents (“**AEVI Indemnitees**”) from and against any and all Losses arising out of any Third Party Claims arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by KKC in this Agreement, or any breach or violation of any covenant or agreement of KKC in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of KKC or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by KKC or its Affiliate or sublicensee of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by KKC or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from KKC’s exercise in accordance with the terms of this Agreement of any intellectual property rights granted by AEVI hereunder. Furthermore, KKC will have no obligation to indemnify the AEVI Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any matter for which AEVI must indemnify KKC. In addition, KKC shall be bound by Section 12.2 of the AEVI In-License in the capacity of “Licensee” in respect

of KKC and its Related Parties' activities under this Agreement and use of the AEVI Technology licensed under the AEVI In-License, and KKC agrees that the Indemnitees (as defined in Section 12.2 of the AEVI In-License) are intended third party beneficiaries of this sentence.

12.10.3 Indemnification Procedure. In the event of any such claim against any AEVI Indemnitee or KKC Indemnitee (individually, an "**Indemnitee**"), the indemnified Party will promptly notify the other Party in writing of the claim and the indemnifying Party will manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee will cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party will not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party's written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Section 12.10.1 or Section 12.10.2 may apply, the indemnifying Party will promptly notify the Indemnitees, which will then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party will be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. If the indemnifying Party does not assume the defense of such claim as described in this Section 12.10.3, above, the Indemnitee may defend such claim but will have no obligation to do so. The defending Party will not settle or compromise such claim without the prior written consent of the other Party, and will not settle or compromise such claim in any manner which would have an adverse effect on such other Party's interests, without the prior written consent of such other Party, which consent, in each case, will not be unreasonably withheld, conditioned, or delayed.

12.10.4 Insurance. Each Party will use its Commercially Reasonable Efforts to maintain insurance, including product liability insurance, with respect to its activities hereunder. Such insurance will be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time in order to fulfill the obligation under Section 12.10.1 or 12.10.2, including, but not limited to, the indemnification against any Losses involving any actual or alleged death or bodily injury arising out of or resulting from the Development, Manufacture or Commercialization of any Licensed Product.

Article 13. MISCELLANEOUS PROVISIONS

13.1 Governing Law. This Agreement will be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York, New York, U.S.A., notwithstanding the provisions governing conflict of laws of any jurisdiction to the contrary.

13.2 Dispute Resolution.

13.2.1 With respect to any disputes between the Parties concerning this Agreement over which AEVI does not have explicit final decision-making authority pursuant to Section 3.1.3, the dispute will be submitted to escalating levels of AEVI and KKC senior management

for review. If the dispute cannot be resolved despite such escalation, then the matter will be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers will be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party may submit such dispute for arbitration pursuant to Section 13.2.2.

13.2.2 Arbitration.

(a) If any dispute will arise between KKC and AEVI in connection with or relating to this Agreement, then such dispute will be resolved exclusively by and through an arbitration proceeding to be conducted under the auspices of, and pursuant to, the Commercial Rules of the International Chamber of Commerce (together with any successor organization thereto, the “**ICC**”) in New York, New York, U.S.A. Such arbitration proceeding will be conducted in the English language applying the law provided in Section 13.1 and in such an expedited manner as is then permitted by the ICC’s commercial arbitration rules. The Parties also agree to take reasonable discovery, with reasonableness to be determined by the arbitrators. Each of the foregoing agreements to arbitrate all disputes and the results, determinations, findings, judgments and awards rendered through such arbitration will be final, non-appealable and legally binding on KKC and AEVI and may be entered and enforced by any court or tribunal of competent jurisdiction. Notwithstanding anything to the contrary in this Section 13.2, a Party may seek injunctive relief in any court of competent jurisdiction.

(b) Any arbitration proceeding will be initiated by written notice from either KKC or AEVI to the other Party. The arbitration will be conducted before a panel of three (3) arbitrators. Each of KKC and AEVI will have the right to select one (1) arbitrator. The third arbitrator will be selected by the mutual agreement of the arbitrators appointed by the Parties. The Party initiating the arbitration proceeding will appoint its arbitrator within ten (10) days following service of the demand for arbitration to the other Party, who will in turn appoint its arbitrator within thirty (30) days of receiving service of the demand. The two appointed arbitrators will agree upon an arbitrator within thirty (30) days of the date of the appointment by the parties of the second arbitrator. If either Party or their appointees fail to appoint an arbitrator within the specified time period, the ICC will exercise its powers pursuant to Article 9 of the ICC Rules of Arbitration to appoint such arbitrator. The ICC’s appointment will be binding on the Parties. Each arbitrator will be an attorney in good standing in the Bar of New York and experienced in commercial disputes involving pharmaceutical companies. Time is of the essence of this arbitration procedure, and KKC and AEVI will instruct the arbitrators to render their decision within ninety (90) days of the arbitration’s completion. The cost of the arbitration (including, without limitation, reasonable attorneys’ fees, expenses and disbursements) will be borne as the arbitrators will decide; otherwise such costs (including, without limitation, the prevailing Party’s reasonable attorneys’ and accountants’ fees, expenses and disbursements) will be borne by the Party against which the judgment of the arbitrator is to be enforced.

13.3 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent

of the other Party. Notwithstanding the foregoing, (a) KKC may monetize the value of its payments under this Agreement by assigning to a Third Party the right to receive payments and the right to receive payment reports from AEVI; provided that KKC gives thirty (30) days prior written notice to AEVI, and (b) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate (but subject to the consent of CHOP in respect of the AEVI Technology licensed under the AEVI In-License in the case of assignment by KKC) or pursuant to a Change of Control (but subject to the consent of Sanofi, to the extent required under Applicable Law, in respect of the KKC Technology licensed under the KKC In-License with Sanofi in the case of assignment by AEVI). The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned to such assignee.

13.4 Entire Agreement; Amendments. This Agreement and the Schedules and Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, except that Article 1 through 10 of the Clinical Development and Option Agreement will govern with respect to matters occurring prior to the Effective Date. Any amendment or modification to this Agreement will be made in writing signed by both Parties.

13.5 Notices. Any consent or notice required to be given or made under this Agreement by one of the Parties to the other will be in writing and (a) delivered by hand, (b) sent by internationally recognized overnight delivery service or (c) sent by facsimile transmission and confirmed by sender by prepaid, registered or certified mail letter, and will be deemed to have been properly served to the addressee upon receipt of such written communication, in any event to the following addresses:

If to KKC:

Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Business Development Department
Facsimile No.: +81-3-5205-7129

with a copy to:

Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Legal Affairs Group, Legal and Intellectual
Property Department
Facsimile No.: +81-3-5205-7130

If to AEVI:

Aevi Genomic Medicine, LLC
435 Devon Park Drive, Bldg 700, Suite 715
Wayne, PA 19087
Attention: Chief Executive Officer
Facsimile No.: +1 (443) 304-8001

with a copy to:

Pepper Hamilton LLP
Two Logan Square
18th & Arch Streets
Philadelphia, Pennsylvania 19103-2799
Attention: Brian M. Katz
Facsimile No.: +1 (215) 981-4750

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) if personally delivered, when delivered; (b) if sent by internationally-recognized overnight courier, on the Business Day of the sender during which the sender delivers the notice to the courier; or (c) if sent by facsimile, when all pages of the notice are successfully transmitted (as shown by a report generated by the sender's facsimile machine) during a Business Day of the sender.

13.6 Force Majeure. The failure of either Party to timely perform any obligation under this Agreement by reason of epidemic, earthquake, riot, civil commotion, fire, act of God, war, terrorist act, strike, flood, or governmental act or restriction, or other cause that is beyond the reasonable control of such Party, will not be deemed to be a breach of this Agreement, but will be excused to the extent and for the duration of such cause, and the affected Party will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and will use

its Commercially Reasonable Efforts to avoid or remove such cause, and will perform its obligation(s) with the utmost dispatch when the cause is removed. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than one hundred eighty (180) days, the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

13.7 Compliance with Export Regulations. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

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

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

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

13.11 Performance by Affiliates. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided, however*, that such other Party will remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

13.12 Construction. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein means including, without limiting the generality of any description that precedes such term, and will be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import regardless of whether such words are actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after the word “including” but not others). References to “Article”, “Articles”, “Section”, “Sections”, “Exhibit” or “Exhibits” are references to the numbered Article(s), Section(s), or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, (a) references to a particular law, rule or regulation mean such law, rule or regulation as in effect

as of the relevant time, including all rules and regulations thereunder and any successor law, rule or regulation in effect as of the relevant time, and including the then-current amendments thereto; (b) the word “or” has the inclusive meaning that is typically associated with the phrase “and/or”; (c) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (d) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; (e) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; and (f) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits).

13.13 No Implied Waivers; Rights Cumulative. No failure on the part of KKC or AEVI to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

13.14 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one (1) or several provisions of this Agreement will 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.

13.15 No Third Party Beneficiaries. Except as expressly set forth in Section 12.10.2, no person or entity other than AEVI, KKC and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[Remainder of Page Left Blank Intentionally. Schedules Follow.]

Schedule 1.5
AEVI IN-LICENSE

License Agreement between The Children's Hospital of Philadelphia and AEVI Medical Israel Ltd. dated November 12, 2014.

Schedule 1.10

AEVI PATENT RIGHTS

(***)	(***)	(***)	(***)	(***)
(***)				
(***)	(***)	(***)	(***)	(***)
(***)	(***)	(***)	(***)	(***)
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(***)	(***)	(***)	(***)	(***)
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(***)	(***)	(***)	(***)	(***)
(***)	(***)	(***)	(***)	(***)

Schedule 1.15

AMINO ACID SEQUENCE OF ANTI-LIGHT MAB

(***)

Schedule 1.24

Commercialization Costs

Examples of Commercialization Costs

Commercialization Costs will include, but will not be limited to, the following, in each case attributable to, or reasonably allocable to, Commercialization of Licensed Products in the Field in the Territory:

Detailing costs - costs associated with interactive face-to-face visits by a sales representative with a medical professional who has prescribing authority or is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses.

Distribution costs - costs identifiable to the distribution of a Licensed Product to a customer (and not otherwise deducted from Net Sales), including customer and specialty pharmacy services (including costs associated with establishing and running customer call centers), collection of data about sales to hospitals, clinics and other customers, order entry, billing, shipping, logistics, warehousing, product insurance, freight not paid by customers, credit and collection and other like activities the costs of which are includable in “distribution costs” in accordance with the Accounting Standards.

Early Access Program or EAP costs – costs associated with any program to provide patients with products free of charge. Early access programs include treatment INDs / protocols and compassionate use programs, as applicable. For clarity, an EAP with respect to a Licensed Product may continue to be performed following Regulatory Approval of a Licensed Product and costs may continue to be incurred in accordance with the performance of such EAP after Regulatory Approval.

Patient Assistance Programs – costs associated with establishing and administering patient assistance programs.

Health Care Reform fees - costs for fees paid to the U.S. government as defined in the Patient Protection and Affordable Care Act and similar taxes and governmental fees.

Commercial Operations Costs – costs of the commercial operations team supporting Commercialization of the Licensed Products in the Field, including, without limitation:

(a) **Marketing Expenses**, which includes costs identifiable to the advertising, promotion and marketing of Licensed Products in the Field, and related professional education;

(b) **Advertising**, which includes costs associated with media costs, direct mails, production expenses, agency fees, and medical congresses and meetings;

(c) **Promotion**, which includes costs associated with professional samples, professional literature, promotional material, patient aids, detailing aids, reimbursement of patient assistance programs, public relations and communications expenses, web and social media expenses, patient advocacy support, development of information and data for national accounts, managed care organizations and group purchasing organizations;

(d) **Market Research**, which includes costs associated with market information, focus groups, and market research professional staff and related out-of-pocket costs such as travel, business meals, and training;

(e) **Marketing Management**, which includes the costs of product management and sales promotion management compensation and departmental expenses as well as costs associated with developing overall sales and marketing strategies and planning;

(f) **Reimbursement/Access Services**, which includes costs incurred to manage reimbursement programs, marketing costs (educational material) as well as coupon or co-pay programs;

(g) **Health Policy/Advocacy**, which includes costs associated with advocacy as well as any specific policy lobbying and trade and government relations related expenses; and

(h) **Selling Support**, which includes costs associated with logistics and document support and the operation of the sales/medical science liaison team such as meeting planning.

Medical Affairs Expenses - costs with respect to: medical affairs and other activities associated with clinical studies conducted after Regulatory Approval in the Territory (to the extent not otherwise included within Development Costs); medical and scientific information and response to external inquiries or complaints; pharmacovigilance, investigator initiated research if not covered in the Phase V Clinical Trials, costs of establishing and maintaining patient registries, medical education, Health Economics and Outcomes Research (HECOR, HEMAR), speaker programs, advisory boards, educational grants and fellowships, drug safety, government affairs (including costs associated with compliance with the Sunshine Act and other similar government regulation); and field-based medical science liaisons, medical affairs clinical trial management, MD's in field (separate from medical science liaisons), publications, medical communications and field medical education.

Recall Expenses – costs, to the extent not otherwise covered by KKC's indemnity obligations, associated with notification, retrieval and return of Licensed Products in the Field in the Territory, destruction of such returned Licensed Products in the Field, and distribution of the replacement Licensed Products in the Field.

Selling Costs - costs directly attributable to selling Licensed Product in the Field, including the FTE Costs for sales representatives/medical science liaisons and first line sales managers, exhibits at shows or conventions including samples, charges for space, sales aids and brochures, sales meetings, consultants, call reporting and other Third Party monitoring/tracking services, automobile allowance, meal expenses, travel/housing for meetings, costs of computer and other

equipment of sales representatives/medical science liaisons and other incidental expenses incurred by sales representatives/medical science liaisons in respect of selling the Licensed Product in the Field.

Other Commercialization Costs - any other costs attributable or allocable to Commercialization of Licensed Products in the Field in the Profit Share Territory in accordance with Accounting Standards, to the extent not included in one of the other categories or definitions of costs under this Exhibit 1.24.

Schedule 1.46

FTE Rates

1. The following table sets forth the FTE Rates for AEVI FTEs:

(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)

2. The following table sets forth the FTE Rates for KKC FTEs:

(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)

Schedule 1.51

KKC IN-LICENSES

License Agreement between La Jolla Institute for Allergy and Immunology and Kyowa Hakko Kirin Co., Ltd. (***) This is the LJI Agreement referred to in Section 1.61.

(***) Agreement between Lonza Sales AG and Kyowa Hakko Kirin Co., Ltd (***)

(***) Agreement between Bristol-Myers Squibb Company and Kyowa Hakko Kirin Co., Ltd. (***)

Letters between Kyowa Hakko Kirin Co., Ltd. and Sanofi (***) and sublicensing of rights to AEVI.

Schedule 1.55

KKC PATENT RIGHTS

[illegible]

EXHIBIT C
PLAN B LICENSE AGREEMENT

See Attached

LICENSE AGREEMENT

by and between

KYOWA KIRIN CO., LTD.

and

AEVI GENOMIC MEDICINE, LLC

<u>Article 1. DEFINITIONS</u>	1
<u>Article 2. EFFECTIVENESS OF THIS AGREEMENT</u>	15
<u>Article 3. GOVERNANCE</u>	16
<u>Article 4. DEVELOPMENT</u>	17
<u>Article 5. COMMERCIALIZATION</u>	21
<u>Article 6. DILIGENCE</u>	23
<u>Article 7. LICENSES</u>	24
<u>Article 8. FINANCIAL PROVISIONS</u>	27
<u>Article 9. INTELLECTUAL PROPERTY</u>	34
<u>Article 10. CONFIDENTIALITY</u>	44
<u>Article 11. TERM AND TERMINATION</u>	46
<u>Article 12. REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION</u>	54
<u>Article 13. MISCELLANEOUS PROVISIONS</u>	61

Schedules

Schedule 1.5 – AEVI In-License
 Schedule 1.10 – AEVI Patent Rights
 Schedule 1.15 – Amino Acid Sequence of Anti-Light mAb
 Schedule 1.24 – Commercialization Costs
 Schedule 1.45 – FTE Rates
 Schedule 1.50 – KKC In-Licenses
 Schedule 1.54 – KKC Patent Rights

LICENSE AGREEMENT

This License Agreement (this “**Agreement**”), effective as of the Effective Date (as defined in Section 2.1), is by and between Kyowa Kirin Co., Ltd., a company organized and existing under the laws of the Japan and having its principal office at 1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan and formerly known as Kyowa Hakko Kirin Co., Ltd. (“**KKC**”), and Aevi Genomic Medicine, LLC, a Delaware limited liability company and successor to Medgenics, Inc., a Delaware corporation (“**AEVI**”). KKC and AEVI may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

INTRODUCTION

WHEREAS, the Parties have entered into the Amended and Restated Clinical Development and Option Agreement, effective as of May 28, 2020 (the “**Clinical Development and Option Agreement**”); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct the Initial Development (as defined in the Clinical Development and Option Agreement) with respect to Anti-LIGHT mAb (as defined in Section 1.15); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct one or more signal finding studies in the Field (as defined in Section 1.41) and an option to obtain an exclusive license to Develop, Manufacture and Commercialize products containing Anti-LIGHT mAb at KKC’s election either under the terms and conditions of this Agreement (the “**Plan B Election**”) or under the terms and conditions of the license agreement attached to Exhibit B to the Clinical Development and Option Agreement (the “**Plan A Election**”); and

WHEREAS, this Agreement will become fully effective in accordance with Section 2.1 of this Agreement only upon KKC making or being deemed to have made the Plan B Election pursuant to the terms and conditions of the Clinical Development and Option Agreement; and

WHEREAS, this Agreement will not become effective and be rendered null and void in accordance with Section 2.2 of this Agreement.

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

Article 1. DEFINITIONS

When used in this Agreement, each of the following terms will have the meanings set forth in this Article 1:

1.1 “**Accounting Standards**” means with respect to a Party, as applicable, (a) United States generally accepted accounting principles (“**GAAP**”), (b) Japanese generally accepted accounting standards, or (c) International Financial Reporting Standards, in each case consistently applied.

1.2 “**Acquirer Intellectual Property**” means the Patent Rights and Know-How owned or controlled by a Third Party acquirer of AEVI or KKC, as the case may be, immediately prior to a

Change of Control transaction, and Inventions thereto following the effective date of such Change of Control.

1.3 “**Administrative Contact**” means any contact to or from a Regulatory Authority that is general or administrative in nature (e.g., notification by a Regulatory Authority of the assignment of a new reviewer or a notification of a new address or new contact information).

1.4 “**AEVI Business Day**” means a day on which banking institutions in New York, New York are open for business other than Saturday or Sunday.

1.5 “**AEVI In-License**” means each Third Party agreement listed on Schedule 1.5.

1.6 “**AEVI Inventions**” means any and all Inventions made or generated hereunder solely by employees or contractors of AEVI (or its Affiliates), as determined by the United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.7 “**AEVI Know-How**” means Know-How that is (a) Controlled by AEVI or any of its Affiliates on the Effective Date or during the Term (other than KKC Know-How pursuant to the licenses granted hereunder) and (b) reasonably necessary or useful in connection with Development, Manufacture, use or Commercialization of Licensed Products.

1.8 “**AEVI Licensor**” means The Children’s Hospital of Philadelphia (“**CHOP**”).

1.9 “**AEVI Lonza License Agreement**” means an agreement between AEVI and Lonza that licenses to AEVI the intellectual property rights subject to the (***) Agreement between Lonza and KKC (***), to the extent related to the Licensed Product in the Field in the Territory and the European Union, including the right to sublicense to another contract manufacturer such that such contract manufacturer can perform process development and supply of anti-LIGHT-mAb.

1.10 “**AEVI Patent Rights**” means (a) the United States and foreign patents and patent applications listed on Schedule 1.10 and any Patent Rights arising from those patents and patent applications during the Term, (b) any Patent Rights included within AEVI Inventions that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products and (c) any Patents Rights included in Third Party Technology (i) in respect of which AEVI obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products.

1.11 “**AEVI Technology**” means AEVI Know-How, AEVI Patent Rights and AEVI Inventions other than Acquirer Intellectual Property.

1.12 “**Affiliate**” means, with respect to any person or entity, any other person or entity which controls, is controlled by, or is under common control with such person or entity. A person or entity will be regarded as in control of another entity if it owns or controls more than fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of

directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.13 “**Allowable Expenses**” means, with respect to Profit-Share Products and each Contract Quarter, all FTE Costs and Out-of-Pocket Costs incurred by AEVI or its Related Parties that are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory, and Manufacture of such Profit-Share Products for Commercialization, during the applicable Contract Quarter, including such FTE Costs and Out-of-Pocket Costs which are: (a) Manufacturing Costs; (b) Commercialization Costs; and (c) Third Party Technology Costs, in each case determined from the books and records of AEVI or its Related Parties maintained in accordance with Accounting Standards and in each case of (a)-(c) as are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory during the applicable Contract Quarter. For clarity, no milestone payment made to KKC or its Affiliates pursuant to Section 8.3 will be an Allowable Expense. For purposes of clarity, it is understood that there will be no double-counting of expenses within the definition of Allowable Expenses.

1.14 “**Applicable Law**” means the laws, rules and regulations, including without limitation any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, Manufacturing or Commercialization of Licensed Products or other activities conducted by the Parties under this Agreement, that may be in effect from time to time in the applicable territory.

1.15 “**Anti-LIGHT mAb**” means the fully human monoclonal antibody targeting LIGHT (TNFSF14) consisting of the amino acid sequence set forth on Schedule 1.15.

1.16 “**Bankruptcy Code**” means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.17 “**Biosimilar**” means, with respect to a reference brand biologic product and a particular jurisdiction, a biologic product: (a) that is highly similar to such reference brand biologic product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences from such reference brand biologic product in terms of safety, purity and potency; and (c) for which a Biosimilar Application is approved by the relevant Regulatory Authority of such jurisdiction. Notwithstanding anything to the contrary in this Agreement, a “Biosimilar” does not include any biologic product sold under a BLA or approved Biosimilar Application of any Party or any of its Related Parties or manufactured or produced by or on behalf of a Party or any of its Related Parties.

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

1.19 “**BLA**” means a Biologics License Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.

1.20 “**BMS**” means Bristol-Myers Squibb Company.

1.21 “**Business Day**” means, with respect to KKC, a KKC Business Day, and, with respect to AEVI, an AEVI Business Day.

1.22 “**Change of Control**” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates.

1.23 “**Commercialization**” means importing, exporting, marketing, promoting, distributing, offering for sale and selling a Licensed Product and, solely with respect to Section 7.5, a Competing Product in the Field and will include activities required to fulfill ongoing post-approval regulatory obligations, including adverse event reporting and sales force training but excluding any Phase 4 Clinical Trial (as defined in Section 1.33). When used as a verb, “**Commercialize**” will mean to engage in Commercialization.

1.24 “**Commercialization Costs**” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of AEVI or its Related Parties in accordance with this Agreement and attributable to, or reasonably allocable to, the Commercialization of the Licensed Products in the Field in the Territory, including marketing costs, sales costs, distribution costs, importing and exporting costs, Phase 5 Clinical Trial costs, insurance costs incurred in connection with Commercialization activities, medical affairs costs and certain general and administrative costs (but excluding Development Costs) as further defined in Schedule 1.24. In this Agreement, “**Phase 5 Clinical Trial**” means a post-registration clinical trial that is not required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.25 “**Commercially Reasonable Efforts**” means, with respect to a Party, the carrying out of obligations in a diligent and sustained manner using such effort and employing such resources as would normally be exerted or employed by a similarly situated biopharmaceutical company for a product of similar commercial or strategic importance, and at a similar stage of its product life, based on conditions then prevailing, taking into consideration safety and efficacy, development costs, the anticipated prescription label, the nature of the Licensed Product, the clinical setting in which it is expected to be used and all other relevant factors. Commercially Reasonable Efforts will be determined on a country-by-country basis.

1.26 “**Competing Product**” means (***), other than a Licensed Product, (***).

1.27 “**Confidential Information**” means, with respect to each Party, proprietary data or information of such Party or its Affiliates or sublicensees, including, without limitation, (a) with

respect to KKC, all KKC Technology, and, with respect to AEVI, all AEVI Technology, (b) any information designated as Confidential Information of such Party hereunder, in all cases that is identified as confidential either in writing or orally, provided that any orally disclosed information is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral disclosure requesting that such information be treated as Confidential Information hereunder, and (c) all information that is manifestly confidential, whether or not marked as such.

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

1.29 “**Contract Year**” means the twelve (12) month period beginning on January 1 and ending on December 31 of each calendar year, provided, however, that the first Contract Year will be the period of time beginning on the Effective Date and ending on December 31, 2016. Each Contract Year, except the first Contract Year, will be divided into four (4) Contract Quarters.

1.30 “**Control**” or “**Controlled**” means with respect to any (a) material, item of information, method, data or other Know-How, or (b) intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by the referenced Party or its Affiliates of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.

1.31 “**Data Exclusivity Period**” means, with respect to a particular jurisdiction, the time period of legal protection and confidential treatment provided for clinical test data required to be submitted to a Regulatory Authority for such jurisdiction in order to demonstrate safety and efficacy of a new drug or biologic, and all similar protections on such clinical test data intended to prevent generic drug manufacturers or biosimilar manufacturers from relying on this data in their own Biosimilar applications.

1.32 “**Development**” means, with respect to a Licensed Product and, solely with respect to Section 7.5, a Competing Product in the Field, non-clinical and clinical drug development activities performed on or after the Effective Date, including without limitation the conduct of clinical trials, test method development, toxicology, pharmacology, pharmacokinetics formulation, data management, statistical analysis and report writing and clinical studies, and regulatory affairs and all activities associated with obtaining and maintaining Regulatory Approvals. When used as a verb, “Develop” means to engage in Development.

1.33 “**Development Costs**” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of a Party in accordance with this Agreement and attributable to, or reasonably allocable to, the Development of the Licensed Products in the Field in the Territory and that are materially consistent, as applicable, with the Development Plan, including costs and expenses for Regulatory Approvals and pricing and/or reimbursement approvals, and costs incurred after Regulatory Approval, including Phase 4 Clinical Trial costs, costs of non-clinical studies, costs of clinical studies for additional Indications in the Field,

insurance costs incurred in connection with Development activities (but excluding costs that are allocable to Commercialization Costs and the costs of general company management, financial, legal or business development personnel). Development Costs will not include any costs incurred by either Party prior to the Effective Date, including, without limitation, costs for purchasing raw materials, for manufacturing clinical supplies of Licensed Product or for any labeling or packaging materials, whether or not such raw materials, clinical supplies or labeling or packaging materials are used by the Parties for Development activities after the Effective Date. In this Agreement, “**Phase 4 Clinical Trial**” means a post-registration clinical trial or post-marketing surveillance study performed in accordance with Applicable Laws and required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.34 “**Development Plan**” means (a) the written comprehensive plan for (i) the Development of any Licensed Product in the Field in the Territory, including, but not limited to, activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing Regulatory Approval Applications in the Territory and (ii) the preparation and submission of related Regulatory Approval Applications in the Territory and (b) an annual budget for Development Costs setting forth both internal and external resources and expenses for the then-current Contract Year.

1.35 “**EMA**” means the European Medicines Agency and any successor agency having substantially the same functions.

1.36 “**European Union**” means all countries over which EMA has jurisdiction from time to time and all countries that exit the jurisdiction of the EMA from time to time.

1.37 “**Executive Officers**” means the Chief Executive Officer of AEVI (or an executive of AEVI designated by such Chief Executive Officer) and the Chief Executive Officer of KKC (or an executive of KKC designated by such Chief Executive Officer).

1.38 “**Fair Market Value**” means (a) with respect to investment by a Third Party in exchange for equity securities of AEVI, (i) for so long as AEVI’s common stock is publicly traded on a securities exchange, the volume weighted average closing price of a share of AEVI’s common stock on the principal exchange on which such stock is then trading for the ten (10) trading days ending on the date that is twenty (20) trading days on such exchange prior to the first public announcement of such equity investment, and (ii) if AEVI’s common stock is no longer publicly traded on a securities exchange, the fair market value of a share of common stock of AEVI as of the date of closing such investment as determined in good faith by the board of directors of AEVI, taking into account such factors and for such time period as the board of directors of AEVI reasonably deems is appropriate, and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned, and (b) with respect to any non-cash consideration (other than equity securities), the fair market value of such consideration as determined in good faith by the board of directors of AEVI and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned.

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

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

1.41 “**Field**” means treatment, prevention, and diagnosis (***) of pediatric (18 and below) onset rare and orphan disease (***) Crohn Disease, Ulcerative Colitis, (***), Juvenile Idiopathic Arthritis, Psoriasis, (***). Pediatric onset patients who survive into adulthood will be included in the scope of the Field.

1.42 “**First Commercial Sale**” means, with respect to a given Licensed Product in a country, the first commercial sale in an arms-length transaction of such Licensed Product to a Third Party by or on behalf of a Party, its Affiliate or its sublicensee in such country following receipt of applicable Regulatory Approval of such Licensed Product in such country.

1.43 “**FTE**” means a full time equivalent person year (consisting of a total of two thousand (2,000) hours per Contract Year, subject to a proportionate reduction in the first Contract Year) of scientific, technical, marketing, sales, distribution and certain general and administrative activities related to the Development of Licensed Products and/or the Commercialization of the Licensed Products in the Field in accordance with this Agreement. For the avoidance of doubt, no individual will count as more than one (1) FTE, and any individual who works less than two thousand (2,000) hours in a given Contract Year performing activities under this Agreement will be counted as a fraction of one (1) FTE, the numerator of which is the number of hours such individual performs activities under this Agreement and the denominator of which is two thousand (2,000) hours.

1.44 “**FTE Costs**” means all costs for FTEs calculated by multiplying (a) the actual number of FTEs utilized by KKC or AEVI in performing activities in accordance with any Development Plan and/or Commercialization Plan by (b) the applicable FTE Rate, provided that, to the extent either Party is unable to fully track the number of FTEs utilized, the Parties will agree on a mechanism for estimating such number.

1.45 “**FTE Rate**” means, with respect to an FTE, the applicable amount set forth on Schedule 1.45, as such amount may be adjusted pursuant to Section 8.7.

1.46 “**IND**” means an Investigational New Drug Application, as defined in the FD&C Act, or similar application or submission that is required to be filed with any Regulatory Authority before beginning clinical testing of a Licensed Product in human subjects.

1.47 “**Inventions**” means any and all ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other

technology or intellectual property, whether or not patentable or copyrightable, and all Patent Rights and other intellectual property rights in any of the foregoing.

1.48 “**Joint Inventions**” means any and all Inventions made or generated hereunder jointly by at least one employee or contractor of each Party (or its respective Affiliates), as determined by United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.49 “**KKC Business Day**” means a day on which banking institutions in Tokyo, Japan are open for business other than a Saturday or Sunday.

1.50 “**KKC In-Licenses**” means the Third Party agreements listed on Schedule 1.50.

1.51 “**KKC Inventions**” means any and all Inventions made or generated hereunder solely by employees or contractors of KKC (or its Affiliates), as determined by the United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.52 “**KKC Know-How**” means Know-How that is (a) Controlled by KKC on the Effective Date or during the Term (other than AEVI Know How pursuant to the licenses granted hereunder) and (b) is reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory.

1.53 “**KKC Licensor**” means LJI, BMS, Lonza, and Sanofi, respectively defined in this Article 1, and its respective successor and assigns, which has licensed rights to KKC pursuant to the KKC In-Licenses.

1.54 “**KKC Patent Rights**” means (a) the United States and foreign patents and patent applications listed on Schedule 1.54 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (b) the United States and foreign patents and patent applications licensed to KKC under the KKC In-Licenses but not listed on Schedule 1.54 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (c) any Patent Rights included within KKC Inventions prior to the completion of the Term that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory and (d) any Patents Rights included in Third Party Technology prior to the completion of the Term (i) in respect of which KKC obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory.

1.55 “**KKC Technology**” means KKC Patent Rights, KKC Know-How and KKC Inventions other than Acquirer Intellectual Property.

1.56 “**Know-How**” means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, material, technology or other know-how, whether or not patentable or copyrightable.

1.57 “**Licensed Product**” means any product containing as an active ingredient the Anti-LIGHT mAb.

1.58 “**LIGHT**” means TNFSF14 (Unigene cluster number: Hs. 129708).

1.59 “**LJI**” means La Jolla Institute for Immunology (formerly, La Jolla Institute for Allergy and Immunology) and its respective successor and assigns, which has licensed rights to KKC pursuant to the LJI Agreement.

1.60 “**LJI Agreement**” means License Agreement between La Jolla Institute for Immunology and Kyowa Hakko Kirin Co., Ltd. (**).

1.61 “**Lonza**” means Lonza Sales AG and its Affiliates.

1.62 “**Manufacturing**” means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of Licensed Products and, solely with respect to Section 7.5, a Competing Product, including without limitation process and formulation development, process validation, stability testing, process development, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, “**Manufacture**” will mean to engage in Manufacturing.

1.63 “**Manufacturing Costs**” means:

(d) With respect to Licensed Product manufactured by AEVI, its fully-burdened costs (including the costs associated with product testing and release activities) of producing (including startup and validation but excluding what will be covered under Section 4.3.3) and packaging Licensed Product for sale in a given country, determined in accordance with the applicable Accounting Standard, based on the sum of the following components: (i) direct costs, including manufacturing labor and materials directly incurred in producing and packaging such Licensed Product; (ii) manufacturing and accounting personnel costs incurred by AEVI and attributable and reasonably allocable to the manufacture of Licensed Product, including quality labor and manufacturing and quality supervisory services, depreciation, and other operating and administrative costs which of the manufacturing, quality and accounting departments and associated occupancy costs which are allocable to such company departments based on space occupied or headcount, or other activity based method of allocation; (iii) any other reasonable and customary Out-of-Pocket Costs incurred by AEVI for the testing, transport, customs clearance, duty, insurance and/or storage of such Licensed Products, including payments made by AEVI to Third Parties for filing, finishing, packaging, labeling, testing, storage and shipment of such Licensed Product and AEVI’s handling cost with respect thereto, as applicable; and (iv) AEVI’s reasonably allocated share of cost of Licensed Product process improvements developed by AEVI or a Third Party on behalf of AEVI. For Licensed Products manufactured by AEVI, Manufacturing Cost will not include any general corporate overhead, any excess capacity cost or charges or cost for process development (except to the extent expressly provided above).

(e) With respect to Licensed Product manufactured for AEVI by one or more Third Parties and supplied to KKC hereunder amounts actually paid (net of any discounts, credits or refunds) by such Party to such Third Parties for the manufacture and supply of such Licensed Product.

1.64 “**Medical Affairs Activities**” means, with respect to a Licensed Product, activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, such Licensed Product, including, with respect to such Licensed Product: (a) conducting service based medical activities including providing input and assistance with consultancy meetings, recommending investigators for clinical trials and providing input in the design of such trials and other research related activities, and delivering non-promotional communications and conduct non-promotional activities including presenting new clinical trial data and other scientific information; (b) grants to support continuing medical education, symposia, or Third Party research specifically related to such Licensed Product; (c) development, publication and dissemination of publications relating to such Licensed Product and relevant disease states; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call or email; (e) conducting advisory board meetings or other consultant programs; (f) support of investigator-initiated clinical trials; (g) managing relationships with cooperative groups, physician/hospital networks and advocacy groups; and (h) establishing and implementing risk, evaluation and mitigation strategies.

1.65 “**Net Sales**” means the gross invoiced sales by a Party and/or its Related Parties to Third Parties for Licensed Products sold, less deductions, consistent with applicable Accounting Standards used in the applicable reporting period for such Party’s consolidated financial reporting purposes, which will be limited to: (a) price adjustments, chargeback payments, credits, or rebates (or the equivalent thereof), allowances allowed and taken, quantity or other trade discounts and other amounts paid on sale of Licensed Products, including those granted to and actually used by group purchasing organizations or other buying groups, managed healthcare organizations, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other healthcare institutions (including hospitals), Third Party health care administrators or patient assistance or other similar program, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors and other trade customers; (b) sales, use, tariffs, value-add, and/or excise taxes, or other governmental charges and tariffs incurred in connection with exportation or importation directly imposed and with reference to particular sales; (c) reasonable and customary freight, postage, shipping, insurance and other transportation expenses and delayed ship order credits reflected in the applicable invoice and paid by the customer; and (d) amounts allowed, repaid or credited due to defects, returns, rejections, recalls, rebates and replacements and allowances of goods or because of retroactive price reductions; (e) normal and customary rebates, trade, cash or quantity discounts; billing errors; coupons for price reductions; (f) required distribution commissions/fees payable to Third Party wholesalers for distribution of the Licensed Products; (g) allowance and write-offs for bad debt made in accordance with generally accepted accounting principles, consistently applied to all of such Party’s products; (h) discounts pursuant to indigent patient programs and patient discount programs including coupon discounts; and (i) any item, substantially similar in character or substance to any of the foregoing

permitted by the applicable Accounting Standards and customary in the pharmaceutical industry. Net Sales also includes the Fair Market Value of any non-cash consideration received in connection with the sale of the Licensed Products. In the case of any sale of Licensed Product for value other than in an arm's length transaction exclusively for cash, Net Sales will be determined by referencing Net Sales at which substantially similar quantities of such Licensed Product are sold in an arm's length transaction for cash. For purposes of calculating Net Sales, transfers of Licensed Product between a Party and its Related Parties, whether or not value is exchanged therefor, will not be booked as sales.

1.66 “**Out-of-Pocket Costs**” means, with respect to specified activities hereunder, direct expenses paid or payable by a Party or its Related Parties to Third Parties (other than employees of such Party or its Related Parties) that are specifically identifiable and incurred to conduct such activities.

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

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

1.69 “**Product Labels and Inserts**” means (a) all labels and other written, printed or graphic matter affixed to any container, packaging or wrapper utilized with Licensed Product, or (b) any written material physically accompanying Licensed Product, including product package inserts.

1.70 “**Product Trademarks**” means the trademark(s), service mark(s), accompanying logos, trade dress and/or indicia of origin used in connection with the Commercialization of each Licensed Product in the Territory. For purposes of clarity, the term Product Trademark(s) will not include, without limitation, the corporate names and logos of either Party, and will include any internet domain names incorporating such Product Trademarks.

1.71 “**Profit**” means with respect to all Profit-Share Products with respect to a Contract Quarter and a country in the Territory: (a) Net Sales of such Profit-Share Products in the Field in the Territory by AEVI and its Affiliates, plus (b) Profit-Share Product Proceeds, minus (c) Allowable Expenses, to the extent such deductions have not already or otherwise been deducted in calculating the amounts described in (a) and (b) above. If a calculation of Profit for a given Contract Quarter pursuant to the preceding sentence would result in a negative number, the amount of such Profit for such Contract Quarter will be zero (0).

1.72 “**Profit-Share Product**” means a Licensed Product Commercialized by AEVI or its Related Parties in the Territory.

1.73 “**Profit-Share Product Proceeds**” means, with respect to Profit-Share Products, any proceeds received by AEVI or its Affiliates from Third Parties with respect to the Development, Manufacture, supply, or Commercialization of such Profit-Share Products in the Field in the Territory, including proceeds attributable to a grant of a license or sublicense, or a grant of distribution rights, to permitted sublicensees and distributors under this Agreement, to Develop, Manufacture or Commercialize such Profit-Share Products (or, if rights in addition to such rights to such Profit-Share Products are granted to such Third Party, then reasonably allocated to the rights granted to such Third Party with respect to such Profit-Share Products). In the event any Third Party sublicensee makes a bona fide investment in any equity securities issued by AEVI or any of its Affiliates, the cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in exchange therefor will be excluded from the calculation of Profit-Share Product Proceeds, up to the Fair Market Value of such equity securities, and the sum of any cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in excess of the Fair Market Value of such equity securities will be included in the calculation of Profit-Share Product Proceeds.

1.74 “**Regulatory Approval**” means the approval of the applicable Regulatory Authority necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Licensed Product in a regulatory jurisdiction, including, where required, separate pricing and/or reimbursement approvals.

1.75 “**Regulatory Approval Application**” means an application submitted to the appropriate Regulatory Authority seeking Regulatory Approval of a Licensed Product in a regulatory jurisdiction, including without limitation a BLA.

1.76 “**Regulatory Authority**” means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity involved in granting of Regulatory Approval for a Licensed Product in a regulatory jurisdiction, including without limitation the FDA and the EMA.

1.77 “**Regulatory Materials**” means any regulatory submissions, notifications, registrations, approvals and/or other filings and correspondence made to or with a Regulatory Authority, and any other records required to be maintained for possible audit by a Regulatory Authority, that may be necessary or reasonably desirable to Develop, Manufacture, or Commercialize Licensed Products in the Territory.

1.78 “**Related Party**” means, with respect to a Party, such Party’s Affiliates and permitted licensees and sublicensees, which term does not include wholesale distributors of such Party or its Affiliates, which distributors purchase a Licensed Product from such Party or its Affiliates in an arm’s-length transaction.

1.79 “**Royalty-Bearing Sales**” means Net Sales by KKC and its Affiliates of Licensed Products worldwide.

1.80 “**Sanofi**” means Sanofi, successor in interest to Sanofi-Aventis.

1.81 “**Significant Impact**” means a decrease in AEVI’s and its Related Parties’ Net Sales of Licensed Products (***).

1.82 “**Substantive Contact**” means any contact to or from a Regulatory Authority that is not an Administrative Contact.

1.83 “**Sublicensing Royalties**” means royalties and sales milestones received by KKC from its licensees or sublicensees on Net Sales by such licensees or sublicensees of Licensed Products worldwide.

1.84 “**Territory**” means the United States and its territories and possessions, the European Union, and Canada.

1.85 “**Third Party**” means any person or entity other than a Party or any of its Affiliates.

1.86 “**Third Party Technology**” means any Patent Rights, Know-How, inventions, or other intellectual property owned, in whole or in part, by or licensed to a Third Party.

1.87 “**Third Party Technology Costs**” means, with respect to a Profit-Share Product, royalties, license fees or other payments, as applicable, that are made to any Third Party for the use of any Third Party Technology and are reasonably allocable to and reasonably necessary or useful for, the Development, Manufacturing or Commercialization of such Licensed Product in the Field in the Territory. For the avoidance of doubt:

(a) the amounts payable to the KKC Licensors under the KKC In-Licenses are Third Party Technology Costs, provided however that:

(iv) with respect to payments paid by KKC to LJI (***), only payments stipulated in paragraphs (1) and (3) of Section 12 of such addendum will be included in the Third Party Technology Costs and all other costs such as milestone payments will be solely borne by KKC and not included in Third Party Technology Costs;

(v) with respect to payments paid by KKC to Lonza (***), only payments stipulated in Section 5.2 of such agreement will be included in the Third Party Technology Costs and all other costs except for annual maintenance fee which is stipulated in Section 8.6.4(c) in this Agreement, will be solely borne by KKC and not included in Third Party Technology Costs;

(vi) with respect to payments paid by KKC to BMS (***), only payments stipulated in Section 10.6.1(a)(i) of such agreement will be included in the Third Party Technology Costs and all other costs will be solely borne by KKC and not included in Third Party Technology Costs;

(b) the amounts payable by AEVI:

(iii) to the AEVI Licensor pursuant to Section 6.4.1 and, with respect to amounts payable after receipt of the first Regulatory Approval for a Licensed Product in the Field in the Territory, pursuant to Section 6.2 under the AEVI In-License will be included in the

Third Party Technology Costs, and payments paid by AEVI to CHOP with respect of all other costs under the AEVI In-License, including but not limited to milestone payments, will be solely borne by AEVI and not included in Third Party Technology Costs; and

(iv) as royalties under the AEVI Lonza License Agreement shall be treated as Third Party Technology Costs; and

(c) the amounts payable for obtaining rights to Third Party Technology for the Territory under Section 9.5 are Third Party Technology Costs.

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

Term	Section
<i>“AEVT”</i>	Preamble
<i>“AEVI Indemnitees”</i>	12.10.2
<i>“Agreement”</i>	Preamble
<i>“Audited Party”</i>	8.6.6
<i>“BPCIA”</i>	9.6.2
<i>“Challenge”</i>	11.2.4
<i>“CHOP”</i>	1.8
<i>“Clinical Development and Option Agreement”</i>	Introduction
<i>“Commercialization Plan”</i>	5.2
<i>“Co-Chairperson”</i>	3.1.1(b)
<i>“Controlling Party”</i>	9.3.3
<i>“Cooperating Party”</i>	9.3.3
<i>“Defending Party”</i>	9.4.2(a)
<i>“Defensive Actions”</i>	9.3.2
<i>“Disclosing Party”</i>	10.1.1
<i>“Effective Date”</i>	2.1
<i>“Enforcement Expense”</i>	9.3.3
<i>“EU5 Countries”</i>	6.2
<i>“GAAP”</i>	1.1
<i>“Global Clinical Study”</i>	4.2.4
<i>“ICC”</i>	13.2.2(a)
<i>“Indemnitee”</i>	12.10.3
<i>“Infringement Claim”</i>	9.4.1
<i>“Inspecting Party”</i>	5.3.3
<i>“IP”</i>	11.7
<i>“Joint Patent”</i>	9.2.2
<i>“Joint Steering Committee” or “JSC”</i>	3.1.1
<i>“KKC”</i>	Preamble

“ <i>KKC Indemnities</i> ”	12.10.1
“ <i>KKC Managed Patent Rights</i> ”	9.2.1
“ <i>KKC Territory Royalty Rate</i> ”	8.5.1
“ <i>Losses</i> ”	12.10.1
“ <i>Other Royalty Rate</i> ”	8.5.1
“ <i>Party</i> ” or “ <i>Parties</i> ”	Preamble
“ <i>Phase 3 Clinical Trial</i> ”	4.2.5
“ <i>Phase 4 Clinical Trial</i> ”	1.33
“ <i>Phase 5 Clinical Trial</i> ”	1.24
“ <i>Plan A Election</i> ”	Introduction
“ <i>Plan B Election</i> ”	Introduction
“ <i>Prosecuting Party</i> ”	9.2.2
“ <i>Publications</i> ”	10.2.2
“ <i>Receiving Party</i> ”	10.1.1
“ <i>Recoveries</i> ”	9.3.3
“ <i>Reference Product Sponsor</i> ”	9.6.2
“ <i>Requesting Party</i> ”	8.6.6
“ <i>Section 351(k) Applicant</i> ”	9.6.1
“ <i>SPC</i> ”	9.8
“ <i>Supply Agreement</i> ”	5.3.2
“ <i>Term</i> ”	11.1
“ <i>Territory Royalty Rate</i> ”	8.5.1
“ <i>Third Party Claim</i> ”	12.10.1

Article 2. EFFECTIVENESS OF THIS AGREEMENT

2.1 Effectiveness of this Agreement upon the Plan B Election. This Agreement is not and will not become effective except as set forth in this Section 2.1. As of the date on which (a) KKC provides notice to AEVI that KKC has elected the Plan B Election or (b) KKC is deemed to have made the Plan B Election, in each case in accordance with Section 4.1.4 of the Clinical Development and Option Agreement, this Agreement shall automatically become effective. Such date is referred to in this Agreement as the “***Effective Date***.”

2.2 Non-Effectiveness of this Agreement. Upon the earliest to occur of (a) the termination of the Clinical Development and Option Agreement pursuant to any of Section 7.2, 7.3, 7.4 or 7.5 thereof, (b) KKC making the Plan A Election in accordance with Section 4.1.4 of the Clinical Development and Option Agreement or (c) the expiration of the Clinical Development and Option Agreement pursuant to Section 7.1(i)(a) or 7.1(ii)(a) thereof, this Agreement will not

become effective and be rendered null and void. For the avoidance of doubt, upon this Agreement becoming effective, this Agreement shall survive the expiration or termination of the Clinical Development and Option Agreement for any reason.

Article 3. **GOVERNANCE**

3.1 Joint Steering Committee.

3.1.1 Establishment of JSC. As soon as practicable and no later than (***) after the Effective Date, the Parties will establish a committee to facilitate the Development and Commercialization of Licensed Products under this Agreement (the “*Joint Steering Committee*” or “*JSC*”) as follows:

(a) Composition of the Joint Steering Committee. The JSC will be comprised of two (2) representatives designated by each of the Parties. Each representative will be an individual with significant experience or expertise in biopharmaceutical drug development. Each Party will appoint its respective initial representatives to the JSC (***) after the Effective Date, and may from time to time substitute its representatives, in its sole discretion, effective upon notice to the other Party of such change. Additional representatives or consultants may from time to time be invited to attend JSC meetings, subject to such representatives’ and consultants’ written agreement to comply with the requirements of Article 10. Each Party will bear its own expenses relating to attendance at such meetings by its representatives and consultants.

(b) Chairperson. Each Party will designate one (1) of its representatives to be a co-chairperson (“*Co-Chairperson*”). Each Co-Chairperson or its designee will conduct the following activities of the Joint Steering Committee cooperatively: (i) scheduling meetings at least once per Contract Year, but more frequently if the JSC determines it necessary; (ii) setting agendas for meetings with solicited input from representatives of each Party; (iii) preparing and confirming minutes of the meetings, which will provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations made by the JSC, and delivering minutes to each Party’s senior management for review and final approval; and (iv) conducting effective meetings, including ensuring that objectives for each meeting are set and achieved.

(c) Meetings. The JSC will meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Contract Year. The JSC may meet by means of teleconference, videoconference or other similar communications equipment.

(d) Role. The JSC is a consultative body and may discuss any matter that a Party’s Co-Chairperson includes in the agenda for the meeting including:

(i) sharing information and discussing all Development Plans and amendments and updates thereto as well as KKC’s development of the Licensed Product outside the Territory including Development of indications beyond the initial indication;

(ii) sharing information, discussing, and coordinating global regulatory strategy, global clinical development strategy, and global clinical supply strategy;

(iii) sharing information and discussing Commercialization of the Licensed Products, including strategic objectives and plans (including pricing and reimbursements), the Commercialization Plans and budgets and material amendments or updates thereto submitted to KKC by AEVI and Commercialization issues; and

(iv) discussing disputes between the Parties and discussing potential resolutions thereto.

3.1.2 Decision-Making. The JSC is a consultative body only and has no decision making power. For the avoidance of doubt, AEVI has sole decision-making power to with respect to Development, Manufacturing and Commercialization of the Licensed Product in the Field in the Territory.

Article 4. **DEVELOPMENT**

4.1 Overview. AEVI will be responsible for all Development of the Licensed Product in the Field in the Territory. AEVI will bear all costs and expenses incurred in connection with the Development of Licensed Product in the Field in the Territory, including any and all regulatory activities, and, for clarity, none of such costs will be included in Allowable Expenses.

4.2 Development Plans.

4.2.1 Development Plans. AEVI has delivered to KKC the most current version of the clinical protocol for the Adolescent Study (as defined in the Clinical Development and Option Agreement). AEVI will provide KKC with an updated Development Plan in accordance with Section 4.2.3.

4.2.2 Additional Indications. At any time, AEVI may Develop in the Territory Licensed Products for additional indications in the Field (i.e., in addition to the first indication). In case KKC or any of its Related Parties wishes to Develop any Licensed Product for additional indications in the Field in any jurisdiction, and if in such cases AEVI is not Developing the same or similar indication in the Field in the Territory, the Parties will discuss in good faith regarding such Development by KKC or its Related Parties. Neither KKC nor any of its Related Parties will Develop any Licensed Product for additional indications in the Field in any jurisdiction unless AEVI is also Developing the same or similar indication in the Field in the Territory or AEVI otherwise consents in writing after the discussion with KKC set forth above.

4.2.3 Updates. No later than (***) prior to the beginning of the next Contract Year, AEVI will update each Development Plan and submit such updated Development Plans to KKC for informational purposes. Each Development Plan will contain the specific Development objectives to be achieved by AEVI during the then-current Contract Year and the annual budget for such Contract Year and the timeline for performing such Development activities. AEVI will

use its Commercially Reasonable Efforts to perform the activities set forth in each Development Plan.

4.2.4 Global Clinical Study. If AEVI conducts a Global Clinical Study in the Field in any country in the Territory, at KKC's request AEVI will in good faith discuss with KKC including sites in countries outside of the Territory for such Global Clinical Study in order for KKC to join such Global Clinical Study. In order for AEVI to include such sites in the Global Clinical Trial, such discussions must result in a mutually satisfactory amendment to this Agreement that addresses all relevant matters including operational matters (such as allocation of responsibilities between the Parties), regulatory matters (such as preparation of any required IND, management of communications with Regulatory Authorities and which Party will be the holder of the IND/sponsor of the trial), risk matters (including KKC indemnifying AEVI for Losses resulting from Third Party Claims arising from the trial at such sites including product liability and from AEVI's performance of its allocated responsibilities) and KKC bearing all costs associated with all of the foregoing. In this Agreement, "**Global Clinical Study**" means, with respect to Development of Licensed Products, a study with a unique protocol, the results of which are designed to be submitted to Regulatory Authorities of the United States and European Union and other countries as mandatory for obtaining Regulatory Approval of such Licensed Products in the respective countries.

4.2.5 Development Event Notices. AEVI will inform KKC of the occurrence of each of the following events in writing within (***) after such occurrence: (a) commencement of the first Phase 3 Clinical Trial for any Licensed Product in the Territory; and (b) receipt of the first Regulatory Approval for any Licensed Product in the Territory. In this Agreement, "**Phase 3 Clinical Trial**" means a registration or pivotal clinical trial performed in accordance with applicable laws and conducted in subjects with a particular disease or condition which is designed to establish the efficacy and safety of a Licensed Product given its intended use and to define warnings, precautions and adverse events that are associated with such Licensed Product in the dosage range intended to be prescribed.

4.3 Development Responsibilities for Licensed Products. AEVI will be responsible for Development activities for Licensed Product for the Field for Territory as follows:

4.3.1 Regulatory Matters.

(a) **Strategy.** AEVI will develop a regulatory strategy for the Field for the Territory (subject to Section 6.1.1 in the case of terminated countries in the European Union and Section 6.1.2 in the case of Canada), that is consistent with the terms of this Agreement. Pursuant to and in accordance with such regulatory strategy, AEVI will use Commercially Reasonable Efforts to prepare Regulatory Approval Applications or other submissions to Regulatory Authorities that are suitable in content and format for use in all geographies in the applicable Territory (e.g., use of ICH eCTD format).

(b) **Communications with Regulatory Authorities.** AEVI will be responsible for all communications with Regulatory Authorities concerning the Licensed Product in the Field in the Territory. AEVI will disclose to KKC any and all material correspondence between AEVI and

any Regulatory Authority in the Territory and minutes concerning the Development of the Licensed Product in the Field in the Territory received from any Regulatory Authority within (***) after receipt or transmission thereof. AEVI will keep KKC informed of any planned or actual communications with any Regulatory Authority regarding Development of the Licensed Product in the Field in the Territory.

(c) Regulatory Approvals.

(i) AEVI will be responsible for preparing and filing Regulatory Approval Applications for the Licensed Products in the Field for the Territory (subject to Section 6.1.1 in the case of terminated countries in the European Union and Section 6.1.2 in the case of Canada). Such Regulatory Approval Applications and any resulting Regulatory Approvals of the Licensed Products in the Field in the Territory will be made and issued in the name of AEVI or its Related Parties. AEVI will provide KKC with drafts of any Regulatory Approval Applications for the Licensed Products in the Field for the Territory sufficiently in advance of submission to allow KKC to review and comment on such documents.

(ii) AEVI grants KKC a right of reference to Regulatory Approval Applications filed by AEVI in the Territory for purposes of KKC obtaining Regulatory Approval (a) outside the Field in the Territory and (b) outside the Territory and will provide the FDA with any required document to effect such right of reference. In addition, AEVI will provide KKC manufacturing information for the CMC section of KKC's Regulatory Approval Applications for the Licensed Product outside the Territory where applicable.

(d) Assistance. Each Party will cooperate with the other Party to provide all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law, including, but not limited to, reporting adverse drug experiences (and serious adverse drug experiences) to the applicable Regulatory Authorities.

4.3.2 Clinical Development. AEVI will develop a clinical development strategy for the Field for the Territory. Each Development Plan will be consistent with such clinical development strategy. AEVI will conduct clinical Development for Licensed Product in the Field for the Territory as necessary for preparing and submitting Regulatory Approval Applications in the Territory. AEVI will provide reasonable consultation to KKC upon KKC's request in connection with Development of the Licensed Product outside the Territory.

4.3.3 CMC. AEVI will be solely responsible for all chemistry, manufacturing and control activities for the Licensed Product to support Regulatory Approval in the Field in the Territory, which, for clarity includes all CMC activities up to and including manufacturing process development, commercial scale-up and validation. AEVI will bear all costs and expenses incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development in the Field in the Territory (including failed batches and any batches, or parts thereof, that are Manufactured after the Effective Date, in anticipation of clinical studies but which are not actually used), and disposal of clinical samples, and, for clarity, none of such costs will be included in Allowable Expenses.

4.3.4 Preclinical Development. If deemed necessary by AEVI, AEVI will develop a preclinical strategy for the Territory, which strategy may include each of the Parties (subject to KKC's consent over activities to be performed by KKC, which may be withheld in KKC's sole discretion), (a) preparing and reviewing the preclinical sections of all Regulatory Approval Applications and other submissions to any Regulatory Authorities for the Territory, and (b) providing pharmacokinetic, pathology, toxicology and bioanalytical support for the clinical program.

4.4 Drug Safety.

4.4.1 Responsibility Before First Commercial Sale. Prior to the First Commercial Sale of a Licensed Product anywhere in the world, whether inside or outside the Field, AEVI will hold and manage a safety database and will lead safety monitoring and reporting in the Field in the Territory, and when KKC conducts any clinical trials for the Licensed Product, KKC will hold and manage a safety database during clinical development and will lead safety monitoring and reporting outside the Field in the Territory and outside the Territory. Each Party will allow the other Party and its Affiliates and sublicensees or Third Parties acting on their respective behalf, to:

- (a) review all serious adverse events within time frames that comply with 21 CFR 312.32;
- (b) review IND safety reports, investigator brochure amendments, patient consent forms and clinical protocols;
- (c) review monthly line listings;
- (d) read and write to each Party's database;
- (e) participate in signaling discussions; and
- (f) review all periodic reporting required by Regulatory Authorities (e.g., IND Annual Reports, EU Annual Safety Reports, etc.).

The Parties agree to jointly develop and enter into a global safety data exchange and pharmacovigilance agreement to facilitate this exchange of information no later than (***) prior to the date of initiation of the first clinical study sponsored by KKC if and when KKC decides to Develop the Licensed Product in its jurisdiction. In such case, AEVI will be responsible for holding and maintaining the global database for the Licensed Product.

4.4.2 After First Commercial Sale. In case the Parties have not entered in to a global safety data exchange and pharmacovigilance agreement according to Section 4.4.1, when KKC decides to Commercialize the Licensed Product in its jurisdiction, no later than (***) prior to the date of initiation of the first clinical study of the Licensed Product sponsored by KKC, if any, or the anticipated First Commercial Sale of a Licensed Product by KKC, AEVI and KKC will jointly develop and enter into a global safety data exchange and pharmacovigilance

agreement. In such case, AEVI will be responsible for holding and maintaining the global database for the Licensed Product.

4.5 Records. Each Party will maintain scientific records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of Development under this Agreement by such Party. Each Party will have the right, during normal business hours and upon reasonable notice, to inspect and copy (or request the other Party to copy) all records of the other Party maintained in connection with the work done and results achieved in the performance of Development under this Agreement. All such records and the information disclosed therein will be maintained in confidence by the recipient in accordance with Article 10.

4.6 Know-How Transfer. In order to facilitate Development of Licensed Products, from time to time during the Term, each Party will disclose or transfer to the other Party any applicable KKC Know-How or AEVI Know-How, as the case may be, existing as of the Effective Date or developed after the Effective Date that is reasonably necessary or useful for the Development or Manufacture of the Licensed Products. Except as otherwise provided under this Agreement or explicitly authorized in writing by a Party, all Know-How delivered by such Party to the other Party will remain the sole property of such Party.

Article 5.

COMMERCIALIZATION

5.1 Commercialization. AEVI will be solely responsible for all Commercialization activities relating to the Licensed Products in the Field in the Territory, and as between AEVI and KKC, AEVI will record all revenues in connection with the Commercialization of Licensed Products in the Field in the Territory. KKC will be solely responsible for all Commercialization activities relating to the Licensed Products (a) outside the Field in the Territory and (b) outside the Territory, and as between AEVI and KKC, KKC will record all revenues in connection with the Commercialization of Licensed Products (i) outside the Field in the Territory and (ii) outside the Territory. AEVI will provide reasonable consultation to KKC upon KKC's request in connection with Commercialization of the Licensed Product outside the Territory.

5.2 Commercialization Plans and Budgets. Commencing at least (***) prior to the projected First Commercial Sale of a Licensed Product in the Field in the Territory, AEVI will commence preparing a commercialization plan (each, a “**Commercialization Plan**”) for such Licensed Product in the Field in the Territory, including but not limited to marketing strategies and materials, and patient advocacy, and its planned annual budget estimating with reasonable detail Allowable Expenses expected to be incurred by AEVI in connection with the Commercialization of Profit-Share Products. No later than (***) prior to the projected First Commercial Sale of such Licensed Product in the Territory, AEVI will submit a Commercialization Plan to KKC for information only. After the launch of such Licensed Product, no later than (***) prior to the beginning of the next Contract Year, AEVI will update the Commercialization Plan for the Field in the Territory for such Licensed Product and submit such updates to KKC for information only. During the course of AEVI's initial preparation of

the Commercialization Plan and any subsequent updates, KKC may provide input on Commercialization strategies for Field for the Territory. AEVI will give reasonable consideration to KKC's input, but KKC acknowledges that AEVI has the final decision-making authority over Commercialization activities in the Field in the Territory.

5.3 Manufacturing and Supply.

5.3.1 Responsibility. AEVI will develop a manufacturing and supply strategy for the Territory. Pursuant to this strategy, AEVI will be solely responsible for operational management of Manufacturing and supplying any Licensed Product for Commercialization in the Field in the Territory.

5.3.2 Supply by AEVI. AEVI will Manufacture and supply all of KKC's requirements of Licensed Product for Commercialization and/or Development outside the Field in the Territory and outside the Territory. AEVI will supply KKC with unlabeled vialled Licensed Product for clinical trials conducted (a) outside the Territory, and (b) outside of the Field in the Territory and unlabeled vialled Licensed Product for Commercialization (i) outside the Territory or (ii) outside the Field in the Territory, in each case (***). AEVI's distribution of Licensed Product will be to a single distributor or Affiliate of KKC, as directed by KKC. AEVI will ship all Licensed Product FCA (INCOTERMS 2020) AEVI's point of destination. The Parties will use Commercially Reasonable Efforts to complete within (***). after the Effective Date a supply agreement governing the terms of such supply by AEVI to KKC containing reasonable and customary terms contained herein and those additional terms typically associated with supply of pharmaceutical products (the "**Supply Agreement**").

5.3.3 Inspection Rights. Not more than once per year, if KKC (the "**Inspecting Party**") has any reasonable concerns regarding AEVI's or its Related Parties' Manufacturing of any Licensed Products or any other reasonable necessities for inspection or audit, the Inspecting Party will have the right, at the Inspecting Party's expense and on not less than (***). prior notice, to inspect the facilities where the other Party or its Related Parties Manufacture, or have Manufactured, any Licensed Products and to audit the procedures of such other Party or its Related Parties for the Manufacturing of Licensed Products for purposes of quality control.

5.4 Medical Affairs Activities. AEVI will be solely responsible for Medical Affairs Activities with the Licensed Products in the Field in the Territory, and KKC will be solely responsible for Medical Affairs Activities with the Licensed Products outside the Territory. The applicable Party that is responsible for Medical Affairs Activities will have the exclusive right to respond to all questions or requests for information about the Licensed Products made by any medical professionals or any other Person in its respective territory and field that are beyond the scope of the Product Labels and Inserts.

5.5 Cross Territory Sales.

5.5.1 KKC Restrictions. KKC will not Commercialize or authorize the Commercialization of any Licensed Product in the Field in the Territory. KKC will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship,

consign, or otherwise transfer any Licensed Products in the Field in the Territory; provided that KKC may ship, consign, or otherwise transfer any Licensed Product inside Territory for purposes of Manufacturing the Licensed Products for Development and Commercialization of the Licensed Products outside Territory or outside the Field in the Territory. KKC will use Commercially Reasonable Efforts to ensure that Licensed Products sold by or on behalf of KKC outside the Territory are not Commercialized in the Field in the Territory, including use via re-importation from a country or jurisdiction outside the Territory. Without limiting the generality of the foregoing, KKC will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product in the Field in the Territory. KKC will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of KKC's contracts with any of the foregoing.

5.5.2 AEVI Restrictions. AEVI will not Commercialize or authorize the Commercialization of any Licensed Product outside the Territory or outside the Field in the Territory. AEVI will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Licensed Product outside the Territory or outside the Field in the Territory; provided that AEVI may ship, consign, or otherwise transfer any Licensed Product outside the Territory for purposes of Manufacturing the Licensed Products and/or Developing the Licensed Products for Commercialization in the Field in the Territory. AEVI will use Commercially Reasonable Efforts to ensure that Licensed Products sold by or on behalf of AEVI in the Territory are not Commercialized outside the Territory. Without limiting the generality of the foregoing, AEVI will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product outside the Field in the Territory or facilitate the use of such Licensed Product outside the Territory. AEVI will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of AEVI's contracts with any of the foregoing.

Article 6.

DILIGENCE

6.1 Diligence in Development.

6.1.1 Generally. AEVI will use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in the Territory (both in United States and in the European Union, subject, with respect to Canada, to Section 6.1.2) and to obtain Regulatory Approvals for the Licensed Product in the Field in the Territory (subject, with respect to Canada, to Section 6.1.2). Subject to Section 6.1.2, if, with respect to any country in the Territory or the European Union, AEVI (a) does not (**), or (b) (**) files a Regulatory Approval Application but does not obtain Regulatory Approval and no additional clinical Development or Manufacturing activities are being conducted (**), then KKC will have the right to terminate this Agreement with respect to such country. For the avoidance of doubt, the filing of a Regulatory Approval

Application with the EMA is considered a filing of a Regulatory Approval Application in all countries of the European Union.

6.1.2 Canada. With respect to Canada, the Parties will discuss Development of a Licensed Product in the Field in Canada at an appropriate time after Development of the Licensed Product for the initial indication in the Field in the Territory and the European Union is substantially advanced. Such discussion should take place no later than when AEVI decides to file the first Regulatory Approval Application for the Licensed Products in the Field in the United States, following the data readout of the Phase 3 Clinical Trial. If the Parties unanimously agree not to proceed with the Development of a Licensed Product in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, then AEVI will not be required to use Commercially Reasonable Efforts to Develop a Licensed Product and to obtain Regulatory Approvals for the Licensed Product in the Field in Canada. If AEVI elects not to proceed with the Development of a Licensed Product in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, and KKC does not agree to the foregoing, then KKC may terminate this Agreement pursuant to Section 11.2.3 solely with respect to Canada, and AEVI will not be required to use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in Canada and to obtain Regulatory Approvals for the Licensed Product in the Field in Canada.

6.2 Diligence in Commercialization. AEVI will use Commercially Reasonable Efforts to Commercialize each Licensed Product in the United States and Canada after Regulatory Approval is obtained in such country, including identifying and committing sufficient resources for pre-launch, launch and subsequent Commercialization activities. AEVI will use Commercially Reasonable Efforts to Commercialize each Licensed Product in the United Kingdom, France, Germany, Spain, and Italy (“**EU5 Countries**”); provided that Regulatory Approval is obtained for such country, including identifying and committing sufficient resources for pre-launch, launch and subsequent Commercialization activities. Both Parties acknowledge and agree that there may be cases that AEVI may use Commercially Reasonable Efforts and choose not to Commercialize the Licensed Product in some of the EU5 Countries due to reimbursement pricing or for some other reasons, and in such cases AEVI will not be liable for a breach of the diligence obligation set forth in this Section 6.2 in respect of such country.

6.3 Reports. On a semiannual basis but not later than June 30 and December 31 of each Contract Year, AEVI will provide to KKC a written report summarizing its (a) Development (including the status of any Regulatory Approval process) activities in the Territory and (b) Commercialization activities with respect to the Licensed Products in the Territory on a Licensed Product-by-Licensed Product and country-by-country basis during the just-ended semiannual period.

Article 7.

LICENSES

7.1 License Grants to AEVI. Subject to the terms and conditions of this Agreement, KKC grants to AEVI, under the KKC Technology, an exclusive, non-transferable (except in

accordance with Section 13.3) license, with the right to grant sublicenses solely as provided in Section 7.4, to:

7.1.1 Develop Licensed Products in the Field in the Territory;

7.1.2 Manufacture or have Manufactured (subject to Sections 7.4.4 and 7.6) Licensed Products; and

7.1.3 use, offer for sale, sell, have sold and otherwise Commercialize Licensed Products in the Field in the Territory; in each of clause (i), (ii), and (iii) in accordance with this Agreement.

7.2 License Grants to KKC. Subject to the terms and conditions of this Agreement, AEVI grants KKC, under the AEVI Technology, a non-exclusive license, royalty-free (except as to the AEVI In-License as set forth in Section 8.6.4(b)) license, with the right to sublicense solely as provided in Section 7.4, to:

7.2.1 Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized Licensed Products outside the Field in the Territory and in any and all fields outside the Territory; and

7.2.2 Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized any diagnostic product that is reasonably necessary or useful in connection with the Manufacture, use, offer for sale, and/or sale of the Licensed Product outside the Field in the Territory and in any and all fields outside the Territory.

7.3 Rights of Reference. Each Party hereby grants to the other Party the right to reference any and all Regulatory Approval Applications and Regulatory Approvals filed or obtained by the other Party in respect of a Licensed Product solely for use in connection with exercising such Party's rights under Section 7.1 or 7.2, as applicable.

7.4 Sublicenses.

7.4.1 Right to Sublicense. AEVI may not sublicense the rights granted to it under Section 7.1 to its Related Parties or Third Parties without the prior written consent of KKC, which consent will not be unreasonably withheld, conditioned or delayed. KKC may not sublicense the rights granted to it under Section 7.2 to its Related Parties or Third Parties without the prior written consent of AEVI, which consent will not be unreasonably withheld, conditioned or delayed. The sublicensing Party will remain responsible for the performance of its sublicensees under this Agreement, including for all payments due hereunder. The sublicensing Party will provide the other Party with notice of each sublicense granting rights to Commercialize Licensed Products promptly after execution of such sublicense. In addition, each Party will provide a copy of any such sublicense to the other Party after execution of such sublicense. All such notices of sublicenses provided by the sublicensing Party under this Section 7.4.1 will be deemed to be Confidential Information of the sublicensing Party subject to the

provisions of Article 10 whether or not so marked. AEVI acknowledges and agrees that sublicensing of Manufacturing rights to, or subcontracting Manufacturing activities with respect to, the Licensed Product, and the right for using any Patent Rights, Know-How, inventions, or other intellectual property owned or controlled by Sanofi or Lonza and licensed to KKC may be subject to Sanofi's or Lonza's written consent, respectively. (***) for nominal consideration to the extent reasonably necessary or useful for the Manufacture of Licensed Products (**).

7.4.2 Terms. Each sublicense granted by a Party pursuant to Section 7.4.1 will be subject and subordinate to the terms and conditions of this Agreement and will contain terms and conditions consistent with those in this Agreement. Agreements with any sublicensee that include the right to Commercialize any Licensed Product(s) will contain the following provisions: (a) the requirement set forth in Section 8.6.4(c); and (b) a requirement that such sublicensee comply with the confidentiality and non-use provisions of Article 10 with respect to both Parties' Confidential Information.

7.4.3 Effect of Termination on Sublicenses. If this Agreement terminates for any reason, each Party agrees to use Commercially Reasonable Efforts to enter into direct licenses with the other Party's sublicensees; provided that the sublicensee is not in breach of its sublicense agreement and such sublicensee agrees to comply with all of the terms of this Agreement to the extent applicable from the rights originally sublicensed to it by the sublicensing Party.

7.4.4 Subcontracting. The Parties will be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development activities; provided that each Party will remain at all times fully liable for its respective responsibilities under each Development Plan and this Agreement. Any agreement with a Third Party to perform a Party's responsibilities under this Agreement will include confidentiality and non-use provisions which are no less stringent than those set forth in Article 10 and intellectual property provisions that will allow such Party to comply with Article 9. Notwithstanding the foregoing, AEVI will not have the right to have the Licensed Product Manufactured by any Third Party without the prior written consent of KKC, which consent will not be unreasonably withheld, conditioned or delayed.

7.5 Exclusivity. Until expiration of all Data Exclusivity Periods for the Licensed Product in a jurisdiction in the Territory, AEVI and its Affiliates will not Commercialize, directly or indirectly, or in-license or otherwise acquire any product that is a Competing Product in the Field in such jurisdiction; provided, however, if AEVI or its Affiliates obtains such a Competing Product through a Change of Control or other acquisition or merger with, a Third Party, then AEVI or its Affiliate will have a period of (**), or such longer period as may be reasonable under the circumstances provided that AEVI or its Affiliate (**). KKC has the right to Develop, Manufacture or Commercialize, directly or indirectly, or in-license or otherwise acquire any product that is a Competing Product.

7.6 In-Licenses.

7.6.1 KKC In-Licenses. All licenses and other rights granted to AEVI by KKC under this Article 7 are subject to the rights and obligations of KKC under the KKC In-Licenses. For the avoidance of doubt, if KKC Controls only a non-exclusive license under a KKC In-License, KKC's grant of exclusive license rights pursuant to Section 7.1 means that KKC and its Affiliates will not exercise and will not sublicense such rights with respect to Licensed Products in the Field in the Territory. AEVI and its Related Parties, and the applicable rights and licenses granted to AEVI hereunder, shall be subject to the rights retained, and obligations imposed, by the US government pursuant to the Bayh-Dole Act, Chapter 18 of Title 35 of the United States Code, Sections 200-212 with respect to the KKC Patent Rights solely owned by LJI. AEVI agrees to be bound by the pertinent sections of Section 1 of, and Sections 2.2, 2.3, 2.4, 2.5, 3.1, 5.3, 7.3, 7.4, 7.6, 7.9, 8.4, 8.5, 8.6, 10.4, 10.5, 10.6, 11.1, 12.6, 12.7 and 12.10 of, the LJI Agreement to the same extent that KKC is bound thereby.

7.6.2 AEVI In-Licenses. All licenses and other rights granted to KKC by AEVI under this Article 7 are subject to the rights and obligations under the AEVI In-License. KKC and its Related Parties, and the applicable rights and licenses granted to KKC hereunder, shall be subject to the rights retained, and obligations imposed, by the US government pursuant to the Bayh-Dole Act, Chapter 18 of Title 35 of the United States Code, Sections 200-212 with respect to the AEVI Patent Rights described in clause (a) of Section 1.10. KKC agrees to be bound by the pertinent sections of Sections 2, 3.6, 8.1, 9.2 and 12.3 of the AEVI In-License to the same extent that AEVI is bound thereby. In addition, the sublicense to KKC of the AEVI Technology licensed to AEVI under the AEVI In-License automatically terminates if and to the extent of termination of the AEVI In-License, subject to the right of KKC to request a direct license from CHOP.

7.7 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party, as a result of this Agreement, obtain any ownership interest or other right in any intellectual property rights of the other Party, including items Controlled or developed by the other Party, or provided by the other Party to such Party at any time pursuant to this Agreement. Unless expressly provided otherwise in this Agreement, KKC will retain all rights (including but not limited to Development and Commercialization rights) to the Licensed Products outside the Territory and outside the Field in the Territory.

Article 8.

FINANCIAL PROVISIONS

8.1 Initial License Fee. Within (***) after the Effective Date, AEVI will pay to KKC an initial license fee of (***)

8.2 Development Costs.

(a) The responsibility for payment of the Development Costs incurred during the Term will be borne solely by AEVI, and, for clarity, none of such costs will be included in Allowable Expenses.

(b) Development Costs will not include any Manufacturing-related development costs, including but not limited to the process and analytical method developments, the comparability studies, stability program, process characterization and validation, method qualifications and validations, or the cost incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development in the Territory, which costs will be borne solely by AEVI pursuant to Section 4.3.3, and, for clarity, none of such costs will be included in Allowable Expenses. All payments made by a Party to a Third Party in connection with the performance of its activities under the applicable Development Plan will be charged as Development Costs at such Party's actual Out-of-Pocket Costs.

8.3 Milestones.

8.3.1 Milestone Payments. AEVI will pay to KKC the amounts set forth below no later than (***) after the earliest date on which AEVI or any of its Related Parties receives written notification that the corresponding milestone event has first been achieved with respect to a Licensed Product:

<u>Milestone Event</u>	<u>Payment</u>
(**) for a Licensed Product by AEVI or its Related Party	(**\$)**
(**) for a Licensed Product by AEVI or its Related Party	(**\$)**
(**) for a Licensed Product filed with FDA by AEVI or its Related Party	(**\$)**
(**) for a Licensed Product filed with EMA by AEVI or its Related Party	(**\$)**

8.3.2 One Time Milestone Payments. Once AEVI has made any particular milestone payment under Section 8.3.1, AEVI will not be obligated to make any payment under Section 8.3.1 with respect to the re-occurrence of the same milestone, whether or not such re-occurrence is with respect to a different or the same Licensed Product.

8.4 Sharing of Profit.

8.4.1 Allocation. Profit will be allocated (**) to AEVI and (**) to KKC.

8.4.2 Reconciliation. From and after the First Commercial Sale of a Licensed Product in the Field in the Territory, the Parties will conduct a quarterly reconciliation of Profit as follows:

(a) Within (**) after the end of each Contract Quarter, AEVI will submit to KKC a preliminary written report setting forth the following information, estimated where necessary, revenues and expenses included in Profit for Profit-Share Products for the first two (2) months of such Contract Quarter, including, as applicable:

(i) all sales in units and in Net Sales value of such Profit-Share Products in the Territory made by AEVI and its Related Parties during such two (2) month period, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such two (2) month period;

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to such Profit-Share Products during such two (2) month period; and

(iv) good faith estimate of revenues and expenses included in Profit for Profit-Share Products for the last month of such Contract Quarter, for financial reporting purposes.

(b) Within (***) after the end of each Contract Quarter, AEVI will submit to KKC a final written report setting forth, as applicable:

(i) all sales in units and in Net Sales value of Profit-Share Products in the Territory made by AEVI and its Related Parties during such Contract Quarter, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such Contract Quarter; and

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to Profit-Share Products during such Contract Quarter.

8.4.3 Tax Reporting. Together with the report submitted by AEVI pursuant to Section 8.4.2(b), AEVI will submit to KKC the calculation of Profit, the amount of any taxes required to be withheld and the calculation of the net amount owed by AEVI to KKC in order to ensure the sharing of Profit set forth in Section 8.4.1 and the proper allocation of withholding taxes pursuant to Section 8.6.1. The net amount payable with respect to Profit, after appropriate adjustment for any withholding taxes, will be paid by AEVI within (***) following receipt of invoice for such amount.

8.4.4 Supporting Documents. In addition to providing the information set forth in Section 8.4.2, AEVI will provide reasonable supporting documentation of Allowable Expenses included in the calculation of Profit.

8.5 KKC Royalties.

8.5.1 Royalty Percentages. During the Term, but subject to any applicable offsets contained herein, KKC will pay to AEVI royalties on Royalty-Bearing Sales or Sublicensing Royalties, as applicable, on a country-by-country basis, subject to any applicable offsets or reductions pursuant to Section 8.5.2, 8.5.3, and/or 8.5.4, at the rate of: (a) (***) (the “***KKC Territory Royalty Rate***”) of (i) Royalty-Bearing Sales by KKC and its Affiliates in the Field outside of the Territory and (ii) Sublicensing Royalties resulting from sales in the Field outside of the Territory; (b) (***) (the “***Other Royalty Rate***”) of Royalty-Bearing Sales by KKC and/or its Affiliates outside of the Field outside of the Territory and Sublicensing Royalties resulting from sales outside of the Field outside of the Territory; and (c) (***) (as adjusted, if applicable,

pursuant to the following sentence, the “***Territory Royalty Rate***”) of Royalty-Bearing Sales by KKC and its Affiliates in the Territory and Sublicensing Royalties resulting from sales in the Territory. In the event that AEVI’s Net Sales of Licensed Products in a country in the Territory experience a Significant Impact as a result of KKC or any of its Related Parties commercializing Licensed Product in the Territory, the Parties will negotiate in good faith to increase the Territory Royalty Rate for such country to offset the Significant Impact, which Territory Royalty Rate will not exceed (***) in any country.

8.5.2 Third Party License Offsets. If KKC enters into an agreement with a Third Party (other than a KKC Licensor) to obtain a license under Third Party Technology (including without limitation under Section 9.5) that KKC reasonably believes or expects to be necessary to Commercialize one or more Licensed Products outside the Territory or outside of the Field, then KKC may offset (***) of the amount of commercially reasonable royalties or other payments payable by KKC to such Third Party with respect to a particular Licensed Product against amounts KKC is obligated to pay AEVI under Section 8.5.1 for Royalty-Bearing Sales by KKC and/or its Affiliates and Sublicensing Royalties, provided that in no event will any such offset (a) with respect to sales in the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(a) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field outside of the Territory, (b) with respect to sales outside the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(b) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties outside the Field outside of the Territory, or (c) with respect to sales in the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(c) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Territory; provided further that, if such (***) offset of such Third Party royalties or other payments exceeds the amount of payments withheld by KKC under this Section 8.5.2 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.3 Claimed Infringement of Third Party Rights Offsets. If costs and expenses and damages are incurred by the Parties in connection with the defense of an Infringement Claim outside the Field or outside the Territory pursuant to Section 9.4, then KKC may offset (***) of such costs and expenses and damages with respect to a particular Licensed Product against amounts KKC is obligated to pay AEVI under Sections 8.5.1 and 8.5.2 on sales of such Licensed Product, provided that in no event will any such offset (a) with respect to sales in the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(a) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Field outside of the Territory, (b) with respect to sales outside the Field outside of the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(b) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties outside the Field outside of the Territory, or (c) with respect to sales in the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(c) in particular Contract Years below (***) of Royalty-Bearing Sales and Sublicensing Royalties in the Territory; provided further that, if such (***) offset of such costs and expenses and damages incurred by the Parties exceeds the amount

of payments withheld by KKC under this Section 8.5.3 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.4 Royalty Reduction for Biosimilars.

(a) If a Biosimilar version(s) of any Licensed Product is commercialized in any country in which there are Royalty-Bearing Sales, then the royalty rate payable to AEVI pursuant to Sections 8.5.1, 8.5.2 and 8.5.3 applicable for the sale of Licensed Products in such country will be reduced by (i) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is (***) in such country, (ii) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is (***) in such country, (iii) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is (***) in such country, (iv) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is (***) in such country; and (v) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is (***) in such country. For clarity, the reduction in royalty rates permitted pursuant to this Section 8.5.4 will be taken after any reduction taken pursuant to Section 8.5.2 and Section 8.5.3. For the avoidance of doubt, each of the minimum KKC Territory Royalty Rate and the minimum Other Royalty Rate will be (***) and the minimum Territory Royalty Rate (on a country-by-country basis) will be no less than (***) of the Territory Royalty Rate (on a country-by-country basis) then in-effect prior to the adjustments permitted by this Section 8.5.4; provided that, if such reduction permitted under this Section 8.5.4 exceeds the amount of payments withheld by KKC under this Section 8.5.4 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

(b) The Parties will utilize a mutually-agreed (such agreement not to be unreasonably withheld, delayed, or conditioned) measure of the market share of any relevant Biosimilars in each country where a Biosimilar version(s) of a Licensed Product is being commercialized and will adjust the royalty rate payable to AEVI for the sale of Licensed Products in such country every six (6) months, to the extent permitted pursuant to Section 8.5.4(a). If the royalty rate payable to AEVI for the sale of Licensed Products has been adjusted pursuant to Section 8.5.4(a), then such royalty rates in such country may not thereafter be adjusted upwards.

8.5.5 Reports and Royalty Payments. Within (***) after the end of each Contract Quarter during the Term, KKC will deliver to AEVI a report setting forth for the previous Contract Quarter the following information on a Licensed Product-by-Licensed Product and country-by-country basis: (a) the gross sales and Royalty-Bearing Sales of each Licensed Product, (b) the number of units sold by KKC or its Affiliate, (c) the Sublicensing Royalty received by KKC, (d) the basis for any adjustments to the royalty payable for the sale of each Licensed Product, (e) the royalty due hereunder for the sales of each Licensed Product, and (f) the applicable exchange rate as determined pursuant to Section 8.6.2. The total royalty due for the sale of Licensed Products during such Contract Quarter will be remitted at the time such report is made but no later than (***) after the end of each Contract Quarter during the Term.

Along with such reports, KKC will also provide the Sales Tracking Methodologies used to determine Royalty-Bearing Sales outside the Field in the Territory.

8.6 Payment Provisions Generally.

8.6.1 Taxes and Withholding. If Applicable Laws require withholding of income taxes or other taxes imposed upon payments set forth in Article 8, the paying Party will make such withholding payments as required and subtract such withholding payments from the payments set forth in Article 8. The paying Party will submit appropriate proof of payment of the withholding taxes to the payee Party within a reasonable period of time. At the request of the payee Party, the paying Party will, at the payee Party's cost, give the payee Party such reasonable assistance, which will include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable the payee Party to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and will upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.

8.6.2 Payment and Currency Exchange. All amounts payable and calculations hereunder will be in United States dollars and will be paid by bank wire transfer in immediately available funds to such bank account as may be designated in writing by the payee Party from time to time. Whenever for the purposes of calculating the Profit or royalties payable under Section 8.4 or 8.5, conversion from any foreign currency will be required, all amounts will first be calculated in the currency in which the activity was paid or sale was recorded and then converted into United States dollars by applying the rate of exchange quoted in the New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter.

8.6.3 Overdue Payments. If any payment due under this Agreement (other than payments that are the subject of a good faith dispute between the Parties) is overdue by more than thirty (30) days, the paying Party will pay interest to the payee Party at a rate per annum equal to the lesser of the prime rate of interest, as reported by New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter, or the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due.

8.6.4 Financial Matters Relating to Existing In-Licenses.

(a) All amounts payable in respect of Profit-Share Products under the KKC In-Licenses will be paid directly by KKC or its Related Parties to the KKC Licensor, AEVI will reimburse KKC such amounts as defined in Section 1.87(a), and any such amounts reimbursed by AEVI will be treated as Allowable Expenses.

(b) All amounts payable in respect of Profit-Share Products under AEVI In-Licenses will be paid directly by AEVI or its Related Parties to the applicable AEVI Licensor and such amounts as defined in Section 1.87(b) will be treated as Allowable Expenses to the extent paid by AEVI or any of its Related Parties. All amounts required to be paid pursuant to

Section 6.4.1 of the AEVI In-License as a direct result of sales of any Licensed Product sold by KKC or its Related Parties will be paid and borne solely by KKC and its Related Parties. In addition, all amounts required to be paid pursuant to Section 6.4.2 of the AEVI In-License as a direct result of sales of any diagnostic sold by KKC or its Related Parties will be paid and borne solely by KKC and its Related Parties and will not be a part of Third Party Technology Costs described in Section 1.87(b). For avoidance of doubt, all amounts required to be paid pursuant to Section 6.4.2 of the AEVI In-License as a direct result of sales of any diagnostic sold by AEVI or its Related Parties will be paid and borne solely by AEVI and its Related Parties and will not be a part of Third Party Technology Costs described in Section 1.87(b).

(c) (**), for the supply of the Licensed Product, and the entry into such contract triggers any payment obligation by KKC to Lonza, then AEVI will reimburse KKC (**), provided that any such reimbursement obligations of AEVI will not exceed (**). Such payment to Lonza will be first payable within (**) of signature of a manufacturing agreement with such Third Party or grant of sublicense to such contract manufacturer and will continue for the duration of such manufacture by such Third Party or sublicense. No payment made by AEVI under this Section 8.6.4(c) will be included in Allowable Expenses.

(d) Notwithstanding anything to the contrary in Section 8.6.4(c), if AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date, AEVI may deduct (**) from the initial license fee and milestone payments payable to KKC by AEVI under Sections 8.1 and 8.3, (**).

(e) If AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date and AEVI has an obligation to pay an annual fee to Lonza pursuant to such agreement for conducting the process development or Manufacture of the Licensed Product using a contract manufacturer that is not Lonza, as between the Parties, AEVI will (**). For clarity, no portion of (**) will be subject to the deduction set forth in Section 8.6.4(d) or will be included in Allowable Expenses.

8.6.5 Record-Keeping. Each Party will keep, and will cause their respective Related Parties to keep, books and accounts of record in connection this Agreement in sufficient detail to permit accurate determination of all figures necessary for any and all financial calculations required by this Agreement, including without limitation all elements of Allowable Expense, Developments Costs, Net Sales, Royalty-Bearing Sales, and Profit. Each Party will maintain, and will cause their respective Related Parties to maintain, such records for a period of at least five (5) years after the end of the Contract Year in which they were generated.

8.6.6 Audits. Upon thirty (30) days' prior written notice from a Party (the "**Requesting Party**"), the Party receiving the written notice (the "**Audited Party**") will permit an independent certified public accounting firm of nationally recognized standing selected by the Requesting Party and reasonably acceptable to the Audited Party, to examine, at the Requesting Party's sole expense, the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the amounts reporting or payable by the Audited Party to the Requesting Party. An examination by a Requesting Party under this Section 8.6.6 will occur not more than once in any Contract Year and will be limited to the pertinent books and records

for any Contract Year ended not more than five (5) years before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination will be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm will provide both the Audited Party and the Requesting Party a written report disclosing any discrepancies in the reports submitted by the Audited Party or, as applicable, the amounts payable under this Agreement, and in each case, the specific details concerning any discrepancies. No other information will be provided to the Requesting Party.

8.6.7 Underpayments/Overpayments. If such accounting firm concludes that additional amounts were due to the Requesting Party, the Audited Party will make such payments as is necessary for the Requesting Party to have been paid the correct amount due under this Agreement for the audited periods. If such underpayment exceeds five percent (5%) of the amounts that were to be paid, the Audited Party also will reimburse the Requesting Party for all Out-of-Pocket Costs incurred in conducting the audit. If such accounting firm correctly concludes that the Audited Party overpaid amounts due to the Requesting Party, the Requesting Party will refund such overpayments to the Audited Party within sixty (60) days of the date the Requesting Party receives such accountant's report so correctly concluding.

8.6.8 Confidentiality. All financial information of a Party that is subject to review under this Section 8.6 will be deemed to be Confidential Information of such Audited Party subject to the provisions of Article 10, and the Requesting Party will not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than verifying payments to be made by the Audited Party to the Requesting Party hereunder.

8.7 Adjustment of FTE Rates. Effective upon each anniversary of the Effective Date, the FTE Rates will increase by the percentage increase, if any, in the Consumer Price Index published by the United States Bureau of Labor Statistics during the most recent preceding one (1) year period for which final data is available, and such increase will be effective for the then-current and all subsequent FTE Costs hereunder unless and until further modified under this Section 8.7. In addition, within sixty (60) days after the third anniversary of the Effective Date and every three (3) years thereafter, each Party will have the right to require the other Party to conduct a salary survey in respect of FTEs and provide the result of such survey. In addition, a Party may conduct a salary survey at its own discretion in respect of FTEs and provide such survey to the other Party. Following receipt of such survey from each Party, the Parties may agree in writing to adjust one or more of the FTE Rates.

Article 9.

INTELLECTUAL PROPERTY

9.1 Ownership of and Rights to Intellectual Property

9.1.1 AEVI Technology. As between the Parties, AEVI is and will remain the sole owner of the AEVI Technology. KKC acknowledges that certain of the AEVI Patent Rights have been licensed to AEVI from the AEVI Licensor pursuant to the AEVI In-License.

9.1.2 KKC Technology. As between the Parties, KKC is and will remain the sole owner of the KKC Technology. AEVI acknowledges that certain of the KKC Patent Rights have been licensed to KKC from the KKC Licensors pursuant to the KKC In-Licenses.

9.1.3 Joint Inventions. The Parties will jointly own all Joint Inventions, and each will have an undivided interest in the Joint Inventions subject to the licenses granted under this Agreement.

9.1.4 Inventorship. For purposes of determining whether an invention is solely invented by AEVI or solely invented by KKC, or a Joint Invention, questions of inventorship will be resolved in accordance with United States patent laws.

9.2 Filing, Prosecution and Maintenance of Patent Rights

9.2.1 KKC Patent Rights. This Section 9.2 will not apply to the KKC Patent Rights over which KKC has no right to control the filing, prosecution or maintenance thereof, and, for purposes of this Section 9.2, the KKC Patent Rights over which KKC has the right to control the filing, prosecution and maintenance thereof, including those described in clauses (a) and (c) of Section 1.54, but excluding those described in clause (b) of Section 1.54, are referred to as the “***KKC Managed Patent Rights***.”

(a) As between KKC and AEVI, KKC, through counsel of its choosing, will control (but not be obligated to control) the prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of the KKC Patent Rights in the Territory. AEVI will provide all reasonable assistance required to prosecute the KKC Patent Rights in the Territory. AEVI will have the right to review and comment upon any substantive communications received from the applicable patent offices with respect to the KKC Managed Patent Rights, including, but not limited to, official actions, examination reports, documents relating to patentability and/or amendment or cancellation of the claims, and documents related to patent term adjustment and patent term extension. KKC will consider all comments received from AEVI with respect to the KKC Managed Patent Rights and will comply with all reasonable requests. In addition, AEVI will have the right to review and comment upon any substantive communications that KKC plans to make to an applicable patent office in the Territory with respect to the KKC Managed Patent Rights, including, but not limited to, draft responses to official actions, draft responses to examination reports, drafts relating to amendment or cancellation of the claims, and drafts relating to patent term adjustment and/or extension. KKC will provide AEVI with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. KKC will consider all comments received from AEVI and will comply with all reasonable requests. In addition to the above, KKC will keep AEVI reasonably informed with respect to all such prosecution and

maintenance activities to which KKC has access, including written communications with patent office officials, and consult with AEVI regarding such matters, including the planned abandonment of claims thereof.

(b) At AEVI's sole cost and expense, KKC will keep AEVI reasonably informed with respect to all prosecution and maintenance activities concerning Patent Rights outside the Territory that correspond to the KKC Patent Rights. AEVI will have the right to review any substantive communications received from the applicable patent offices with respect to the KKC Managed Patent Rights, including, but not limited to, official actions, examination reports, documents relating to patentability and/or amendment or cancellation of the claims, and documents related to patent term adjustment and patent term extension. In addition, AEVI will have the right to review any substantive communications that KKC plans to make to an applicable patent office outside of the Territory with respect to the KKC Managed Patent Rights, including, but not limited to, draft responses to official actions, draft responses to examination reports, drafts relating to amendment or cancellation of the claims, and drafts relating to patent term adjustment and/or extension.

(c) If KKC determines in its sole discretion to abandon or not maintain any KKC Managed Patent Rights, in one or more country(ies) or in the entire Territory, then KKC will provide AEVI with at least sixty (60) days prior written notice of such determination to abandon or cease maintenance (or such other longer period of time reasonably necessary to allow AEVI to assume such responsibilities). If KKC provides such a notification, then AEVI will have the right (but not the obligation), to control the prosecution and maintenance of any such KKC Managed Patent Rights in its sole discretion and at AEVI's sole cost and expense by providing KKC with notice thereof within such sixty (60) day period. In the event that AEVI so elects to control the prosecution and maintenance of any KKC Managed Patent Rights, then in the concerned country(ies) or in the entire Territory, as applicable, KKC will provide all reasonable assistance required to prosecute such KKC Managed Patent Rights in the concerned country(ies) or in the entire Territory, at AEVI's sole cost and expense, including allowing AEVI to exercise all rights of KKC under the KKC In-License with LJI relevant to prosecution and maintenance of the KKC Managed Patent Rights. KKC will have the right to review and comment upon any substantive communications and filings made by AEVI with respect to the prosecution of such KKC Managed Patent Rights before they are sent to any patent offices in the entire Territory. AEVI will provide KKC with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. With respect to all such prosecution and maintenance AEVI will keep KKC reasonably informed with respect to such activities (including by providing KKC with access to all filings and correspondence with and from any patent offices or officials upon request by KKC), and consult with KKC regarding such matters, including the abandonment of claims thereof

(d) Notwithstanding anything to the contrary in this Agreement (including [Section 9.3.1\(a\)](#)), the following terms and conditions will apply with respect to the KKC Patent Rights: (i) with respect to those KKC Patent Rights solely owned by LJI, LJI and KKC will have the joint right to control the filing, prosecution and maintenance of such KKC Patent Rights, including the extension of the patent term(s) of such KKC Patent Rights, and if both LJI and

KKC determine in their sole discretion to abandon or not maintain such KKC Patent Rights, then AEVI will have the right, subject to Section 9.3.1(a) and the other applicable terms and conditions of this Agreement, to control the prosecution and maintenance of any such KKC Patent(s) and KKC will request LJI to provide all reasonable assistance required to prosecute and maintain such KKC Patent Rights; and (ii) with respect to those KKC Patent Rights jointly owned by LJI, on the one hand, and KKC and/or its Affiliates, on the other hand, in the event that both KKC and AEVI determine in their sole discretion to abandon or not maintain any such KKC Patent(s), then (A) LJI will have the right to control the filing, prosecution and maintenance (including, without limitation, the extension of the patent term(s)) of such KKC Patents, and (B) all rights and licenses granted to KKC under the LJI Agreement (and therefore the sublicense to AEVI under this Agreement) in and to such KKC Patent(s) will immediately terminate.

(e) Notwithstanding anything to the contrary in this Agreement, to the extent that KKC does not have the right to control or participate in the prosecution or maintenance of Patent Rights under a KKC In-License, no right to prosecute or maintain such Patent Rights are granted to AEVI by this Agreement.

(f) All information, if any, exchanged between the Parties or between KKC's outside patent counsel and AEVI regarding preparation, filing, prosecution or maintenance of the KKC Patent Rights will be deemed Confidential Information of KKC. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution and maintenance of the KKC Patent Rights, the interests of the Parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the KKC Patent Rights including without limitation, privilege under the common interest doctrine and similar or related doctrines.

9.2.2 Joint Inventions. With respect to any potentially patentable Joint Invention, the Parties will meet and agree upon which Party will lead (in a joint effort with the other Party) the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of patent applications covering such Joint Invention (any such patent application and any patents issuing therefrom a "**Joint Patent**") in any jurisdiction. Joint Patents are included within both the KKC Technology and AEVI Technology and within the licenses granted to each Party hereunder. The Party that leads prosecution of a patent application in the Joint Patents (the "**Prosecuting Party**") will provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patents in the particular jurisdictions, and such other Party will provide the Prosecuting Party reasonable assistance in such efforts, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. The Prosecuting Party will provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and will provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the

other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party will no longer be obligated to pay any costs for filing, prosecution or maintenance thereof; (ii) the disclaiming Party will, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration and (iii) if such assignment is effected, any such Joint Patent would thereafter be deemed a patent of AEVI in the case of assignment to AEVI, or a patent of KKC in the case of assignment to KKC.

9.2.3 New Inventions. AEVI will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all AEVI Inventions, and KKC will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all KKC Inventions. All the foregoing will be included in the license granted by each Party to the other Party in Article 7. Each Party will disclose any such inventions or improvements to the other Party within (***) of filing a patent application claiming the Invention.

9.2.4 Cooperation. Each Party hereby agrees: (a) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution as contemplated by this Agreement; (b) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights that are subject to this Agreement; and (c) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the prosecution and maintenance of the other Party's patent applications that are subject to this Agreement.

9.2.5 Patent Costs. KKC will bear all of the costs and expenses of filing, prosecuting and maintaining the KKC Patent Rights, and AEVI will bear all of the costs and expenses of filing, prosecuting and maintaining the AEVI Patent Rights described in clause (a) of Section 1.10. The costs and expenses of filing, prosecuting and maintaining the Joint Patents shall be borne solely by AEVI for costs and expenses incurred inside the Territory, and shall be borne solely by KKC for costs and expenses incurred outside the Territory. For clarity, costs and expenses outside of the Territory will be borne solely by KKC for the KKC Patent Rights and solely by AEVI for the AEVI Patent Rights.

9.3 Enforcement of Patent Rights

9.3.1 Notification. Each Party will promptly report in writing to the other Party during the Term any (a) known or suspected infringement by a Third Party of any KKC Patent Rights, AEVI Patent Rights or Patent Rights covering Joint Inventions or (b) unauthorized use or misappropriation by a Third Party of any Confidential Information, including KKC Know-How or AEVI Know-How, of which it becomes aware, and will provide the other Party with all available evidence supporting such infringement or unauthorized use or misappropriation.

9.3.2 Rights to Enforce. KKC will have the right, but not the obligation, to take any reasonable measures it deems appropriate to: (a) stop infringing activities described in Section 9.3.1 in respect of the KKC Technology in the Territory including initiating or prosecuting an infringement or other appropriate suit or action against the alleged infringer, but not granting adequate rights and licenses necessary for continuing such activities by the alleged infringer or (b) defend the KKC Technology in the Territory against any declaratory judgment, opposition, patentability or invalidity actions (“**Defensive Actions**”). KKC may request that AEVI grant such adequate rights and licenses; provided that AEVI will have no obligation to grant any such rights or licenses; and provided further that upon making such request, AEVI will have the right to participate in all negotiations with the alleged infringer concerning such adequate rights and licenses. Before KKC takes any action to stop the infringing activity against an alleged infringer of the KKC Technology in the Territory, KKC will consult in good faith with AEVI concerning the alleged infringement, including selection of counsel, litigation strategy, litigation risks, the damage being caused to KKC and/or AEVI and any other matter relevant to enforcement of the KKC Technology against the alleged infringer in the Territory. In particular, KKC will consider in good faith a request from AEVI to not take any actions to enforce the KKC Technology against the alleged infringer in the Territory and only take such actions, in light of such request from AEVI, if KKC is suffering material harm from the infringement in the Territory. Subject to the provisions of the LJI Agreement, in the event that KKC elects to not take action or cease action with respect to the KKC Managed Patent Rights pursuant to this Section 9.3.2 with respect to the Territory, including declining or ceasing to defend Defensive Actions, KKC will so notify AEVI in writing of its intention (***) prior to any deadlines by which an action must be taken to establish, preserve or maintain any enforcement rights or defend or continue to defend the Defensive Action, and, subject to Section 9.3.4, AEVI will have the right, but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer or defend the Defensive Action, in which event, upon AEVI’s request, KKC will exercise its rights under the LJI Agreement to the extent necessary for the enforcement or defense of KKC Managed Patent Rights that are subject to the LJI Agreement.

9.3.3 Procedures; Expenses and Recoveries. The Party having the right to initiate any infringement suit or defend a Defensive Action under Section 9.3.2 (the “**Controlling Party**”) will have the sole and exclusive right to select counsel for and control any such suit or Defensive Action. The expenses of the suit or the Defensive Action, including attorneys’ fees and court costs and the reasonable Out-of-Pocket Costs the other Party (the “**Cooperating Party**”) in rendering assistance requested by the Controlling Party (“**Enforcement Expense**”), will be borne (***). If required under Applicable Law in order for the Controlling Party to initiate and/or maintain such suit or to defend the Defensive Action, or if either Party is unable to initiate or prosecute such suit or defend the Defensive Action solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party will join as a party to the suit or Defensive Action and will execute and cause its Affiliates to execute all documents necessary for the Controlling Party to initiate litigation to prosecute and maintain such action or defend the Defensive Action. In addition, at the Controlling Party’s request, the Cooperating Party will provide reasonable assistance to the Controlling Party in connection with an infringement suit (***). The Cooperating Party will have the right to participate and be

represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation) ("**Recoveries**") in the Territory, such amounts will be allocated as follows:

(***)).

KKC will have the sole right to take action and earn all Recoveries outside of the Territory.

9.3.4 LJI Enforcement Rights. The Parties acknowledge and agree that in the event that (***), LJI will have the right but not the obligation under the LJI Agreement to bring, defend, or maintain any appropriate suit or action involving such infringement or Defensive Action at its own cost and expense against alleged infringers and to defend such KKC Patent Rights from Defensive Actions. Subject to the foregoing, if LJI finds it necessary or reasonably desirable to join AEVI and/or KKC into such suit or action, AEVI and/or KKC will execute all papers and perform such other acts as may be reasonably required, and AEVI and/or KKC, at their respective options, may be represented by respective counsel(s) of their own choice, provided that (a) (***), and (b) if any amount is recovered on any such action or suit, whether by judgment or settlement (any such settlement requiring the consent of KKC), the balance of any such recovery will be paid to or retained (***) (including, for clarity, the LJI (***) set forth on Schedule 1.50) in respect of the applicable KKC Patent Right(s) and Licensed Product(s), after reimbursement for the reasonable attorneys' fees incurred with respect to such suit or action by LJI, KKC and AEVI.

9.4 Claimed Infringement of Third Party Rights.

9.4.1 Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of such Party's respective Related Parties, claiming infringement of such Third Party's Patent Rights or unauthorized use or misappropriation of such Third Party's Know-How, based upon an assertion or claim arising out of the Development, Manufacture or Commercialization of a Licensed Product (each, an "**Infringement Claim**"), such Party will promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served. Each Party agrees to make available to the other Party its advice and counsel regarding the technical merits of any such claim at no cost to the other Party and to offer reasonable assistance to the other Party at no cost to the other Party.

9.4.2 Right to Defend. AEVI will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product in the Field in the Territory. KKC will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product outside the Field and/or outside the Territory.

(a) Procedure. The Party having the obligation or first right to defend an Infringement Claim in which either Party is named as defendant will be referred to as the “**Defending Party**.” The Defending Party will have the sole and exclusive right to select counsel for any Infringement Claim; provided that it will consult with the other Party with respect to selection of counsel for such defense. The Defending Party will keep the other Party informed, and will from time to time consult with the other Party regarding the status of any such claims and will provide the other Party with copies of all documents filed in, and all written communications relating to, any suit brought in connection with such claims. The other Party will also have the right to participate and be represented in any such claim or related suit, at its own expense. The other Party will have the sole and exclusive right to control the defense of an Infringement Claim in the event the Defending Party fails to exercise its right to assume such defense within (***) following written notice from the other Party of such Infringement Claim. No Party will settle any claims or suits involving rights of another Party without obtaining the prior written consent of such other Party, which consent will not be unreasonably withheld. Any recoveries by the Defending Party of attorneys’ fees or costs in defense of a claim in the Territory under this Section 9.4, and any sanctions awarded to Defending Party and against a party asserting a claim in the Territory being defended under this Section 9.4, will be (***). The costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim in the Territory will be treated as Allowable Expense in the Territory. The costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim outside the Field or outside the Territory will be allocated between the Parties as follows: (***). AEVI and KKC will have the right to take action to invalidate Third Party’s patents which would be infringed by the activity under this Agreement. The cost and expenses of such action will be shared in the same way as set forth above.

9.4.3 Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTION 12.10, THE FOREGOING STATES THE ENTIRE RESPONSIBILITY OF KKC AND AEVI, AND THE SOLE AND EXCLUSIVE REMEDY OF KKC OR AEVI, AS THE CASE MAY BE, IN THE CASE OF ANY CLAIMED INFRINGEMENT OF ANY THIRD PARTY PATENT RIGHTS OR UNAUTHORIZED USE OR MISAPPROPRIATION OF ANY THIRD PARTY’S KNOW-HOW.

9.5 Third Party Technology. If either Party reasonably determines that any Third Party Technology is reasonably necessary for the Development, Manufacture, or Commercialization of a Licensed Product in the Field, then such Party will notify the other Party. The Parties will determine which Party will negotiate the most favorable license. The chosen Party will obtain a license to such Third Party Technology with the right to sublicense to the other Party. Subject to the foregoing, the terms and conditions involved in obtaining such rights will be determined at such chosen Party’s sole discretion. If such chosen Party elects not to obtain rights to such Third Party Technology, or is unsuccessful in obtaining such Third Party Technology, then the other Party will have the right (but not the obligation) to negotiate and obtain rights from such Third Party at its sole discretion and expense. Notwithstanding anything to the contrary in this Section 9.5, AEVI will pay to a Third Party any and all royalties and other payments pursuant to any agreement under which a Party acquires rights to intellectual property that would otherwise block the Development and/or Commercialization of a Profit-Share Product in the Field in the

Territory. Any such payments will be included in Third Party Technology Costs and, for clarity, will be included in Allowable Expenses for the applicable Profit-Share Product. The costs outside the Field will be borne solely by KKC, provided that such costs will be subject to royalties reduction to AEVI in accordance with Section 8.5.2. Notwithstanding the foregoing, with respect to any lump sum payment under any such agreement that is made with respect to a license covering countries or jurisdictions both inside and outside of the Territory, the Parties will negotiate and decide in good faith the allocation of the payment based on the scope and territory of the acquired rights.

9.6 Other Infringement Resolutions.

9.6.1 Notice of Third Party Applications. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the type described in Sections 9.3 or 9.4, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) will apply. Notwithstanding anything herein to the contrary, within (***) after Regulatory Approval is achieved with respect to a BLA for a Licensed Product in the Territory (or such shorter time as the Parties agree in the case of a Licensed Product in the Territory that does not earn reference product exclusivity under the PHS Act), the Parties will consult as to potential strategies with respect to unexpired Patent Rights Controlled by either Party that potentially could be asserted if an unlicensed person engaged in the making, using, offering to sell, selling, or importing into the United States of a product described in a Biosimilar Application filed by a Third Party applicant (a “**Section 351(k) Applicant**”).

9.6.2 Cooperation and Enforcement. If either Party who is the reference product sponsor of the Licensed Product within the meaning of section 351(l)(1)(A) of the PHS Act (“**Reference Product Sponsor**”) receives notice of a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product and related manufacturing information in accordance with section 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with section 351(l)(8)(A) of the PHS Act, then such Party will provide notice to the other Party, and the Parties will discuss and cooperate with each other in determining the Reference Product Sponsor’s course of action with regard to (a) engaging in the information exchange provisions of the Biologics Price Competition and Innovation Act of 2009, Section 351(k) of the Public Health Service Act, as may be amended, supplemented, or replaced (the “**BPCIA**”), including providing a list of patents that relate to the relevant Licensed Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under Section 351(l)(6) of the BPCIA. In the event that the Parties do not agree with respect to the exercise of any such rights, KKC will make the final determination with respect thereto, including without limitation with respect to (a), (b) and (c) above. If any patent litigation commences with respect to a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product, then the provisions of Section 9.3 will thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.

9.7 Product Trademarks.

9.7.1 Product Trademarks in the Territory. AEVI will own the Product Trademarks for each Licensed Product in the Territory and will be solely responsible for filing and maintaining the Product Trademarks in the Territory (including payment of costs associated therewith). AEVI hereby grants to KKC a non-exclusive, nontransferable (except as provided in Section 13.3) license, with the right to grant sublicenses solely in accordance with Section 7.4, under the Product Trademarks, to use and display the Product Trademarks in connection with Commercialization outside the Territory.

9.7.2 Product Trademarks Outside the Territory. KKC will own the Product Trademarks for each Licensed Product outside the Territory and will be solely responsible for filing and maintaining the Product Trademarks outside the Territory (including payment of costs associated therewith).

9.7.3 Each Party agrees to (a) conduct its business in a manner that will not damage the reputation or integrity of the Trademarks of the other Party, (b) conduct its business in a manner that will not damage in any way the goodwill associated with the Trademarks of the other Party, (c) use the Trademarks of the other Party in a manner that will not cause a negative impact upon the good name of such other Party, (d) conduct its business in compliance with all applicable trademark Laws and (e) use the other Party's Trademarks only in accordance with this Agreement.

9.8 Patent Term Extensions. The Parties will use reasonable efforts to obtain all available supplementary protection certificates ("**SPC**") and other extensions of Patent Rights. Each Party will execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties will cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to Patent Rights. The Party first eligible to seek patent term restoration or extension of any such Patent Rights or any SPC related thereto will have the right to do so; provided that if in any country the first Party has an option to extend the patent term for only one of several patents, the first Party will consult with the other Party before making the election. If more than one patent is eligible for extension or patent term restoration, KKC will select in good faith a strategy that will maximize patent protection and commercial value for each Licensed Product. All filings for such extensions and certificates will be made by the Party to whom responsibility for prosecution and maintenance of the Patent Rights are assigned, provided that in the event that the Party to whom such responsibility is assigned elects not to file for an extension or SPC, such Party will (a) inform the other Party of its intention not to file and (b) grant the other Party the right to file for such extension or SPC in the patentee's name, and (c) provide all necessary assistance in connection therewith.

9.9 Patent Marking. AEVI (and its Related Parties) will mark Licensed Products marketed and sold by AEVI (and/or its Related Parties, as applicable) with appropriate numbers of the KKC Patent Rights printed on the appropriate portion of the packaging. Without limiting the foregoing, AEVI shall mark each Licensed Product sold or offered for sale by or on behalf of AEVI with the patent number or numbers of any issued patents encompassed within the KKC

Patent Rights solely owned by LJI, if applicable, and AEVI shall ensure that the content, form, location and language of such markings is in accordance with the applicable laws and practices of each jurisdiction in which the Licensed Products are made, used or sold.

Article 10. **CONFIDENTIALITY**

10.1 Confidentiality.

10.1.1 **Confidential Information.** All Confidential Information disclosed by or on behalf of a Party (together with its Affiliates, the “**Disclosing Party**”) to the other Party (together with its Affiliates, the “**Receiving Party**”) during the Term will be used by the Receiving Party solely in connection with the activities contemplated by this Agreement, will be maintained in confidence by the Receiving Party and will not otherwise be disclosed by the Receiving Party to any other person, firm, or agency, governmental or private (other than a Party’s Affiliates or as set forth in Section 10.1.2), without the prior written consent of the Disclosing Party, except to the extent that the Confidential Information (as determined by competent documentation):

(a) was known or used by the Receiving Party without restriction as to its use or disclosure prior to its date of disclosure to the receiving Party; or

(b) either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party without restriction as to its use or disclosure by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or

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

(d) is independently developed by or for the Receiving Party without reference to or reliance upon the Confidential Information.

All obligations of confidentiality imposed under this Article 10 will expire five (5) years following termination of this Agreement.

10.1.2 **Required Disclosures.** Section 10.1.1 will not preclude the Receiving Party from disclosing Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure. If a public disclosure is required by any Applicable Laws, including, without limitation, in a filing with the Securities and Exchange Commission or submission to an exchange on which any securities of a Party is listed, the disclosing Party will provide copies of the disclosure (but shall be permitted to redact or omit portions of any filing, submission or disclosure not relevant to this Agreement)

reasonably in advance of such filing or other disclosure, for the non-disclosing Party's prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The disclosing Party will negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.

10.1.3 Permitted Disclosures. KKC and AEVI each agree that they will provide Confidential Information received from the other Party only to their respective directors, officers, employees, consultants, suppliers, sublicensees, collaborators and advisors, and to those of such Party's Related Parties, who have a need to know for such Party's development, manufacture, and commercialization of Licensed Products in accordance with this Agreement, including in connection with Regulatory Filings and obtaining Regulatory Approvals, provided that such Third Parties are bound by confidentiality obligations at least as strict as this Article 10. In addition, each Party may not disclose the terms of this Agreement (to the extent such terms are confidential) to any Third Party except to actual or prospective lenders, investors, acquirers, licensees/sublicensees or strategic partners (including the KKC Licensors and AEVI Licensor) or to a Party's accountants, attorneys and other professional advisors; provided that such disclosures will be subject to continued confidentiality obligations at least as strict as this Article 10.

10.2 Publication Review.

10.2.1 Publications by the Parties. Subject to Section 10.2.2 and except as required by Applicable Law, during the Term, each Party agrees that, unless explicitly authorized in this Agreement, it will not without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed, file patent application, issue any press release, make any public announcement, or issue any scientific or other presentations or publications, with respect to the results of any Development work relating to this Agreement without the opportunity for prior review by the other Party. With respect to any such proposed publications or presentations by one of the Parties, each Party will provide to the other Party for information and review any (a) abstracts, posters and slide presentations that the Party proposes prior to any scientific meetings and the other Party will provide feedback to the publishing Party within ten (10) of its Business Days of its receipt of such abstracts, posters and slide presentations, and (b) primary and final manuscripts and review articles that the Party proposes prior to journal submission and the other Party will provide feedback within fifteen (15) of its Business Days of its receipt of such manuscript or article. Each Party agrees, upon request from the other Party, not to submit any abstract or manuscript for publication or to make any scientific presentation until the other Party is given up to forty-five (45) days from the date of such written request to seek appropriate patent protection for any material in such publication or presentation which it reasonably believes is patentable. Once such abstracts, manuscripts or presentations have been reviewed by the other Party and have been approved for publication, the same abstracts, manuscripts or presentations do not have to be provided again to the other Party for review for a later submission for publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Parties. The other Party also will

have the right to require that its Confidential Information that may be disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation.

10.2.2 Publications by Third Parties. Notwithstanding Section 10.2.1, the Parties understand and agree that any restrictions on scientific or other presentations or publications will not be construed to prohibit the clinical investigators of any clinical trials conducted under this Agreement (including without limitation CHOP), from making scholarly publications, manuscripts, abstracts, oral presentations or other disclosures with respect to the results of any Development work, including without limitation clinical data resulting from such clinical trials ("**Publications**"); provided that AEVI will ensure that (a) any such clinical investigator must agree to submit to KKC for its review and comment, a copy of any proposed Publication, abstract or other disclosure resulting from such activities, simultaneous with submission of the same to AEVI and at least forty-five (45) days prior to any such presentation or publication, (b) such publication will not contain any references to, or otherwise disclose any of, the Confidential Information (other than clinical data) without KKC's prior written consent, and (c) at KKC's request, such clinical investigator will, for a reasonable period of up to ninety (90) days from initial delivery to KKC, delay revealing any subject matter included in the clinical data in any publication or disclosure in order to permit the filing of patent applications.

10.3 Public Announcements and Use of Names. Except for public disclosures (a) resulting from the issuance of one or more press releases to be mutually-agreed upon by the Parties, (b) otherwise permitted under this Article 10 or (c) required by Applicable Law or by the rules and regulations of any securities exchange on which a Party's securities are traded, neither Party will disclose any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the execution of this Agreement, the subject matter of this Agreement, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party.

Article 11.

TERM AND TERMINATION

11.1 Term. This Agreement will commence on the Effective Date and will remain in full force and effect for as long as any Licensed Product(s) is Commercialized by either Party and/or its Related Parties, unless terminated earlier pursuant to Section 11.2 or 11.3 (the "**Term**").

11.2 Termination by KKC.

11.2.1 Insolvency. To the extent permitted under Applicable Laws, KKC will have the right to terminate this Agreement in its entirety, at KKC's sole discretion, upon delivery of written notice to AEVI upon the filing by AEVI in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of AEVI or its assets, upon the proposal by AEVI of a written agreement of composition or extension of its debts, or if AEVI is served by a Third Party (and not by KKC) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st)

day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by AEVI of an assignment for the benefit of its creditors.

11.2.2 Breach. KKC will have the right to terminate this Agreement in its entirety, at KKC's sole discretion, subject to Section 11.2.5, upon delivery of written notice to AEVI in the event of any material breach by AEVI of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and KKC's intention to terminate is given by KKC to AEVI; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by KKC (except that in the case of a bona fide dispute over whether or to what extent a payment by AEVI to KKC is due, this Section 11.2.2 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Such termination will be effective upon expiration of the applicable time period set forth in this Section 11.2.2. Subject to Section 11.2.5, any such termination of this Agreement will become effective at the end of the applicable cure period, unless AEVI has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, KKC's right of termination will be suspended only if and for so long as AEVI has provided to KKC a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to KKC (such acceptance not to be unreasonably withheld, conditioned, or delayed), and AEVI commits to and carries out such plan as provided to KKC.

11.2.3 Termination as to a Country.

(a) European Union. KKC will have the right to terminate this Agreement, solely in the European Union if AEVI fails to satisfy its obligations set forth in Section 6.1.1 with respect to the European Union or Section 6.2 with respect to the EU5 Countries.

(b) Canada. KKC will have the right to terminate this Agreement, solely as it relates to Canada, if (a) both Parties decide to not proceed with Development in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, (b) AEVI declines to proceed with Development in the Field in Canada and not to obtain Regulatory Approval for the Licensed Product in the Field in Canada, and the Parties do not agree, in each case as set forth in Section 6.1.2, or (c) if AEVI fails to satisfy its obligations set forth in Section 6.2 with respect to Canada.

11.2.4 Termination for Patent Challenge. If AEVI or any of its Affiliates directly claim, or cause a Third Party to claim, or knowingly supports (other than as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or in response to a subpoena or court or administrative law request or order), including by providing information, documents, and/or funding, a claim (a) to the validity, scope, enforceability or patentability of any of the KKC Patent Rights in any formal legal or administrative action or proceeding, or (b) that no Earned Royalties, Sublicense Royalties, Net Receipts, milestone payments, Patent Costs or other payments (as such capitalized terms are defined under the LJI Agreement) are due or required to be paid to LJI under the LJI Agreement because the applicable KKC Patents licensed by LJI to KKC under the LJI Agreement covering or claiming a Licensed Product are invalid or unenforceable except where such KKC Patent Rights have been found to be unpatentable, invalid

or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal is taken or can be taken, or have been admitted or determined to be invalid or unenforceable through reissue, re-examination, disclaimer or similar formal proceeding, or where a pending application within the KKC Patent Rights has been abandoned or finally rejected (in each case, other than pursuant to a claim by KKC, AEVI or their respective Affiliates or by a Third Party caused by any of the foregoing entities) in any Challenge, then (x) if and to the extent permitted by Applicable Law, (***) during and after the pendency of such Challenges from the date KKC, AEVI, or any of their respective Affiliates first institute or make such challenges. In such event, notwithstanding anything to the contrary in this Agreement, (i) AEVI will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of KKC or any of its Affiliates (in which case, KKC will be responsible for (***)), and (ii) KKC will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of AEVI or any of its Affiliates (in which case, AEVI will (***)). KKC's right to terminate this Agreement under this Section 11.2.4 (x) may be exercised at any time after AEVI (or any of its Affiliates) may have Challenged or knowingly supports (other than in response to a subpoena or court order) a Challenge to the validity, enforceability or patentability of any of the KKC Patent Rights. If a sublicensee of AEVI Challenges the validity, scope or enforceability of or otherwise opposes any of the KKC Patent Rights under which such sublicensee is sublicensed, then AEVI will, upon written notice from KKC, promptly terminate such sublicense. "**Challenge**" under this Section 11.2.4 will refer to a legal action or filing with a patent authority or tribunal or a court that could, if successful, result in a holding of invalidity, unenforceability, or unpatentability of a patent or application within the KKC Patent Rights.

11.2.5 Dispute. If AEVI reasonably and in good faith disagrees as to whether KKC has a basis for terminating this Agreement pursuant to Section 11.2.2, AEVI may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by KKC pursuant to Section 11.2.2 will be effective unless and until KKC's right to terminate this Agreement under Section 11.2.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.2.6 Abandonment. If AEVI, in its discretion, decides to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, AEVI will promptly notify KKC in writing of its intent to do so. KKC will have the right to terminate this Agreement immediately upon receipt of such notice.

11.3 Termination by AEVI.

11.3.1 Insolvency. To the extent permitted under Applicable Law, AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, upon delivery of written notice to KKC upon the filing by KKC in any court or agency pursuant to any

statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of KKC or its assets, upon the proposal by KKC of a written agreement of composition or extension of its debts, or if KKC is served by a Third Party (and not by AEVI) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by KKC of an assignment for the benefit of its creditors.

11.3.2 Breach. AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, subject to Section 11.3.4, upon delivery of written notice to KKC in the event of a material breach by KKC of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and AEVI's intention to terminate is given by AEVI to KKC; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by AEVI (except that in the case of a bona fide dispute over whether or to what extent a payment by KKC to AEVI is due, this Section 11.3.2 will not be triggered provided that KKC will pay the amount in dispute into escrow until such dispute is resolved). Such termination will be effective upon expiration of the applicable time period set forth in this Section 11.3.2. Subject to Section 11.3.4, any such termination of this Agreement will become effective at the end of the applicable cure period, unless KKC has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, AEVI's right of termination will be suspended only if and for so long as KKC has provided to AEVI a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to AEVI (such acceptance not to be unreasonably withheld, conditioned, or delayed), and KKC commits to and carries out such plan as provided to AEVI.

11.3.3 Convenience. (***), such termination to be effective at the end of such notice period, AEVI may terminate this Agreement as to such Licensed Product and/or such jurisdiction for any reason or no reason, including if AEVI, in its reasonable discretion, decides to cease all of its Development and/or Commercialization efforts with respect to such Licensed Product in such jurisdiction.

11.3.4 Dispute. If KKC reasonably and in good faith disagrees as to whether AEVI has a basis for terminating this Agreement pursuant to Section 11.3.2, KKC may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by AEVI pursuant to Section 11.3.2 will be effective unless and until KKC's right to terminate this Agreement under Section 11.3.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.4 Consequences of Termination. Upon termination of this Agreement in its entirety or with respect to a country in the Territory or the European Union pursuant to Section 11.2.3(a) and in case of Canada pursuant to Section 11.2.3(b) (in which event the following will apply only with respect to such country):

11.4.1 Reversion. All rights and licenses granted to AEVI in Article 7 will terminate, all rights of AEVI under the KKC Technology will revert to KKC, and AEVI and its Affiliates will cease all use of the KKC Technology. Except as set forth in Sections 11.4.2 through 11.4.9, all rights and licenses granted to KKC in Article 7 will terminate, all rights of KKC under the AEVI Technology will revert to AEVI, and KKC and its Affiliates will cease all use of the AEVI Technology.

11.4.2 Regulatory Filings. AEVI will assign, and hereby does assign effective as of the effective date of such termination, to KKC all Regulatory Filings (including all INDs and NDAs) and Regulatory Approvals and all other documents necessary to further Develop, Manufacture, and Commercialize the Licensed Products, as they exist as of the date of such termination, (and all of AEVI's right, title and interest therein and thereto). AEVI will provide to KKC one (1) copy of the foregoing documents and Regulatory Filings, all documents and filings contained in or referenced in any such Regulatory Filings, together with the raw and summarized data for any preclinical and clinical studies of the Licensed Product. For clarity, KKC will have the right to use the foregoing material information, materials and data developed by AEVI solely in connection with KKC's development, manufacture and commercialization of Licensed Products. KKC will have the right to seek specific performance of AEVI's obligations referenced in this Section 11.4.2 and/or in the event of failure to obtain assignment, AEVI hereby consents and grants to KKC the right to access and reference (without any further action required on the part of AEVI, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose. Without limiting the foregoing in this paragraph, to the extent applicable, AEVI's obligations under this Section 11.4.2 will continue with respect to all countries in the Territory for which there is a failure to obtain assignment of all regulatory filings and Regulatory Approvals.

11.4.3 Know-How Transfer. AEVI will provide to KKC all data and information generated during the Term necessary for the development and/or commercialization of the relevant Licensed Products and assign (or, if applicable, cause its Affiliate to assign) to KKC all of AEVI's (and such Affiliate's) entire right, title and interest in and to all such data and information. AEVI will provide to KKC the tangible embodiments of all other Know-How Controlled by AEVI and its Affiliates in existence as of the effective date of such termination relating to the Development, Manufacturing, and Commercialization of the Licensed Products, including without limitation AEVI's manufacturing processes, techniques and trade secrets necessary for and used in the manufacture of such Licensed Products as of the effective date of such termination and all Know-How specifically relating to any composition, formulation, method of use or manufacture of such Licensed Products. AEVI will grant, and hereby does grant effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide right and license under such Know-How for developing, making, using, importing, selling and offering for sale Licensed Products. AEVI

will reasonably cooperate with KKC to assist KKC with understanding and using the Know How provided to KKC under this Section 11.4.3. If AEVI has decided to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, and this Agreement is terminated pursuant to Section 11.2.6, AEVI will provide to KKC all technology resulting from such abandoned Development and/or Commercialization efforts. KKC will have a royalty-free, irrevocable, world-wide, unlimited license to such abandoned Development and/or Commercialization efforts including the right to sublicense and to contract with Third Parties for further Development and/or Commercialization.

11.4.4 Trademarks. To the extent that AEVI owns any trademark(s) (including without limitation any Product Trademarks) and/or domain names that pertain specifically to an Licensed Product that KKC believes would be necessary for the Commercialization of a Licensed Product (as then currently marketed, but not including any marks that include, in whole or part, any corporate name or logo of AEVI), AEVI will assign (or, if applicable, cause its Affiliate to assign), and hereby does assign effective as of the effective date of such termination, to KKC all of AEVI's (and such Affiliate's) right, title and interest in and to any registered or unregistered trademark, trademark application, trade name or internet domain name in each country.

11.4.5 Termination License. AEVI will grant, and hereby grants effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license under any Patent Rights owned solely by AEVI or its Affiliates as of the effective date of termination to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products. AEVI will grant to KKC, under any Patent Rights that AEVI's Controls but does not own at the time of termination, to the full extent permitted under the agreement(s) of AEVI covering such Patent Rights, a non-exclusive, irrevocable, royalty-free (as to AEVI), transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license, to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products; provided that KKC enters into a written agreement with AEVI with respect to each such Patent Right that (a) ensures compliance with the applicable contract between AEVI and its licensor including KKC agreeing to all provisions thereof that must be imposed on sublicensees, (b) requires KKC to pay all amounts payable to its licensor by AEVI related to KKC's exercise or enjoyment of such rights including milestones, royalties and patent expenses and (c) indemnifies AEVI for any breach of such agreement between KKC and AEVI.

11.4.6 Continued Supply. If AEVI has any inventory of any Licensed Products suitable for use in clinical trials, AEVI will offer to sell such Licensed Products to KKC at (***) (but KKC will be under no obligation to purchase the foregoing inventory of Licensed Products unless it agrees to do so in writing at such time); provided, however, that, in the event of a termination pursuant to Section 11.3.3, (***). If AEVI has the capability in place as of the

effective date of such termination to commercially Manufacture and supply to KKC all or part of KKC's requirements of the applicable Licensed Products, if KKC so elects in its sole discretion, AEVI will use Commercially Reasonable Efforts to supply to KKC (***) as much of KKC's requirements of such Licensed Products (and to develop a reasonable inventory level) during such period, (***) for such Licensed Products, under terms and conditions as may be mutually agreed between the Parties. If KKC, despite its best efforts, is unable to Manufacture, or to secure a supply of, such Licensed Products in an amount sufficient to meet its requirements (***), AEVI will continue to supply such Licensed Products to KKC to the extent necessary to meet KKC's requirements, so long as KKC continues to use its best efforts to develop the capabilities necessary to Manufacture such Licensed Products and/or to secure a supply of such Licensed Products.

11.4.7 Transfer of Manufacturing Technology. In the event, at the time of such termination, (a) AEVI manufactures the Licensed Products at its own facility, AEVI will conduct manufacturing technology transfer to KKC, and (b) if AEVI engages a Third Party to manufacture and supply the Licensed Products, AEVI will, at KKC's election, either (i) have such Third Party conduct manufacturing technology transfer to KKC or (ii) will use reasonable efforts to assist in the transfer of such supply arrangements to KKC.

11.4.8 Continuing Obligations. Neither Party will be relieved of any obligation that accrued prior to the effective date of such termination. All amounts due or payable to KKC that were accrued prior to the effective date of termination will remain due and payable. Except as otherwise expressly provided herein, no additional amounts will be payable based on events occurring after the effective date of termination; provided that the foregoing will not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the effective date of such termination that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the effective date of such termination.

11.4.9 Retention of Payments. KKC will have the right to retain all amounts previously paid to KKC by AEVI.

11.4.10 No Compensation. KKC will not owe any compensation to AEVI for the research, development, manufacture, or commercialization of any Licensed Products in the event of any termination of the Agreement by KKC, without prejudice to any rights that either Party may have to bring a claim for damages arising out of this Agreement and the termination thereof or any other amounts payable with respect to activities conducted prior to the effective date of such termination.

11.4.11 Costs. Any costs and expenses incurred by AEVI in connection with the assignments and transfers made by AEVI under this Section 11.4 will be borne by AEVI.

11.5 Return of Confidential Information. Upon the termination of this Agreement, each Party will promptly return to the other Party, delete or destroy (with written notification of such destruction) all relevant records and materials in such Party's possession or control containing

Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only.

11.6 Effect of Termination; Survival. The termination of this Agreement will not relieve the Parties of any obligation accruing prior to such termination. The provisions of Article 10 (Confidentiality), Article 12 (Representations and Warranties; Indemnification) and Article 13 (Miscellaneous Provisions) and Sections 7.4.3 (Effect of Termination on Sublicenses) and 9.2.2 (Joint Inventions) will survive any termination of this Agreement. Except as set forth in this Article 11 or as otherwise set forth in this Agreement, upon termination of this Agreement all other rights and obligations cease. Any termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

11.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by either Party, including without limitation Article 7, are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter “**IP**”). The Parties agree that each Party, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. In the event of termination of a Party pursuant to Section 11.2.1 or 11.3.1, the terminated Party hereby grants to the other Party and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of intellectual property, which, if not already in such other Party’s possession, will be promptly delivered to it upon such other Party’s written request therefor. The term “embodiments of intellectual property” includes all tangible, electronic or other embodiments of rights and licenses hereunder, including all Licensed Products, all Regulatory Approval Applications and Regulatory Approvals and rights of reference therein, and all Information related to Licensed Products, KKC Technology and AEVI Technology, as applicable. The terminated Party will not interfere with the exercise by the other Party or its Affiliates of rights and licenses to IP and embodiments of intellectual property licensed hereunder in accordance with this Agreement and agrees to assist such other Party and Affiliates of such other Party to obtain the IP and embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for such other Party or Affiliates of such other Party to exercise such rights and licenses in accordance with this Agreement. The Parties acknowledge and agree that milestone payments made under Section 8.3 do not constitute royalties within the meaning of U.S. Bankruptcy Code §365(n) or relate to licenses of intellectual property hereunder.

11.8 No Limitation of Remedies. Except as herein expressly provided, notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination nor prejudice either Party’s right to obtain performance of any obligation. Each Party will be free, pursuant to Section 13.2,

to seek (without restriction as to the number of times it may seek) damages, costs and remedies that may be available under Applicable Law or in equity and will be entitled to offset the amount of any damages and costs obtained in a final determination under Section 13.2 of monetary damages or costs (as permitted by this Agreement) against the other Party against any amounts otherwise due to such other Party under this Agreement. It is understood and agreed that either Party will be entitled to seek specific performance as a remedy to enforce the provisions of this Article 11, in addition to any other remedy to which such Party may be entitled by Applicable Law. Nothing in this Article 11 will be deemed to limit any remedy to which either Party may be entitled by Applicable Law.

Article 12.

REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION

12.1 Mutual Representations and Warranties

. Each Party represents, warrants and covenants to the other Party that as of the Effective Date of this Agreement:

(a) Corporate Existence and Authority. It is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Authorized Execution; Binding Obligation.

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

(ii) This Agreement has been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with this Agreement's terms, except as the same may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws relating to or affecting creditors' rights generally and by general equity principles, including judicial principles affecting the availability of injunction and specific performance.

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

(d) All Consents and Approvals Obtained. Except with respect to any consent required from Lonza or Sanofi, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all governmental authorities and other persons or entities required to be obtained or provided by such Party in connection with the execution,

delivery and performance of this Agreement have been obtained and provided, except for those government approvals, if any, not required at the time of execution of this Agreement.

(e) Compliance with Law. It will at all times comply with Applicable Laws in all material respects. Neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Licensed Products: (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred by the FDA (or subject to a similar sanction of a Regulatory Authority) or (ii) has ever been under indictment for a crime for which a person or entity could be so debarred.

12.2 KKC Representations and Warranties. KKC represents and warrants to AEVI that as of the Effective Date:

(a) KKC Controls the KKC Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The KKC Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by KKC as of the Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. KKC has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(b) To the knowledge of KKC, there is no actual or threatened infringement of the KKC Patent Rights in the Field by any Third Party that would adversely affect AEVI's rights under this Agreement.

(c) To the knowledge of KKC, the KKC Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by KKC or any of its Affiliates relating to the KKC Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and KKC is not aware of any reasonable basis for a claim alleging that (i) the KKC Patent Rights are invalid or unenforceable, (ii) the KKC Patent Rights or the licensing or exploiting of the KKC Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party, or (iii) any Third Party other than a KKC Licenser has any right, title, or interest in, to, and under any KKC Patent Rights.

(d) To the knowledge of KKC, KKC is not in default, and to KKC's knowledge, none of the KKC Licensors is in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, any KKC In-Licenses, and KKC has not waived or allowed to lapse any of its rights under any KKC In-Licenses, and no such rights have lapsed or otherwise expired or been terminated.

(e) There are no claims, judgments or settlements against or owed by KKC or its Affiliates or pending or threatened claims or litigation relating to the KKC Technology.

12.3 KKC Covenants. KKC covenants that during the Term:

(a) KKC will use Commercially Reasonable Efforts to fulfill its obligations under the KKC In-Licenses to the extent such obligations have not been delegated to AEVI and to the extent that failure to do so would materially adversely affect AEVI or its rights hereunder.

(b) KKC will not assign, transfer, convey or otherwise encumber its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(c) KKC will not enter into any subsequent agreement with any KKC Licensor that modifies or amends any KKC In-Licenses in any way that would materially adversely affect AEVI's rights or economic interest under this Agreement without AEVI's prior written consent.

(d) KKC will not terminate any KKC In-Licenses in whole or in part, directly or indirectly, without AEVI's prior written consent if such termination would materially affect AEVI's license granted hereunder; for clarity KKC may (i) terminate any KKC In-Licenses by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and KKC will promptly notify AEVI after the occurrence of each such event.

(e) KKC will furnish AEVI with copies of all notices received by KKC relating to any alleged breach or default by KKC under any KKC In-Licenses within (***) after KKC's receipt thereof and, if KKC cannot or chooses not to cure or otherwise resolve any such alleged breach or default, KKC will so notify AEVI within (***) thereafter.

12.4 AEVI Representations and Warranties. AEVI represents and warrants to KKC that as of the Effective Date:

(a) AEVI Controls the AEVI Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The AEVI Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by AEVI as of the Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. AEVI has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

(b) To the knowledge of AEVI, there is no actual or threatened infringement of the AEVI Patent Rights in the Field by any Third Party that would adversely affect KKC's rights under this Agreement.

(c) To the knowledge of AEVI, the AEVI Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by AEVI or any of its Affiliates relating to the AEVI Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and AEVI is not aware of any reasonable basis for a

claim alleging that (i) the AEVI Patent Rights are invalid or unenforceable, (ii) the AEVI Patent Rights or the licensing or exploiting of the AEVI Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party or (iii) any Third Party other than the AEVI Licensor has any right, title, or interest in, to, and under any AEVI Patent Rights.

(d) To the knowledge of AEVI, the Development activities set forth in the initial Development Plan do not infringe any third party intellectual property rights.

(e) To the knowledge of AEVI, AEVI is not in default, and to AEVI's knowledge, the AEVI Licensor is not in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, the AEVI In-License, and AEVI has not waived or allowed to lapse any of its rights under any AEVI In-License, and no such rights have lapsed or otherwise expired or been terminated.

(f) There are no claims, judgments or settlements against or owed by AEVI or its Affiliates or pending or threatened claims or litigation relating to the AEVI Technology.

12.5 AEVI Covenants. AEVI covenants that during the Term:

(a) AEVI will not engage in any activities that use the KKC Technology in a manner that is outside the scope of the rights granted to it hereunder.

(b) All of AEVI's activities related to its use of the KKC Technology, and the research, Development and Commercialization of the Licensed Products, pursuant to this Agreement will comply with all Applicable Laws.

(c) AEVI will use Commercially Reasonable Efforts to fulfill its obligations under the AEVI In-License to the extent such obligations have not been delegated to KKC and to the extent that failure to do so would materially adversely affect KKC or its rights hereunder.

(d) AEVI will not assign, transfer, convey or otherwise encumber its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

(e) AEVI will not enter into any subsequent agreement with CHOP that modifies or amends the AEVI In-License in any way that would materially adversely affect KKC's rights or economic interest under this Agreement without KKC's prior written consent.

(f) AEVI will not terminate the AEVI In-License in whole or in part, directly or indirectly, without KKC's prior written consent if such termination would materially affect KKC's license granted hereunder; for clarity AEVI may (i) terminate the AEVI In-License by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and AEVI will promptly notify KKC after the occurrence of each such event.

(g) AEVI will furnish KKC with copies of all notices received by AEVI relating to any alleged breach or default by AEVI under the AEVI In-License within (***) after AEVI's receipt thereof and, if AEVI cannot or chooses not to cure or otherwise resolve any such alleged breach or default, AEVI will so notify KKC within (***) thereafter.

12.6 Mutual Covenants. Each Party hereby covenants to the other Party that during the Term:

(a) All employees and officers of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their Inventions, whether or not patentable, if any, to such Party as the sole owner thereof, and under the obligation to maintain as confidential the Confidential Information of such Party.

(b) Such Party will perform its activities pursuant to this Agreement in compliance with good clinical practices and good manufacturing practices, in each case as applicable under the Applicable Laws and regulations of the country and the state and local government wherein such activities are conducted, and also with the standards in the pharmaceutical industry for the development and commercialization of pharmaceutical products.

(c) Such Party will not employ (or, to its knowledge, use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or, to its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority), in the conduct of its activities under this Agreement, and each contractor or consultant used by such Party in connection with the conduct of clinical trials under this Agreement will be subject to a covenant that is the same or substantially the same as the foregoing covenant.

(d) Such Party will not practice or exploit the intellectual property licensed to such Party under this Agreement except to the extent expressly permitted under the terms and conditions of this Agreement.

(e) Such Party will not grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to the other Party hereunder.

12.7 Consequences of Partial Termination of an In-License. In the event that a portion, but not all of KKC's rights under the KKC In-Licenses terminate, then AEVI will owe no further obligations to KKC under this Agreement with respect to such terminated rights. In the event that a portion, but not all of AEVI's rights under the AEVI In-License terminate, then KKC will owe no further obligations to AEVI under this Agreement with respect to such terminated rights.

12.8 Warranty Disclaimer. The Parties acknowledge and agree that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) will be construed as representing an estimate or projection of either (a) the extent to which Licensed Products will be successfully Developed or Commercialized or (b) the anticipated sales or the actual value of

any Licensed Product. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT IT WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT(S). EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

12.9 No Consequential Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.9 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY'S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING CONFIDENTIALITY UNDER ARTICLE 10.

12.10 Indemnification and Insurance.

12.10.1 Indemnification by AEVI. AEVI will indemnify, hold harmless, and defend KKC, its Affiliates, and their respective directors, officers, employees and agents ("***KKC Indemnitees***") from and against any and all damages, losses, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments of any kind (collectively, "***Losses***") arising out of any Third Party claim, suit or proceeding, whether for money or equitable relief (each, a "***Third Party Claim***"), arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by AEVI in this Agreement, or any breach or violation of any covenant or agreement of AEVI or a Related Party in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of AEVI or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by AEVI or its Affiliate or sublicensee (including a sublicensed contract manufacturer) of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by AEVI or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from AEVI's exercise in accordance with the terms of this Agreement of any intellectual property rights granted by KKC hereunder. Furthermore, AEVI will have no obligation to indemnify the KKC Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly,

any matter for which KKC must indemnify AEVI under this Agreement. In addition, AEVI will indemnify, hold harmless, and defend (i) LJI and its directors, officers, employees, and agents from and against any and all Losses (including costs of investigation and court costs) arising at any time from or in any manner connected with, directly or indirectly, any activity of AEVI involving the KKC Patent Rights solely owned by LJI or any information furnished under the LJI Agreement, including the use, handling, storage, distribution, containment, sale and/or disposition of any product (whether or not a Licensed Product), or provision of any service, related to or derived directly or indirectly from or using any KKC Patent Rights solely owned by LJI; and (ii) the KKC Indemnitees from and against any and all Losses arising out of any Third Party Claims related to, directly or indirectly, any activities performed by or on behalf of AEVI or AEVI's Third Party contract manufacturer in connection with the exercise of rights under the KKC Technology licensed under the KKC In-License with Lonza, if, pursuant to Section 7.4.1, KKC sublicenses its rights under such KKC Technology to AEVI or AEVI's Third Party contract manufacturer for the Manufacture of Licensed Products by AEVI or such contract manufacturer.

12.10.2 Indemnification by KKC. KKC will indemnify, hold harmless, and defend AEVI, its Affiliates and their respective directors, officers, employees and agents ("**AEVI Indemnitees**") from and against any and all Losses arising out of any Third Party Claims arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by KKC in this Agreement, or any breach or violation of any covenant or agreement of KKC in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of KKC or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by KKC or its Affiliate or sublicensee of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by KKC or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from KKC's exercise in accordance with the terms of this Agreement of any intellectual property rights granted by AEVI hereunder. Furthermore, KKC will have no obligation to indemnify the AEVI Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any matter for which AEVI must indemnify KKC. In addition, KKC shall be bound by Section 12.2 of the AEVI In-License in the capacity of "Licensee" in respect of KKC and its Related Parties' activities under this Agreement and use of the AEVI Technology licensed under the AEVI In-License, and KKC agrees that the Indemnitees (as defined in Section 12.2 of the AEVI In-License) are intended third party beneficiaries of this sentence.

12.10.3 Indemnification Procedure. In the event of any such claim against any AEVI Indemnitee or KKC Indemnitee (individually, an "**Indemnitee**"), the indemnified Party will promptly notify the other Party in writing of the claim and the indemnifying Party will manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee will cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party will not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party's written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in

Section 12.10.1 or Section 12.10.2 may apply, the indemnifying Party will promptly notify the Indemnitees, which will then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party will be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. If the indemnifying Party does not assume the defense of such claim as described in this Section 12.10.3, above, the Indemnatee may defend such claim but will have no obligation to do so. The defending Party will not settle or compromise such claim without the prior written consent of the other Party, and will not settle or compromise such claim in any manner which would have an adverse effect on such other Party's interests, without the prior written consent of such other Party, which consent, in each case, will not be unreasonably withheld, conditioned, or delayed.

12.10.4 Insurance. Each Party will use its Commercially Reasonable Efforts to maintain insurance, including product liability insurance, with respect to its activities hereunder. Such insurance will be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time in order to fulfill the obligation under Section 12.10.1 or 12.10.2, including, but not limited to, the indemnification against any Losses involving any actual or alleged death or bodily injury arising out of or resulting from the Development, Manufacture or Commercialization of any Licensed Product.

Article 13.

MISCELLANEOUS PROVISIONS

13.1 Governing Law. This Agreement will be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York, New York, U.S.A., notwithstanding the provisions governing conflict of laws of any jurisdiction to the contrary.

13.2 Dispute Resolution.

13.2.1 With respect to any disputes between the Parties concerning this Agreement, the dispute will be submitted to escalating levels of AEVI and KKC senior management for review. If the dispute cannot be resolved despite such escalation, then the matter will be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers will be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party may submit such dispute for arbitration pursuant to Section 13.2.2.

13.2.2 Arbitration.

(a) If any dispute will arise between KKC and AEVI in connection with or relating to this Agreement, then such dispute will be resolved exclusively by and through an arbitration proceeding to be conducted under the auspices of, and pursuant to, the Commercial Rules of the International Chamber of Commerce (together with any successor organization thereto, the "**ICC**") in New York, New York, U.S.A. Such arbitration proceeding will be conducted in the

English language applying the law provided in Section 13.1 and in such an expedited manner as is then permitted by the ICC's commercial arbitration rules. The Parties also agree to take reasonable discovery, with reasonableness to be determined by the arbitrators. Each of the foregoing agreements to arbitrate all disputes and the results, determinations, findings, judgments and awards rendered through such arbitration will be final, non-appealable and legally binding on KKC and AEVI and may be entered and enforced by any court or tribunal of competent jurisdiction. Notwithstanding anything to the contrary in this Section 13.2, a Party may seek injunctive relief in any court of competent jurisdiction.

(b) Any arbitration proceeding will be initiated by written notice from either KKC or AEVI to the other Party. The arbitration will be conducted before a panel of three (3) arbitrators. Each of KKC and AEVI will have the right to select one (1) arbitrator. The third arbitrator will be selected by the mutual agreement of the arbitrators appointed by the Parties. The Party initiating the arbitration proceeding will appoint its arbitrator within ten (10) days following service of the demand for arbitration to the other Party, who will in turn appoint its arbitrator within thirty (30) days of receiving service of the demand. The two appointed arbitrators will agree upon an arbitrator within thirty (30) days of the date of the appointment by the parties of the second arbitrator. If either Party or their appointees fail to appoint an arbitrator within the specified time period, the ICC will exercise its powers pursuant to Article 9 of the ICC Rules of Arbitration to appoint such arbitrator. The ICC's appointment will be binding on the Parties. Each arbitrator will be an attorney in good standing in the Bar of New York and experienced in commercial disputes involving pharmaceutical companies. Time is of the essence of this arbitration procedure, and KKC and AEVI will instruct the arbitrators to render their decision within ninety (90) days of the arbitration's completion. The cost of the arbitration (including, without limitation, reasonable attorneys' fees, expenses and disbursements) will be borne as the arbitrators will decide; otherwise such costs (including, without limitation, the prevailing Party's reasonable attorneys' and accountants' fees, expenses and disbursements) will be borne by the Party against which the judgment of the arbitrator is to be enforced.

13.3 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party. Notwithstanding the foregoing, (a) KKC may monetize the value of its payments under this Agreement by assigning to a Third Party the right to receive payments and the right to receive payment reports from AEVI; provided that KKC gives thirty (30) days prior written notice to AEVI, and (b) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate (but subject to the consent of CHOP in respect of the AEVI Technology licensed under the AEVI In-License in the case of assignment by KKC) or pursuant to a Change of Control (but subject to the consent of Sanofi, to the extent required under Applicable Law, in respect of the KKC Technology licensed under the KKC In-License with Sanofi in the case of assignment by AEVI). The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned to such assignee.

13.4 Entire Agreement; Amendments. This Agreement and the Schedules and Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to

the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, except that Article 1 through 10 of the Clinical Development and Option Agreement will govern with respect to matters occurring prior to the Effective Date. Any amendment or modification to this Agreement will be made in writing signed by both Parties.

13.5 Notices. Any consent or notice required to be given or made under this Agreement by one of the Parties to the other will be in writing and (a) delivered by hand, (b) sent by internationally recognized overnight delivery service or (c) sent by facsimile transmission and confirmed by sender by prepaid, registered or certified mail letter, and will be deemed to have been properly served to the addressee upon receipt of such written communication, in any event to the following addresses:

If to KKC: Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Business Development Department
Facsimile No.: +81-3-5205-7129

with a copy to: Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Legal Affairs Group, Legal and Intellectual
Property Department
Facsimile No.: +81-3-5205-7130

If to AEVI: Aevi Genomic Medicine, LLC
435 Devon Park Drive, Bldg 700, Suite 715
Wayne, PA 19087
Attention: Chief Executive Officer
Facsimile No.: +1 (443) 304-8001

with a copy to: Pepper Hamilton LLP
Two Logan Square
18th & Arch Streets
Philadelphia, Pennsylvania 19103-2799
Attention: Brian M. Katz
Facsimile No.: +1 (215) 981-4750

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been

given: (a) if personally delivered, when delivered; (b) if sent by internationally-recognized overnight courier, on the Business Day of the sender during which the sender delivers the notice to the courier; or (c) if sent by facsimile, when all pages of the notice are successfully transmitted (as shown by a report generated by the sender's facsimile machine) during a Business Day of the sender.

13.6 Force Majeure. The failure of either Party to timely perform any obligation under this Agreement by reason of epidemic, earthquake, riot, civil commotion, fire, act of God, war, terrorist act, strike, flood, or governmental act or restriction, or other cause that is beyond the reasonable control of such Party, will not be deemed to be a breach of this Agreement, but will be excused to the extent and for the duration of such cause, and the affected Party will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and will use its Commercially Reasonable Efforts to avoid or remove such cause, and will perform its obligation(s) with the utmost dispatch when the cause is removed. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than one hundred eighty (180) days, the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

13.7 Compliance with Export Regulations. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

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

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

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

13.11 Performance by Affiliates. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided, however*, that such other Party will remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

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

13.13 No Implied Waivers; Rights Cumulative. No failure on the part of KKC or AEVI to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

13.14 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one (1) or several provisions of this Agreement will 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.

13.15 No Third Party Beneficiaries. Except as expressly set forth in Section 12.10.2, no person or entity other than AEVI, KKC and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[Remainder of Page Left Blank Intentionally. Schedules Follow.]

Schedule 1.5

AEVI IN-LICENSE

License Agreement between The Children's Hospital of Philadelphia and AEVI Medical Israel Ltd. dated November 12, 2014.

Schedule 1.10

AEVI PATENT RIGHTS

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Schedule 1.15

AMINO ACID SEQUENCE OF ANTI-LIGHT MAB

(***)

Schedule 1.24

Commercialization Costs

Examples of Commercialization Costs

Commercialization Costs will include, but will not be limited to, the following, in each case attributable to, or reasonably allocable to, Commercialization of Licensed Products in the Field in the Territory:

Detailing costs - costs associated with interactive face-to-face visits by a sales representative with a medical professional who has prescribing authority or is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses.

Distribution costs - costs identifiable to the distribution of a Licensed Product to a customer (and not otherwise deducted from Net Sales), including customer and specialty pharmacy services (including costs associated with establishing and running customer call centers), collection of data about sales to hospitals, clinics and other customers, order entry, billing, shipping, logistics, warehousing, product insurance, freight not paid by customers, credit and collection and other like activities the costs of which are includable in “distribution costs” in accordance with the Accounting Standards.

Early Access Program or EAP costs – costs associated with any program to provide patients with products free of charge. Early access programs include treatment INDs / protocols and compassionate use programs, as applicable. For clarity, an EAP with respect to a Licensed Product may continue to be performed following Regulatory Approval of a Licensed Product and costs may continue to be incurred in accordance with the performance of such EAP after Regulatory Approval.

Patient Assistance Programs – costs associated with establishing and administering patient assistance programs.

Health Care Reform fees - costs for fees paid to the U.S. government as defined in the Patient Protection and Affordable Care Act and similar taxes and governmental fees.

Commercial Operations Costs – costs of the commercial operations team supporting Commercialization of the Licensed Products in the Field, including, without limitation:

(a) **Marketing Expenses**, which includes costs identifiable to the advertising, promotion and marketing of Licensed Products in the Field, and related professional education;

(b) **Advertising**, which includes costs associated with media costs, direct mails, production expenses, agency fees, and medical congresses and meetings;

(c) **Promotion**, which includes costs associated with professional samples, professional literature, promotional material, patient aids, detailing aids, reimbursement of patient assistance programs, public relations and communications expenses, web and social media expenses, patient advocacy support, development of information and data for national accounts, managed care organizations and group purchasing organizations;

(d) **Market Research**, which includes costs associated with market information, focus groups, and market research professional staff and related out-of-pocket costs such as travel, business meals, and training;

(e) **Marketing Management**, which includes the costs of product management and sales promotion management compensation and departmental expenses as well as costs associated with developing overall sales and marketing strategies and planning;

(f) **Reimbursement/Access Services**, which includes costs incurred to manage reimbursement programs, marketing costs (educational material) as well as coupon or co-pay programs;

(g) **Health Policy/Advocacy**, which includes costs associated with advocacy as well as any specific policy lobbying and trade and government relations related expenses; and

(h) **Selling Support**, which includes costs associated with logistics and document support and the operation of the sales/medical science liaison team such as meeting planning.

Medical Affairs Expenses - costs with respect to: medical affairs and other activities associated with clinical studies conducted after Regulatory Approval in the Territory (to the extent not otherwise included within Development Costs); medical and scientific information and response to external inquiries or complaints; pharmacovigilance, investigator initiated research if not covered in the Phase V Clinical Trials, costs of establishing and maintaining patient registries, medical education, Health Economics and Outcomes Research (HECOR, HEMAR), speaker programs, advisory boards, educational grants and fellowships, drug safety, government affairs (including costs associated with compliance with the Sunshine Act and other similar government regulation); and field-based medical science liaisons, medical affairs clinical trial management, MD's in field (separate from medical science liaisons), publications, medical communications and field medical education.

Recall Expenses – costs, to the extent not otherwise covered by KKC's indemnity obligations, associated with notification, retrieval and return of Licensed Products in the Field in the Territory, destruction of such returned Licensed Products in the Field, and distribution of the replacement Licensed Products in the Field.

Selling Costs - costs directly attributable to selling Licensed Product in the Field, including the FTE Costs for sales representatives/medical science liaisons and first line sales managers, exhibits at shows or conventions including samples, charges for space, sales aids and brochures, sales meetings, consultants, call reporting and other Third Party monitoring/tracking services, automobile allowance, meal expenses, travel/housing for meetings, costs of computer and other

equipment of sales representatives/medical science liaisons and other incidental expenses incurred by sales representatives/medical science liaisons in respect of selling the Licensed Product in the Field.

Other Commercialization Costs - any other costs attributable or allocable to Commercialization of Licensed Products in the Field in the Profit Share Territory in accordance with Accounting Standards, to the extent not included in one of the other categories or definitions of costs under this Exhibit 1.24.

Schedule 1.45

FTE Rates

1. The following table sets forth the FTE Rates for AEVI FTEs:

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2. The following table sets forth the FTE Rates for KKC FTEs:

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(***)	(***)
(***)	(***)
(***)	(***)

Schedule 1.50

KKC IN-LICENSES

License Agreement between La Jolla Institute for Allergy and Immunology and Kyowa Hakko Kirin Co., Ltd. (***). This is the LJI Agreement referred to in Section 1.60.

(***) Agreement between Lonza Sales AG and Kyowa Hakko Kirin Co., Ltd. (***).

(***) Agreement between Bristol-Myers Squibb Company and Kyowa Hakko Kirin Co., Ltd. (***).

Letters between Kyowa Hakko Kirin Co., Ltd. and Sanofi (***), and sublicensing of rights to AEVI.

Schedule 1.54

KKC PATENT RIGHTS

[illegible]

EXHIBIT D
RESERVED

EXHIBIT E
ANTI-LIGHT ANTIBODIES AND RELATED CELLS
(***)

EXHIBIT F
COVID STUDY PROTOCOL

(***)

EXHIBIT G
PLAN C LICENSE AGREEMENT

See Attached

LICENSE AGREEMENT

by and between

KYOWA KIRIN CO., LTD.

and

AEVI GENOMIC MEDICINE, LLC

<u>Article 1. DEFINITIONS</u>	1
<u>Article 2. EFFECTIVENESS OF THIS AGREEMENT</u>	15
<u>Article 3. GOVERNANCE</u>	15
<u>Article 4. DEVELOPMENT</u>	17
<u>Article 5. COMMERCIALIZATION</u>	20
<u>Article 6. DILIGENCE</u>	22
<u>Article 7. LICENSES</u>	22
<u>Article 8. FINANCIAL PROVISIONS</u>	25
<u>Article 9. INTELLECTUAL PROPERTY</u>	31
<u>Article 10. CONFIDENTIALITY</u>	40
<u>Article 11. TERM AND TERMINATION</u>	42
<u>Article 12. REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION</u>	50
<u>Article 13. MISCELLANEOUS PROVISIONS</u>	56

Schedules

Schedule 1.13 – Amino Acid Sequence of Anti-Light mAb
Schedule 1.23 – Commercialization Costs
Schedule 1.43 – FTE Rates
Schedule 1.48 – KKC In-Licenses
Schedule 1.52 – KKC Patent Rights

LICENSE AGREEMENT

This License Agreement (this “**Agreement**”), effective as of the Effective Date (as defined in Section 2.1), is by and between Kyowa Kirin Co., Ltd., a company organized and existing under the laws of the Japan and having its principal office at 1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan and formerly known as Kyowa Hakko Kirin Co., Ltd. (“**KKC**”), and Aevi Genomic Medicine, LLC, a Delaware limited liability company and successor to Medgenics, Inc., a Delaware corporation (“**AEVI**”). KKC and AEVI may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

INTRODUCTION

WHEREAS, the Parties have entered into the Amended and Restated Clinical Development and Option Agreement, effective as of May 28, 2020 (the “**Clinical Development and Option Agreement**”); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct the Initial Development (as defined in the Clinical Development and Option Agreement) with respect to Anti-LIGHT mAb (as defined in Section 1.13); and

WHEREAS, pursuant to the Clinical Development and Option Agreement, KKC granted AEVI the right to conduct one or more signal finding studies of the Anti-LIGHT mAb in the Field (as defined in Section 1.39) and an option to obtain an exclusive license to Develop, Manufacture and Commercialize products containing Anti-LIGHT mAb in the Field at Aevi’s election under the terms and conditions of this Agreement (the “**Plan C Election**”); and

WHEREAS, this Agreement will become fully effective in accordance with Section 2.1 of this Agreement only upon AEVI making the Plan C Election pursuant to the terms and conditions of the Clinical Development and Option Agreement; and

WHEREAS, this Agreement will not become effective and be rendered null and void in accordance with Section 2.2 of this Agreement.

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

Article 1.

DEFINITIONS

When used in this Agreement, each of the following terms will have the meanings set forth in this Article 1:

1.1 “*Accounting Standards*” means with respect to a Party, as applicable, (a) United States generally accepted accounting principles (“**GAAP**”), (b) Japanese generally accepted accounting standards, or (c) International Financial Reporting Standards, in each case consistently applied.

1.2 “*Acquirer Intellectual Property*” means the Patent Rights and Know-How owned or controlled by a Third Party acquirer of AEVI or KKC, as the case may be, immediately prior to a Change of Control transaction, and Inventions thereto following the effective date of such Change of Control.

1.3 “*Administrative Contact*” means any contact to or from a Regulatory Authority that is general or administrative in nature (e.g., notification by a Regulatory Authority of the assignment of a new reviewer or a notification of a new address or new contact information).

1.4 “*AEVI Business Day*” means a day on which banking institutions in New York, New York are open for business other than Saturday or Sunday.

1.5 “*AEVI Inventions*” means any and all Inventions made or generated hereunder solely by employees or contractors of AEVI (or its Affiliates), as determined by the United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.6 “*AEVI Know-How*” means Know-How that is (a) Controlled by AEVI or any of its Affiliates on the Effective Date or during the Term (other than KKC Know-How pursuant to the licenses granted hereunder) and (b) reasonably necessary or useful in connection with Development, Manufacture, use or Commercialization of Licensed Products.

1.7 “*AEVI Lonza License Agreement*” means an agreement between AEVI and Lonza that licenses to AEVI the intellectual property rights subject to the (***) Agreement between Lonza and KKC (***), to the extent related to the Licensed Product in the Field in the Territory and the European Union, including the right to sublicense to another contract manufacturer such that such contract manufacturer can perform process development and supply of anti-LIGHT-mAb.

1.8 “*AEVI Patent Rights*” means (a) any Patent Rights included within AEVI Inventions that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products and (b) any Patents Rights included in Third Party Technology (i) in respect of which AEVI obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products.

1.9 “*AEVI Technology*” means AEVI Know-How, AEVI Patent Rights and AEVI Inventions other than Acquirer Intellectual Property.

1.10 “*Affiliate*” means, with respect to any person or entity, any other person or entity which controls, is controlled by, or is under common control with such person or entity. A person or entity will be regarded as in control of another entity if it owns or controls more than fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.11 “*Allowable Expenses*” means, with respect to Profit-Share Products and each Contract Quarter, all FTE Costs and Out-of-Pocket Costs incurred by AEVI or its Related Parties that are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory, and Manufacture of such Profit-Share Products for Commercialization, during the applicable Contract Quarter, including such FTE Costs and Out-of-Pocket Costs which are: (a) Manufacturing Costs; (b) Commercialization Costs; and (c) Third Party Technology Costs, in each case determined from the books and records of AEVI or its

Related Parties maintained in accordance with Accounting Standards and in each case of (a)-(c) as are specifically identifiable and allocable to the Commercialization of such Profit-Share Products in the Field in the Territory during the applicable Contract Quarter. For clarity, no milestone payment made to KKC or its Affiliates pursuant to Section 8.3 will be an Allowable Expense. For purposes of clarity, it is understood that there will be no double-counting of expenses within the definition of Allowable Expenses.

1.12 “*Applicable Law*” means the laws, rules and regulations, including without limitation any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, Manufacturing or Commercialization of Licensed Products or other activities conducted by the Parties under this Agreement, that may be in effect from time to time in the applicable territory.

1.13 “*Anti-LIGHT mAb*” means the fully human monoclonal antibody targeting LIGHT (TNFSF14) consisting of the amino acid sequence set forth on Schedule 1.13.

1.14 “*Bankruptcy Code*” means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.15 “*BARDA*” means the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services.

1.16 “*Biosimilar*” means, with respect to a reference brand biologic product and a particular jurisdiction, a biologic product: (a) that is highly similar to such reference brand biologic product notwithstanding minor differences in clinically inactive components; (b) has no clinically meaningful differences from such reference brand biologic product in terms of safety, purity and potency; and (c) for which a Biosimilar Application is approved by the relevant Regulatory Authority of such jurisdiction. Notwithstanding anything to the contrary in this Agreement, a “Biosimilar” does not include any biologic product sold under a BLA or approved Biosimilar Application of any Party or any of its Related Parties or manufactured or produced by or on behalf of a Party or any of its Related Parties.

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

1.18 “*BLA*” means a Biologics License Application filed with FDA or the equivalent thereof filed with any other Regulatory Authority.

1.19 “*BMS*” means Bristol-Myers Squibb Company.

1.20 “*Business Day*”

means, with respect to KKC, a KKC Business Day, and, with respect to AEVI, an AEVI Business Day.

1.21 “*Change of Control*” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates.

1.22 “*Commercialization*” means importing, exporting, marketing, promoting, distributing, offering for sale and selling a Licensed Product in the Field and will include activities required to fulfill ongoing post-approval regulatory obligations, including adverse event reporting and sales force training but excluding any Phase 4 Clinical Trial (as defined in Section 1.31). When used as a verb, “*Commercialize*” will mean to engage in Commercialization.

1.23 “*Commercialization Costs*” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of AEVI or its Related Parties in accordance with this Agreement and attributable to, or reasonably allocable to, the Commercialization of the Licensed Products in the Field in the Territory, including marketing costs, sales costs, distribution costs, importing and exporting costs, Phase 5 Clinical Trial costs, insurance costs incurred in connection with Commercialization activities, medical affairs costs and certain general and administrative costs (but excluding Development Costs) as further defined in Schedule 1.23. In this Agreement, “*Phase 5 Clinical Trial*” means a post-registration clinical trial that is not required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.24 “*Commercially Reasonable Efforts*” means, with respect to a Party, the carrying out of obligations in a diligent and sustained manner using such effort and employing such resources as would normally be exerted or employed by a similarly situated biopharmaceutical company for a product of similar commercial or strategic importance, and at a similar stage of its product life, based on conditions then prevailing, taking into consideration safety and efficacy, development costs, the anticipated prescription label, the nature of the Licensed Product, the clinical setting in which it is expected to be used and all other relevant factors. Commercially Reasonable Efforts will be determined on a country-by-country basis.

1.25 “*Confidential Information*” means, with respect to each Party, proprietary data or information of such Party or its Affiliates or sublicensees, including, without limitation, (a) with respect to KKC, all KKC Technology, and, with respect to AEVI, all AEVI Technology, (b) any information designated as Confidential Information of such Party hereunder, in all cases that is identified as confidential either in writing or orally, provided that any orally disclosed information is described in reasonable detail in a written notice sent by the Disclosing Party to the Receiving Party within thirty (30) days of the oral disclosure requesting that such information

be treated as Confidential Information hereunder, and (c) all information that is manifestly confidential, whether or not marked as such.

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

1.27 “*Contract Year*” means the twelve (12) month period beginning on January 1 and ending on December 31 of each calendar year, provided, however, that the first Contract Year will be the period of time beginning on the Effective Date and ending on December 31, 2020. Each Contract Year, except the first Contract Year, will be divided into four (4) Contract Quarters.

1.28 “*Control*” or “*Controlled*” means with respect to any (a) material, item of information, method, data or other Know-How, or (b) intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by the referenced Party or its Affiliates of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing before or after the Effective Date.

1.29 “*Data Exclusivity Period*” means, with respect to a particular jurisdiction, the time period of legal protection and confidential treatment provided for clinical test data required to be submitted to a Regulatory Authority for such jurisdiction in order to demonstrate safety and efficacy of a new drug or biologic, and all similar protections on such clinical test data intended to prevent generic drug manufacturers or biosimilar manufacturers from relying on this data in their own Biosimilar applications.

1.30 “*Development*” means, with respect to a Licensed Product in the Field, non-clinical and clinical drug development activities performed on or after the Effective Date, including without limitation the conduct of clinical trials, test method development, toxicology, pharmacology, pharmacokinetics formulation, data management, statistical analysis and report writing and clinical studies, and regulatory affairs and all activities associated with obtaining and maintaining Regulatory Approvals. When used as a verb, “Develop” means to engage in Development.

1.31 “*Development Costs*” means all costs and expenses, including FTE Costs and Out-of-Pocket Costs, incurred by or on behalf of a Party in accordance with this Agreement and attributable to, or reasonably allocable to, the Development of the Licensed Products in the Field in the Territory and that are materially consistent, as applicable, with the Development Plan, including costs and expenses for Regulatory Approvals and pricing and/or reimbursement approvals, and costs incurred after Regulatory Approval, including Phase 4 Clinical Trial costs, costs of non-clinical studies, costs of clinical studies for additional Indications in the Field, insurance costs incurred in connection with Development activities (but excluding costs that are allocable to Commercialization Costs and the costs of general company management, financial, legal or business development personnel). Development Costs will not include any costs incurred by either Party prior to the Effective Date, including, without limitation, costs for purchasing raw materials, for manufacturing clinical supplies of Licensed Product or for any

labeling or packaging materials, whether or not such raw materials, clinical supplies or labeling or packaging materials are used by the Parties for Development activities after the Effective Date. In this Agreement, “*Phase 4 Clinical Trial*” means a post-registration clinical trial or post-marketing surveillance study performed in accordance with Applicable Laws and required as a condition to, or for the maintenance of, any Regulatory Approval or pricing and/or reimbursement approval for a Licensed Product.

1.32 “*Development Plan*” means (a) the written comprehensive plan for (i) the Development of any Licensed Product in the Field in the Territory, including, but not limited to, activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing Regulatory Approval Applications in the Territory and (ii) the preparation and submission of related Regulatory Approval Applications in the Territory and (b) an annual budget for Development Costs setting forth both internal and external resources and expenses for the then-current Contract Year.

1.33 “*EMA*” means the European Medicines Agency and any successor agency having substantially the same functions.

1.34 “*European Union*” means all countries over which EMA has jurisdiction from time to time and all countries that exit the jurisdiction of the EMA from time to time.

1.35 “*Executive Officers*” means the Chief Executive Officer of AEVI (or an executive of AEVI designated by such Chief Executive Officer) and the Chief Executive Officer of KKC (or an executive of KKC designated by such Chief Executive Officer).

1.36 “*Fair Market Value*” means (a) with respect to investment by a Third Party in exchange for equity securities of AEVI, (i) for so long as AEVI’s common stock is publicly traded on a securities exchange, the volume weighted average closing price of a share of AEVI’s common stock on the principal exchange on which such stock is then trading for the ten (10) trading days ending on the date that is twenty (20) trading days on such exchange prior to the first public announcement of such equity investment, and (ii) if AEVI’s common stock is no longer publicly traded on a securities exchange, the fair market value of a share of common stock of AEVI as of the date of closing such investment as determined in good faith by the board of directors of AEVI, taking into account such factors and for such time period as the board of directors of AEVI reasonably deems is appropriate, and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned, and (b) with respect to any non-cash consideration (other than equity securities), the fair market value of such consideration as determined in good faith by the board of directors of AEVI and agreed to by KKC, such agreement not to be unreasonably withheld, delayed, or conditioned.

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

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

1.39 “*Field*” means treatment, prevention, and diagnosis of (**).

1.40 “*First Commercial Sale*” means, with respect to a given Licensed Product in a country, the first commercial sale in an arms-length transaction of such Licensed Product to a Third Party by or on behalf of a Party, its Affiliate or its sublicensee in such country following receipt of applicable Regulatory Approval of such Licensed Product in such country.

1.41 “*FTE*” means a full time equivalent person year (consisting of a total of two thousand (2,000) hours per Contract Year, subject to a proportionate reduction in the first Contract Year) of scientific, technical, marketing, sales, distribution and certain general and administrative activities related to the Development of Licensed Products and/or the Commercialization of the Licensed Products in the Field in accordance with this Agreement. For the avoidance of doubt, no individual will count as more than one (1) FTE, and any individual who works less than two thousand (2,000) hours in a given Contract Year performing activities under this Agreement will be counted as a fraction of one (1) FTE, the numerator of which is the number of hours such individual performs activities under this Agreement and the denominator of which is two thousand (2,000) hours.

1.42 “*FTE Costs*” means all costs for FTEs calculated by multiplying (a) the actual number of FTEs utilized by KKC or AEVI in performing activities in accordance with any Development Plan and/or Commercialization Plan by (b) the applicable FTE Rate, provided that, to the extent either Party is unable to fully track the number of FTEs utilized, the Parties will agree on a mechanism for estimating such number.

1.43 “*FTE Rate*” means, with respect to an FTE, the applicable amount set forth on Schedule 1.43, as such amount may be adjusted pursuant to Section 8.7.

1.44 “*IND*” means an Investigational New Drug Application, as defined in the FD&C Act, or similar application or submission that is required to be filed with any Regulatory Authority before beginning clinical testing of a Licensed Product in human subjects.

1.45 “*Inventions*” means any and all ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable or copyrightable, and all Patent Rights and other intellectual property rights in any of the foregoing.

1.46 “*Joint Inventions*” means any and all Inventions made or generated hereunder jointly by at least one employee or contractor of each Party (or its respective Affiliates), as determined by United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.47 “*KKC Business Day*” means a day on which banking institutions in Tokyo, Japan are open for business other than a Saturday or Sunday.

1.48 “*KKC In-Licenses*” means the Third Party agreements listed on Schedule 1.48.

1.49 “*KKC Inventions*” means any and all Inventions made or generated hereunder solely by employees or contractors of KKC (or its Affiliates), as determined by the United States patent laws for inventorship, in each case while performing activities under this Agreement.

1.50 “*KKC Know-How*”

means Know-How that is (a) Controlled by KKC on the Effective Date or during the Term (other than AEVI Know How pursuant to the licenses granted hereunder) and (b) is reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory.

1.51 “*KKC Licensor*”

means LJI, BMS, Lonza, and Sanofi, respectively defined in this Article 1, and its respective successor and assigns, which has licensed rights to KKC pursuant to the KKC In-Licenses.

1.52 “*KKC Patent Rights*”

means (a) the United States and foreign patents and patent applications listed on Schedule 1.52 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (b) the United States and foreign patents and patent applications licensed to KKC under the KKC In-Licenses but not listed on Schedule 1.52 and any Patent Rights arising from those patents and patent applications prior to the completion of the Term, (c) any Patent Rights included within KKC Inventions prior to the completion of the Term that are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory and (d) any Patents Rights included in Third Party Technology prior to the completion of the Term (i) in respect of which KKC obtains Control after the Effective Date and (ii) are reasonably necessary or useful in connection with the Development, Manufacture, use or Commercialization of Licensed Products in the Field in the Territory.

1.53 “*KKC Technology*”

means KKC Patent Rights, KKC Know-How and KKC Inventions other than Acquirer Intellectual Property.

1.54 “*Know-How*”

means any non-public, proprietary invention, discovery, process, method, composition, formula, procedure, protocol, technique, result of experimentation or testing, information, data, material, technology or other know-how, whether or not patentable or copyrightable.

1.55 “*Licensed Product*”

means any product containing as an active ingredient the Anti-LIGHT mAb.

1.56 “*LIGHT*”

means TNFSF14 (Unigene cluster number: Hs. 129708).

1.57 “*LJI*”

means La Jolla Institute for Immunology (formerly, La Jolla Institute for Allergy and Immunology) and its respective successor and assigns, which has licensed rights to KKC pursuant to the LJI Agreement.

1.58 “*LJI Agreement*”

means License Agreement between La Jolla Institute for Immunology and Kyowa Hakko Kirin Co., Ltd. (***)

1.59 “*Lonza*”

means Lonza Sales AG and its Affiliates.

1.60 “*Manufacturing*”

means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of Licensed Products and including without limitation process and formulation development, process validation, stability testing, process development, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control, whether such activities are conducted by a Party, its Affiliates or a Third Party contractor of such Party. When used as a verb, “*Manufacture*” will mean to engage in Manufacturing.

1.61 “*Manufacturing Costs*”

means:

(a) With respect to Licensed Product manufactured by AEVI, its fully-burdened costs (including the costs associated with product testing and release activities) of producing (including startup and validation but excluding what will be covered under Section 4.3.2) and packaging Licensed Product for sale in a given country, determined in accordance with the applicable Accounting Standard, based on the sum of the following components: (i) direct costs, including manufacturing labor and materials directly incurred in producing and packaging such Licensed Product; (ii) manufacturing and accounting personnel costs incurred by AEVI and attributable and reasonably allocable to the manufacture of Licensed Product, including quality labor and manufacturing and quality supervisory services, depreciation, and other operating and administrative costs which of the manufacturing, quality and accounting departments and

associated occupancy costs which are allocable to such company departments based on space occupied or headcount, or other activity based method of allocation; (iii) any other reasonable and customary Out-of-Pocket Costs incurred by AEVI for the testing, transport, customs clearance, duty, insurance and/or storage of such Licensed Products, including payments made by AEVI to Third Parties for filing, finishing, packaging, labeling, testing, storage and shipment of such Licensed Product and AEVI's handling cost with respect thereto, as applicable; and (iv) AEVI's reasonably allocated share of cost of Licensed Product process improvements developed by AEVI or a Third Party on behalf of AEVI. For Licensed Products manufactured by AEVI, Manufacturing Cost will not include any general corporate overhead, any excess capacity cost or charges or cost for process development (except to the extent expressly provided above).

(b) With respect to Licensed Product manufactured for AEVI by one or more Third Parties and supplied to KKC hereunder amounts actually paid (net of any discounts, credits or refunds) by such Party to such Third Parties for the manufacture and supply of such Licensed Product.

1.62 "*Medical Affairs Activities*" means, with respect to a Licensed Product, activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, such Licensed Product, including, with respect to such Licensed Product: (a) conducting service based medical activities including providing input and assistance with consultancy meetings, recommending investigators for clinical trials and providing input in the design of such trials and other research related activities, and delivering non-promotional communications and conduct non-promotional activities including presenting new clinical trial data and other scientific information; (b) grants to support continuing medical education, symposia, or Third Party research specifically related to such Licensed Product; (c) development, publication and dissemination of publications relating to such Licensed Product and relevant disease states; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call or email; (e) conducting advisory board meetings or other consultant programs; (f) support of investigator-initiated clinical trials; (g) managing relationships with cooperative groups, physician/hospital networks and advocacy groups; and (h) establishing and implementing risk, evaluation and mitigation strategies.

1.63 "*Net Sales*" means the gross invoiced sales by a Party and/or its Related Parties to Third Parties for Licensed Products sold, less deductions, consistent with applicable Accounting Standards used in the applicable reporting period for such Party's consolidated financial reporting purposes, which will be limited to: (a) price adjustments, chargeback payments, credits, or rebates (or the equivalent thereof), allowances allowed and taken, quantity or other trade discounts and other amounts paid on sale of Licensed Products, including those granted to and actually used by group purchasing organizations or other buying groups, managed healthcare organizations, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other healthcare institutions (including hospitals), Third Party health care administrators or patient assistance or other similar program, or to federal, state/provincial, local and other governments, including their agencies, or to wholesalers, distributors and other trade customers; (b) sales, use, tariffs, value-add, and/or excise taxes, or other governmental charges and tariffs incurred in connection with

exportation or importation directly imposed and with reference to particular sales; (c) reasonable and customary freight, postage, shipping, insurance and other transportation expenses and delayed ship order credits reflected in the applicable invoice and paid by the customer; and (d) amounts allowed, repaid or credited due to defects, returns, rejections, recalls, rebates and replacements and allowances of goods or because of retroactive price reductions; (e) normal and customary rebates, trade, cash or quantity discounts; billing errors; coupons for price reductions; (f) required distribution commissions/fees payable to Third Party wholesalers for distribution of the Licensed Products; (g) allowance and write-offs for bad debt made in accordance with generally accepted accounting principles, consistently applied to all of such Party's products; (h) discounts pursuant to indigent patient programs and patient discount programs including coupon discounts; and (i) any item, substantially similar in character or substance to any of the foregoing permitted by the applicable Accounting Standards and customary in the pharmaceutical industry. Net Sales also includes the Fair Market Value of any non-cash consideration received in connection with the sale of the Licensed Products. In the case of any sale of Licensed Product for value other than in an arm's length transaction exclusively for cash, Net Sales will be determined by referencing Net Sales at which substantially similar quantities of such Licensed Product are sold in an arm's length transaction for cash. For purposes of calculating Net Sales, transfers of Licensed Product between a Party and its Related Parties, whether or not value is exchanged therefor, will not be booked as sales.

1.64 "*Out-of-Pocket Costs*" means, with respect to specified activities hereunder, direct expenses paid or payable by a Party or its Related Parties to Third Parties (other than employees of such Party or its Related Parties) that are specifically identifiable and incurred to conduct such activities.

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

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

1.67 "*Product Labels and Inserts*" means (a) all labels and other written, printed or graphic matter affixed to any container, packaging or wrapper utilized with Licensed Product, or (b) any written material physically accompanying Licensed Product, including product package inserts.

1.68 "*Product Trademarks*" means the trademark(s), service mark(s), accompanying logos, trade dress and/or indicia of origin used in connection with the Commercialization of each Licensed Product in the Territory. For purposes of clarity, the term Product Trademark(s) will not include, without limitation, the corporate names and logos of either Party, and will include any internet domain names incorporating such Product Trademarks.

1.69 “*Profit*” means with respect to all Profit-Share Products with respect to a Contract Quarter and a country in the Territory: (a) Net Sales of such Profit-Share Products in the Field in the Territory by AEVI and its Affiliates, plus (b) Profit-Share Product Proceeds, minus (c) Allowable Expenses, to the extent such deductions have not already or otherwise been deducted in calculating the amounts described in (a) and (b) above. If a calculation of Profit for a given Contract Quarter pursuant to the preceding sentence would result in a negative number, the amount of such Profit for such Contract Quarter will be zero (0).

1.70 “*Profit-Share Product*” means a Licensed Product Commercialized by AEVI or its Related Parties in the Territory.

1.71 “*Profit-Share Product Proceeds*” means, with respect to Profit-Share Products, any proceeds received by AEVI or its Affiliates from Third Parties with respect to the Development, Manufacture, supply, or Commercialization of such Profit-Share Products in the Field in the Territory, including proceeds attributable to a grant of a license or sublicense, or a grant of distribution rights, to permitted sublicensees and distributors under this Agreement, to Develop, Manufacture or Commercialize such Profit-Share Products (or, if rights in addition to such rights to such Profit-Share Products are granted to such Third Party, then reasonably allocated to the rights granted to such Third Party with respect to such Profit-Share Products). In the event any Third Party sublicensee makes a bona fide investment in any equity securities issued by AEVI or any of its Affiliates, the cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in exchange therefor will be excluded from the calculation of Profit-Share Product Proceeds, up to the Fair Market Value of such equity securities, and the sum of any cash consideration and the Fair Market Value of any non-cash consideration received by AEVI and its Affiliates in excess of the Fair Market Value of such equity securities will be included in the calculation of Profit-Share Product Proceeds.

1.72 “*Regulatory Approval*” means the approval of the applicable Regulatory Authority necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Licensed Product in a regulatory jurisdiction, including, where required, separate pricing and/or reimbursement approvals.

1.73 “*Regulatory Approval Application*” means an application submitted to the appropriate Regulatory Authority seeking Regulatory Approval of a Licensed Product in a regulatory jurisdiction, including without limitation a BLA.

1.74 “*Regulatory Authority*” means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council or other government entity involved in granting of Regulatory Approval for a Licensed Product in a regulatory jurisdiction, including without limitation the FDA and the EMA.

1.75 “*Regulatory Materials*” means any regulatory submissions, notifications, registrations, approvals and/or other filings and correspondence made to or with a Regulatory Authority, and any other records required to be maintained for possible audit by a Regulatory Authority, that may be necessary or reasonably desirable to Develop, Manufacture, or Commercialize Licensed Products in the Territory.

1.76 “*Related Party*” means, with respect to a Party, such Party’s Affiliates and permitted licensees and sublicensees, which term does not include wholesale distributors of such Party or its Affiliates, which distributors purchase a Licensed Product from such Party or its Affiliates in an arm’s-length transaction.

1.77 “*Royalty-Bearing Sales*” means Net Sales by KKC and its Affiliates of Licensed Products worldwide.

1.78 “*Sanofi*” means Sanofi, successor in interest to Sanofi-Aventis.

1.79 “*Significant Impact*” means a decrease in AEVI’s and its Related Parties’ Net Sales of Licensed Products (***).

1.80 “*Substantive Contact*” means any contact to or from a Regulatory Authority that is not an Administrative Contact.

1.81 “*Sublicensing Royalties*” means royalties and sales milestones received by KKC from its licensees or sublicensees on Net Sales by such licensees or sublicensees of Licensed Products worldwide.

1.82 “*Territory*” means worldwide.

1.83 “*Third Party*” means any person or entity other than a Party or any of its Affiliates.

1.84 “*Third Party Technology*” means any Patent Rights, Know-How, inventions, or other intellectual property owned, in whole or in part, by or licensed to a Third Party.

1.85 “*Third Party Technology Costs*” means, with respect to a Profit-Share Product, royalties, license fees or other payments, as applicable, that are made to any Third Party for the use of any Third Party Technology and are reasonably allocable to and reasonably necessary or useful for, the Development, Manufacturing or Commercialization of such Licensed Product in the Field in the Territory. For the avoidance of doubt:

(a) the amounts payable to the KKC Licensors under the KKC In-Licenses are Third Party Technology Costs, provided however that:

(i) with respect to payments paid by KKC to LJL (***), only payments stipulated in paragraphs (1) and (3) of Section 12 of such addendum will be included in the Third Party Technology Costs and all other costs such as milestone payments will be solely borne by KKC and not included in Third Party Technology Costs;

(ii) with respect to payments paid by KKC to Lonza (***), only payments stipulated in Section 5.2 of such agreement will be included in the Third Party Technology Costs and all other costs except for annual maintenance fee which is stipulated in Section 8.6.4(b) in this Agreement, will be solely borne by KKC and not included in Third Party Technology Costs;

(iii) with respect to payments paid by KKC to BMS (***), only payments stipulated in Section 10.6.1(a)(i) of such agreement will be included in the Third Party Technology Costs and all other costs will be solely borne by KKC and not included in Third Party Technology Costs;

(b) the amounts payable by AEVI as royalties under the AEVI Lonza License Agreement shall be treated as Third Party Technology Costs; and

(c) the amounts payable for obtaining rights to Third Party Technology for the Territory under Section 9.5 are Third Party Technology Costs.

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

<u>Term</u>	<u>Section</u>
<i>“AEVT”</i>	Preamble
<i>“AEVI Indemnitees”</i>	12.10.2
<i>“Agreement”</i>	Preamble
<i>“Audited Party”</i>	8.6.6
<i>“BARDA Contract”</i>	7.7
<i>“BPCIA”</i>	9.6.2
<i>“Challenge”</i>	11.2.3
<i>“Clinical Development and Option Agreement”</i>	Introduction
<i>“Commercialization Plan”</i>	5.2
<i>“Co-Chairperson”</i>	3.1.1(b)
<i>“Controlling Party”</i>	9.3.3
<i>“Cooperating Party”</i>	9.3.3
<i>“Defending Party”</i>	9.4.2(a)
<i>“Defensive Actions”</i>	9.3.2
<i>“Disclosing Party”</i>	10.1.1
<i>“Effective Date”</i>	2.1
<i>“Enforcement Expense”</i>	9.3.3
<i>“EU5 Countries”</i>	6.2
<i>“GAAP”</i>	1.1
<i>“ICC”</i>	13.2.2(a)
<i>“Indemnitee”</i>	12.10.3
<i>“Infringement Claim”</i>	9.4.1
<i>“Inspecting Party”</i>	5.3.3
<i>“IP”</i>	11.7
<i>“Joint Patent”</i>	9.2.2
<i>“Joint Steering Committee” or “JSC”</i>	3.1.1
<i>“KKC”</i>	Preamble

“ <i>KKC Indemnitees</i> ”	12.10.1
“ <i>KKC Managed Patent Rights</i> ”	9.2.1
“ <i>Losses</i> ”	12.10.1
“ <i>Party</i> ” or “ <i>Parties</i> ”	Preamble
“ <i>Phase 3 Clinical Trial</i> ”	4.2.4
“ <i>Phase 4 Clinical Trial</i> ”	1.31
“ <i>Phase 5 Clinical Trial</i> ”	1.23
“ <i>Plan A Election</i> ”	Introduction
“ <i>Plan B Election</i> ”	Introduction
“ <i>Plan C Election</i> ”	Introduction
“ <i>Prosecuting Party</i> ”	9.2.2
“ <i>Publications</i> ”	10.2.2
“ <i>Receiving Party</i> ”	10.1.1
“ <i>Recoveries</i> ”	9.3.3
“ <i>Reference Product Sponsor</i> ”	9.6.2
“ <i>Requesting Party</i> ”	8.6.6
“ <i>Section 351(k) Applicant</i> ”	9.6.1
“ <i>SPC</i> ”	9.8
“ <i>Supply Agreement</i> ”	5.3.2
“ <i>Term</i> ”	11.1
“ <i>Third Party Claim</i> ”	12.10.1

Article 2.

EFFECTIVENESS OF THIS AGREEMENT

2.1 Effectiveness of this Agreement upon the Plan C Election. This Agreement is not and will not become effective except as set forth in this Section 2.1. As of the date on which AEVI provides notice to KKC that AEVI has exercised the Plan C Option in accordance with Section 4.2.2 of the Clinical Development and Option Agreement, this Agreement shall automatically become effective. Such date is referred to in this Agreement as the “*Effective Date*.”

2.2 Non-Effectiveness of this Agreement. Upon the earliest to occur of (a) the termination of the Clinical Development and Option Agreement pursuant to any of Section 7.2, 7.3, 7.4 or 7.5 thereof, or (b) the expiration of the Clinical Development and Option Agreement pursuant to Section 7.1(i)(a) or 7.1(ii)(a) thereof, this Agreement will not become effective and be rendered null and void. For the avoidance of doubt, upon this Agreement becoming effective, this Agreement shall survive the expiration or termination of the Clinical Development and Option Agreement for any reason.

Article 3.

GOVERNANCE

3.1 Joint Steering Committee.

3.1.1 Establishment of JSC. As soon as practicable and no later than (***) after the Effective Date, the Parties will establish a committee to facilitate the Development and Commercialization of Licensed Products under this Agreement (the “**Joint Steering Committee**” or “**JSC**”) as follows:

(a) Composition of the Joint Steering Committee. The JSC will be comprised of two (2) representatives designated by each of the Parties. Each representative will be an individual with significant experience or expertise in biopharmaceutical drug development. Each Party will appoint its respective initial representatives to the JSC within (***) after the Effective Date, and may from time to time substitute its representatives, in its sole discretion, effective upon notice to the other Party of such change. Additional representatives or consultants may from time to time be invited to attend JSC meetings, subject to such representatives’ and consultants’ written agreement to comply with the requirements of Article 10. Each Party will bear its own expenses relating to attendance at such meetings by its representatives and consultants.

(b) Chairperson. Each Party will designate one (1) of its representatives to be a co-chairperson (“**Co-Chairperson**”). Each Co-Chairperson or its designee will conduct the following activities of the Joint Steering Committee cooperatively: (i) scheduling meetings at least once per Contract Year, but more frequently if the JSC determines it necessary; (ii) setting agendas for meetings with solicited input from representatives of each Party; (iii) preparing and confirming minutes of the meetings, which will provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations made by the JSC, and delivering minutes to each Party’s senior management for review and final approval; and (iv) conducting effective meetings, including ensuring that objectives for each meeting are set and achieved.

(c) Meetings. The JSC will meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Contract Year. The JSC may meet by means of teleconference, videoconference or other similar communications equipment.

(d) Role. The JSC is a consultative body and may discuss any matter that a Party’s Co-Chairperson includes in the agenda for the meeting including:

(i) sharing information and discussing all Development Plans and amendments and updates thereto including Development of indications beyond the initial indication;

(ii) sharing information, discussing, and coordinating global regulatory strategy, global clinical development strategy, and global clinical supply strategy;

(iii) sharing information and discussing Commercialization of the Licensed Products, including strategic objectives and plans (including pricing and reimbursements), the

Commercialization Plans and budgets and material amendments or updates thereto submitted to KKC by AEVI and Commercialization issues; and

(iv) discussing disputes between the Parties and discussing potential resolutions thereto.

3.1.2 Decision-Making. The JSC is a consultative body only and has no decision making power. For the avoidance of doubt, AEVI has sole decision-making power to with respect to Development, Manufacturing and Commercialization of the Licensed Product in the Field in the Territory.

Article 4. **DEVELOPMENT**

4.1 Overview. AEVI will be responsible for all Development of the Licensed Product in the Field in the Territory. AEVI will bear all costs and expenses incurred in connection with the Development of Licensed Product in the Field in the Territory, including any and all regulatory activities, and, for clarity, none of such costs will be included in Allowable Expenses.

4.2 Development Plans.

4.2.1 Development Plans. AEVI will provide KKC with a copy of the initial Development Plan within (***) after AEVI receives written approval of such plan from BARDA.

4.2.2 Additional Indications. At any time, AEVI may Develop in the Territory Licensed Products for additional indications in the Field (i.e., in addition to the first indication).

4.2.3 Updates. No later than (***) prior to the beginning of the next Contract Year, AEVI will update each Development Plan and submit such updated Development Plans to KKC for informational purposes. Each Development Plan will contain the specific Development objectives to be achieved by AEVI during the then-current Contract Year and the annual budget for such Contract Year and the timeline for performing such Development activities. AEVI will use its Commercially Reasonable Efforts to perform the activities set forth in each Development Plan.

4.2.4 Development Event Notices. AEVI will inform KKC of the occurrence of each of the following events in writing within (***) after such occurrence: (a) commencement of the first Phase 3 Clinical Trial for any Licensed Product in the Territory; and (b) receipt of the first Regulatory Approval for any Licensed Product in the Territory. In this Agreement, “**Phase 3 Clinical Trial**” means a registration or pivotal clinical trial performed in accordance with applicable laws and conducted in subjects with a particular disease or condition which is designed to establish the efficacy and safety of a Licensed Product given its intended use and to define warnings, precautions and adverse events that are associated with such Licensed Product in the dosage range intended to be prescribed.

4.3 Development Responsibilities for Licensed Products. AEVI will be responsible for Development activities for Licensed Product for the Field for Territory as follows:

4.3.1 Regulatory Matters.

(a) Strategy. AEVI will develop a regulatory strategy for the Field for the Territory, that is consistent with the terms of this Agreement. Pursuant to and in accordance with such regulatory strategy, AEVI will use Commercially Reasonable Efforts to prepare Regulatory Approval Applications or other submissions to Regulatory Authorities that are suitable in content and format for use in the Territory (e.g., use of ICH eCTD format).

(b) Communications with Regulatory Authorities. AEVI will be responsible for all communications with Regulatory Authorities concerning the Licensed Product in the Field in the Territory. AEVI will disclose to KKC any and all material correspondence between AEVI and any Regulatory Authority in the Territory and minutes concerning the Development of the Licensed Product in the Field in the Territory received from any Regulatory Authority within (***) after receipt or transmission thereof. AEVI will keep KKC informed of any planned or actual material communications with any Regulatory Authority regarding Development of the Licensed Product in the Field in the Territory.

(c) Regulatory Approvals.

(i) AEVI will be responsible for preparing and filing Regulatory Approval Applications for the Licensed Products in the Field for the Territory. Such Regulatory Approval Applications and any resulting Regulatory Approvals of the Licensed Products in the Field in the Territory will be made and issued in the name of AEVI or its Related Parties.

(ii) AEVI grants KKC a right of reference to Regulatory Approval Applications filed by AEVI in the Territory for purposes of KKC obtaining Regulatory Approval outside the Field in the Territory and will provide the FDA with any required document to effect such right of reference. In addition, AEVI will provide KKC manufacturing information for the CMC section of KKC's Regulatory Approval Applications for the Licensed Product.

(d) Assistance. Each Party will cooperate with the other Party to provide all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law, including, but not limited to, reporting adverse drug experiences (and serious adverse drug experiences) to the applicable Regulatory Authorities.

4.3.2 Clinical Development. AEVI will develop a clinical development strategy for the Field in the Territory. Each Development Plan will be consistent with such clinical development strategy. AEVI will conduct clinical Development for Licensed Product in the Field in the Territory as necessary for preparing and submitting Regulatory Approval Applications in Field in the Territory.

4.3.3 CMC. AEVI will be solely responsible for all chemistry, manufacturing and control activities for the Licensed Product to support Regulatory Approval in the Field in the Territory, which, for clarity includes all CMC activities up to and including manufacturing process development, commercial scale-up and validation. AEVI will bear all costs and expenses incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development in the Field in the Territory (including failed batches and any batches, or parts thereof, that are Manufactured after the Effective Date, in anticipation of clinical studies but which are not actually used), and disposal of clinical samples, and, for clarity, none of such costs will be included in Allowable Expenses.

4.3.4 Preclinical Development. If deemed necessary by AEVI, AEVI will develop a preclinical strategy for the Field in the Territory.

4.4 Drug Safety.

4.4.1 Responsibility Before First Commercial Sale. Prior to the First Commercial Sale of a Licensed Product anywhere in the world, whether inside or outside the Field, AEVI will hold and manage a safety database and will lead safety monitoring and reporting in the Field in the Territory, and when KKC conducts any clinical trials for the Licensed Product, KKC will hold and manage a safety database during clinical development and will lead safety monitoring and reporting outside the Field in the Territory. Each Party will allow the other Party and its Affiliates and sublicensees or Third Parties acting on their respective behalf, to:

- (a) review all serious adverse events within time frames that comply with 21 CFR 312.32;
- (b) review IND safety reports, investigator brochure amendments, patient consent forms and clinical protocols;
- (c) review monthly line listings;
- (d) read and write to each Party's database;
- (e) participate in signaling discussions; and
- (f) review all periodic reporting required by Regulatory Authorities (e.g., IND Annual Reports, EU Annual Safety Reports, etc.).

The Parties agree to jointly develop and enter into a global safety data exchange and pharmacovigilance agreement to facilitate this exchange of information no later than (***) prior to the date of initiation of the first clinical study sponsored by KKC if and when KKC decides to Develop the Licensed Product outside the Field. In such case, AEVI will be responsible for holding and maintaining the global database for the Licensed Product.

4.4.2 After First Commercial Sale. In case the Parties have not entered in to a global safety data exchange and pharmacovigilance agreement according to Section 4.4.1, when KKC decides to Commercialize the Licensed Product outside the Field, no later than (***) prior

to the date of initiation of the first clinical study of the Licensed Product sponsored by KKC, if any, or the anticipated First Commercial Sale of a Licensed Product by KKC, AEVI and KKC will jointly develop and enter into a global safety data exchange and pharmacovigilance agreement. In such case, AEVI will be responsible for holding and maintaining the global database for the Licensed Product.

4.5 Records. AEVI will maintain scientific records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of Development under this Agreement by such Party. KKC will have the right, during normal business hours and upon reasonable notice, to inspect and copy (or request the AEVI to copy) all records of AEVI maintained in connection with the work done and results achieved in the performance of Development under this Agreement. All such records and the information disclosed therein will be maintained in confidence by the recipient in accordance with Article 10.

4.6 Know-How Transfer. In order to facilitate Development of Licensed Products, from time to time during the Term, each Party will disclose or transfer to the other Party any applicable KKC Know-How or AEVI Know-How, as the case may be, existing as of the Effective Date or developed after the Effective Date that is reasonably necessary or useful for the Development or Manufacture of the Licensed Products. Except as otherwise provided under this Agreement or explicitly authorized in writing by a Party, all Know-How delivered by such Party to the other Party will remain the sole property of such Party.

Article 5.

COMMERCIALIZATION

5.1 Commercialization. AEVI will be solely responsible for all Commercialization activities relating to the Licensed Products in the Field in the Territory, and as between AEVI and KKC, AEVI will record all revenues in connection with the Commercialization of Licensed Products in Field in the Territory. KKC will be solely responsible for all Commercialization activities relating the License Products outside the Field, and as between AEVI and KKC, KKC will record all revenues in connection with the Commercialization of Licensed Products outside the Field.

5.2 Commercialization Plans and Budgets. Within (***) after finalization thereof, AEVI will submit a commercialization plan (“**Commercialization Plan**”) to KKC for information only. After the launch of such Licensed Product, no later than (***) prior to the beginning of the next Contract Year, AEVI will update the Commercialization Plan for the Field in the Territory for such Licensed Product and submit such updates to KKC for information only. KKC may provide input on Commercialization strategies for the Field in the Territory. AEVI will give reasonable consideration to KKC’s input, but KKC acknowledges that AEVI has the final decision-making authority over Commercialization activities in Field in the Territory.

5.3 Manufacturing and Supply.

5.3.1 Responsibility. AEVI will develop a manufacturing and supply strategy for the Field in the Territory. Pursuant to this strategy, AEVI will be solely responsible for operational management of Manufacturing and supplying any Licensed Product for Commercialization in the Field in the Territory.

5.3.2 Supply by AEVI. AEVI will Manufacture and supply all of KKC's requirements of Licensed Product for Commercialization and/or Development outside the Field in the Territory. AEVI will supply KKC with unlabeled vialled Licensed Product for clinical trials conducted outside of the Field in the Territory and unlabeled vialled Licensed Product for Commercialization outside the Field in the Territory, in each case (***). AEVI will ship all Licensed Product FCA (INCOTERMS 2020) AEVI's point of destination. The Parties will use Commercially Reasonable Efforts to complete within (*** after the Effective Date a supply agreement governing the terms of such supply by AEVI to KKC containing reasonable and customary terms contained herein and those additional terms typically associated with supply of pharmaceutical products (the "**Supply Agreement**").

5.3.3 Inspection Rights. Not more than once per year, if KKC (the "**Inspecting Party**") has any reasonable concerns regarding AEVI's or its Related Parties' Manufacturing of any Licensed Products or any other reasonable necessities for inspection or audit, the Inspecting Party will have the right, at the Inspecting Party's expense and on not less than (*** prior notice, to inspect the facilities where the other Party or its Related Parties Manufacture, or have Manufactured, any Licensed Products and to audit the procedures of such other Party or its Related Parties for the Manufacturing of Licensed Products for purposes of quality control.

5.4 Medical Affairs Activities. AEVI will be solely responsible for Medical Affairs Activities with the Licensed Products in the Field in the Territory. KKC will be solely responsible for Medical Affairs Activities with the Licensed Products outside the Field in the Territory. The applicable Party that is responsible for Medical Affairs Activities will have the exclusive right to respond to all questions or requests for information about the Licensed Products made by any medical professionals or any other Person in its respective territory and field that are beyond the scope of the Product Labels and Inserts.

5.5 Cross Territory Sales.

5.5.1 KKC Restrictions. KKC will not Commercialize or authorize the Commercialization of any Licensed Product in the Field in the Territory. KKC will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Licensed Products in the Field in the Territory; provided that KKC may ship, consign, or otherwise transfer any Licensed Product inside Territory for purposes of Manufacturing the Licensed Products for Development and Commercialization of the Licensed Products outside the Field in the Territory. Without limiting the generality of the foregoing, KKC will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product in the Field in the Territory. KKC will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of KKC's contracts with any of the foregoing.

5.5.2 AEVI Restrictions. AEVI will not Commercialize or authorize the Commercialization of any Licensed Product outside the Field in the Territory. AEVI will not, itself or through any of its Affiliates or any Third Party, directly solicit, advertise, sell, distribute, ship, consign, or otherwise transfer any Licensed Product outside the Field in the Territory. Without limiting the generality of the foregoing, AEVI will not, and will not permit any of its Related Parties to, sell any Licensed Product to a purchaser if it knows that such purchaser does, or intends to, promote the use of such Licensed Product outside the Field in the Territory. AEVI will use Commercially Reasonable Efforts to ensure that its Related Parties comply with all of the foregoing obligations, including via the enforcement of AEVI's contracts with any of the foregoing.

Article 6.
DILIGENCE

6.1 Diligence in Development. AEVI will use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in the Territory and to obtain Regulatory Approvals for a Licensed Product in the Field in France, Germany, Italy, Spain, Japan, the United Kingdom and the United States.

6.2 Diligence in Commercialization. AEVI will use Commercially Reasonable Efforts to Commercialize each Licensed Product in each country for which it receives Regulatory Approval, including identifying and committing sufficient resources for pre-launch, launch and subsequent Commercialization activities in each such country. Both Parties acknowledge and agree that there may be cases that AEVI may use Commercially Reasonable Efforts and choose not to Commercialize the Licensed Product in a given country due to reimbursement pricing or for some other reasons, and in such cases AEVI will not be liable for a breach of the diligence obligation set forth in this Section 6.2 in respect of such country.

6.3 Reports. On a semiannual basis but not later than June 30 and December 31 of each Contract Year, AEVI will provide to KKC a written report summarizing its (a) Development (including the status of any Regulatory Approval process) activities in the Field in the Territory and (b) Commercialization activities with respect to the Licensed Products in the Field in the Territory on a Licensed Product-by-Licensed Product and country-by-country basis during the just-ended semiannual period.

Article 7.
LICENSES

7.1 License Grants to AEVI. Subject to the terms and conditions of this Agreement, KKC grants to AEVI, under the KKC Technology, an exclusive, non-transferable (except in accordance with Section 13.3) license, with the right to grant sublicenses solely as provided in Section 7.4, to:

7.1.1 Develop Licensed Products in the Field in the Territory;

7.1.2 Manufacture or have Manufactured (subject to Section 7.4.4) Licensed Products; and

7.1.3 use, offer for sale, sell, have sold and otherwise Commercialize Licensed Products in the Field in the Territory; in each of clause (i), (ii), and (iii) in accordance with this Agreement.

7.2 License Grants to KKC. Subject to the terms and conditions of this Agreement, AEVI grants KKC, under the AEVI Technology, a non-exclusive license, royalty-bearing license, with the right to sublicense solely as provided in Section 7.4, to:

7.2.1 Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized Licensed Products outside the Field in the Territory; and

7.2.2 Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized any diagnostic product that is reasonably necessary or useful in connection with the Manufacture, use, offer for sale, and/or sale of the Licensed Product outside the Field in the Territory.

7.3 Rights of Reference. Each Party hereby grants to the other Party the right to reference any and all Regulatory Approval Applications and Regulatory Approvals filed or obtained by the other Party in respect of a Licensed Product solely for use in connection with exercising such Party's rights under Section 7.1 or 7.2, as applicable.

7.4 Sublicenses.

7.4.1 Right to Sublicense. AEVI may not sublicense the rights granted to it under Section 7.1 to its Related Parties or Third Parties without the prior written consent of KKC, which consent will not be unreasonably withheld, conditioned or delayed. KKC may not sublicense the rights granted to it under Section 7.2 to its Related Parties or Third Parties without the prior written consent of AEVI, which consent will not be unreasonably withheld, conditioned or delayed. The sublicensing Party will remain responsible for the performance of its sublicensees under this Agreement, including for all payments due hereunder. The sublicensing Party will provide the other Party with notice of each sublicense granting rights to Commercialize Licensed Products promptly after execution of such sublicense. In addition, each Party will provide a copy of any such sublicense to the other Party after execution of such sublicense. All such notices of sublicenses provided by the sublicensing Party under this Section 7.4.1 will be deemed to be Confidential Information of the sublicensing Party subject to the provisions of Article 10 whether or not so marked. AEVI acknowledges and agrees that sublicensing of Manufacturing rights to, or subcontracting Manufacturing activities with respect to, the Licensed Product, and the right for using any Patent Rights, Know-How, inventions, or other intellectual property owned or controlled by Sanofi or Lonza and licensed to KKC may be subject to Sanofi's or Lonza's written consent, respectively. (***) for nominal consideration to the extent reasonably necessary or useful for the Manufacture of Licensed Products (***)

7.4.2 Terms. Each sublicense granted by a Party pursuant to Section 7.4.1 will be subject and subordinate to the terms and conditions of this Agreement and will contain terms and conditions consistent with those in this Agreement. Agreements with any sublicensee that include the right to Commercialize any Licensed Product(s) will contain the following provisions: (a) the requirement set forth in Section 8.6.4(b); and (b) a requirement that such sublicensee comply with the confidentiality and non-use provisions of Article 10 with respect to both Parties' Confidential Information.

7.4.3 Effect of Termination on Sublicenses. If this Agreement terminates for any reason, each Party agrees to use Commercially Reasonable Efforts to enter into direct licenses with the other Party's sublicensees; provided that the sublicensee is not in breach of its sublicense agreement and such sublicensee agrees to comply with all of the terms of this Agreement to the extent applicable from the rights originally sublicensed to it by the sublicensing Party.

7.4.4 Subcontracting. The Parties will be entitled to utilize the services of Third Parties, including Third Party contract research organizations and service providers to perform their respective Development activities; provided that each Party will remain at all times fully liable for its respective responsibilities under each Development Plan and this Agreement. Any agreement with a Third Party to perform a Party's responsibilities under this Agreement will include confidentiality and non-use provisions which are no less stringent than those set forth in Article 10 and intellectual property provisions that will allow such Party to comply with Article 9. Notwithstanding the foregoing, AEVI will not have the right to have the Licensed Product Manufactured by any Third Party without the prior written consent of KKC, which consent will not be unreasonably withheld, conditioned or delayed.

7.5 KKC In-Licenses. All licenses and other rights granted to AEVI by KKC under this Article 7 are subject to the rights and obligations of KKC under the KKC In-Licenses. For the avoidance of doubt, if KKC Controls only a non-exclusive license under a KKC In-License, KKC's grant of exclusive license rights pursuant to Section 7.1 means that KKC and its Affiliates will not exercise and will not sublicense such rights with respect to Licensed Products in the Field in the Territory. AEVI and its Related Parties, and the applicable rights and licenses granted to AEVI hereunder, shall be subject to the rights retained, and obligations imposed, by the US government pursuant to the Bayh-Dole Act, Chapter 18 of Title 35 of the United States Code, Sections 200-212 with respect to the KKC Patent Rights solely owned by LJI. AEVI agrees to be bound by the pertinent sections of Section 1 of, and Sections 2.2, 2.3, 2.4, 2.5, 3.1, 5.3, 7.3, 7.4, 7.6, 7.9, 8.4, 8.5, 8.6, 10.4, 10.5, 10.6, 11.1, 12.6, 12.7 and 12.10 of, the LJI Agreement to the same extent that KKC is bound thereby.

7.6 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party, as a result of this Agreement, obtain any ownership interest or other right in any intellectual property rights of the other Party, including items Controlled or developed by the other Party, or provided by the other Party to such Party at any time pursuant to this Agreement. Unless expressly provided otherwise in this Agreement, KKC will retain all

rights (including but not limited to Development and Commercialization rights) to the Licensed Products outside the Field in the Territory.

7.7 Obligation under the BARDA Contract. AEVI shall be responsible for all requirements and obligations under the contract between AEVI and BARDA (the “**BARDA Contract**”). KKC has no obligation for any research, Development, Manufacturing and/or Commercialization of Licensed Product under the BARDA Contract.

Article 8.
FINANCIAL PROVISIONS

8.1 Initial License Fee. Within (***) after the Effective Date, AEVI will pay to KKC an initial license fee of (***)

8.2 Development Costs.

(a) The responsibility for payment of the Development Costs incurred during the Term will be borne solely by AEVI, and, for clarity, none of such costs will be included in Allowable Expenses.

(b) Development Costs will not include any Manufacturing-related development costs, including but not limited to the process and analytical method developments, the comparability studies, stability program, process characterization and validation, method qualifications and validations, or the cost incurred in connection with the Manufacture of clinical supplies of Licensed Product for Development in the Territory, which costs will be borne solely by AEVI pursuant to Section 4.3.2, and, for clarity, none of such costs will be included in Allowable Expenses. All payments made by a Party to a Third Party in connection with the performance of its activities under the applicable Development Plan will be charged as Development Costs at such Party’s actual Out-of-Pocket Costs.

8.3 Milestones.

8.3.1 Milestone Payments. AEVI will pay to KKC the amounts set forth below no later than (***) after the earliest date on which AEVI or any of its Related Parties receives written notification that the corresponding milestone event has first been achieved with respect to a Licensed Product:

<u>Milestone Event</u>	<u>Payment</u>
(**) for a Licensed Product by AEVI or its Related Party	(***)\$***)
(**) for a Licensed Product by AEVI or its Related Party	(***)\$***)
(**) for a Licensed Product filed with FDA by AEVI or its Related Party	(***)\$***)
(**) for a Licensed Product filed with EMA by AEVI or its Related Party	(***)\$***)

8.3.2 One Time Milestone Payments. Once AEVI has made any particular milestone payment under Section 8.3.1, AEVI will not be obligated to make any payment under

Section 8.3.1 with respect to the re-occurrence of the same milestone, whether or not such re-occurrence is with respect to a different or the same Licensed Product.

8.4 Sharing of Profit.

8.4.1 Allocation. Profit will be allocated (***) to AEVI and (***) to KKC.

8.4.2 Reconciliation. From and after the First Commercial Sale of a Licensed Product in the Field in the Territory, the Parties will conduct a quarterly reconciliation of Profit as follows:

(a) Within (***) after the end of each Contract Quarter, AEVI will submit to KKC a preliminary written report setting forth the following information, estimated where necessary, revenues and expenses included in Profit for Profit-Share Products for the first two (2) months of such Contract Quarter, including, as applicable:

(i) all sales in units and in Net Sales value of such Profit-Share Products in the Territory made by AEVI and its Related Parties during such two (2) month period, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such two (2) month period;

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to such Profit-Share Products during such two (2) month period; and

(iv) good faith estimate of revenues and expenses included in Profit for Profit-Share Products for the last month of such Contract Quarter, for financial reporting purposes.

(b) Within (***) after the end of each Contract Quarter, AEVI will submit to KKC a final written report setting forth, as applicable:

(i) all sales in units and in Net Sales value of Profit-Share Products in the Territory made by AEVI and its Related Parties during such Contract Quarter, together with an accounting of the itemized deductions from gross invoice price to Net Sales;

(ii) all Profit-Share Product Proceeds for Profit-Share Products received from Third Parties in the Territory during such Contract Quarter; and

(iii) the relevant Allowable Expenses incurred by AEVI or its Affiliates with respect to Profit-Share Products during such Contract Quarter.

8.4.3 Tax Reporting. Together with the report submitted by AEVI pursuant to Section 8.4.2(b), AEVI will submit to KKC the calculation of Profit, the amount of any taxes required to be withheld and the calculation of the net amount owed by AEVI to KKC in order to ensure the sharing of Profit set forth in Section 8.4.1 and the proper allocation of withholding

taxes pursuant to Section 8.6.1. The net amount payable with respect to Profit, after appropriate adjustment for any withholding taxes, will be paid by AEVI within (***) following receipt of invoice for such amount.

8.4.4 Supporting Documents. In addition to providing the information set forth in Section 8.4.2, AEVI will provide reasonable supporting documentation of Allowable Expenses included in the calculation of Profit.

8.5 KKC Royalties.

8.5.1 Royalty Percentages. During the Term, but subject to any applicable offsets contained herein, KKC will pay to AEVI royalties on Royalty-Bearing Sales or Sublicensing Royalties, as applicable, on a country-by-country basis, subject to any applicable offsets or reductions pursuant to Section 8.5.2, 8.5.3, and/or 8.5.4, at the rate of (a) (***) of Royalty-Bearing Sales by KKC and/or its Affiliates outside of the Field in the Territory and Sublicensing Royalties resulting from sales outside of the Field in the Territory. In the event that AEVI's Net Sales of Licensed Products in a country in the Territory experience a Significant Impact as a result of KKC or any of its Related Parties commercializing Licensed Product in the Territory, the Parties will negotiate in good faith to increase the royalty rate under this Section 8.5.1 for such country to offset the Significant Impact, which royalty rate will not exceed (**) in any country. For the avoidance of doubt, if (a) either the Plan A License Agreement or the Plan B License Agreement become effective and (b) this Agreement (i.e. Plan C License Agreement as defined in the Clinical Development and Option Agreement) becomes effective, KKC will only pay royalties to AEVI under this Agreement and not under the other License Agreement.

8.5.2 Third Party License Offsets. If KKC enters into an agreement with a Third Party (other than a KKC Licensor) to obtain a license under Third Party Technology (including without limitation under Section 9.5) that KKC reasonably believes or expects to be necessary to Commercialize one or more Licensed Products outside of the Field, then KKC may offset (**) of the amount of commercially reasonable royalties or other payments payable by KKC to such Third Party with respect to a particular Licensed Product against amounts KKC is obligated to pay AEVI under Section 8.5.1 for Royalty-Bearing Sales by KKC and/or its Affiliates and Sublicensing Royalties, provided that in no event will any such reduce the payments otherwise due to AEVI pursuant to Section 8.5.1 in particular Contract Years below (**) of the royalties otherwise due to AEVI pursuant to Section 8.5.1; provided further that, if such (**) offset of such Third Party royalties or other payments exceeds the amount of payments withheld by KKC under this Section 8.5.2 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.3 Claimed Infringement of Third Party Rights Offsets. If costs and expenses and damages are incurred by the Parties in connection with the defense of an Infringement Claim outside the Field pursuant to Section 9.4, then KKC may offset (**) of such costs and expenses and damages with respect to a particular Licensed Product against amounts KKC is obligated to pay AEVI under Sections 8.5.1 and 8.5.2 on sales of such Licensed Product, provided that in no event will any such offset (a) with respect to sales outside the Field, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1(b) in particular Contract Years below (**) of

Royalty-Bearing Sales and Sublicensing Royalties outside the Field outside of the Territory, or (b) with respect to sales in the Territory, reduce the payments otherwise due to AEVI pursuant to Section 8.5.1 in particular Contract Years below (***) of the amounts otherwise due under Section 8.5.1; provided further that, if such (***) offset of such costs and expenses and damages incurred by the Parties exceeds the amount of payments withheld by KKC under this Section 8.5.3 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

8.5.4 Royalty Reduction for Biosimilars.

(a) If a Biosimilar version(s) of any Licensed Product is commercialized in any country in which there are Royalty-Bearing Sales, then the royalty rate payable to AEVI pursuant to Sections 8.5.1, 8.5.2 and 8.5.3 applicable for the sale of Licensed Products in such country will be reduced by (i) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is at least (***) in such country, (ii) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is at least (***) in such country, (iii) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is at least (***) in such country, (iv) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is at least (***) in such country; and (v) (***) applicable for the first Contract Quarter during which the market share of such Biosimilars is at least (***) in such country. For clarity, the reduction in royalty rates permitted pursuant to this Section 8.5.4 will be taken after any reduction taken pursuant to Section 8.5.2 and Section 8.5.3. For the avoidance of doubt, the minimum royalty under Section 8.5.1 (on a country-by-country basis) will be no less than (***) of the royalty otherwise due under Section 8.5.1 prior to the adjustments permitted by this Section 8.5.4; provided that, if such reduction permitted under this Section 8.5.4 exceeds the amount of payments withheld by KKC under this Section 8.5.4 in any Contract Quarter, the excess may be carried over as a credit on the same basis into succeeding Contract Quarters.

(b) The Parties will utilize a mutually-agreed (such agreement not to be unreasonably withheld, delayed, or conditioned) measure of the market share of any relevant Biosimilars in each country where a Biosimilar version(s) of a Licensed Product is being commercialized and will adjust the royalty rate payable to AEVI for the sale of Licensed Products in such country every six (6) months, to the extent permitted pursuant to Section 8.5.4(a). If the royalty rate payable to AEVI for the sale of Licensed Products has been adjusted pursuant to Section 8.5.4(a), then such royalty rates in such country may not thereafter be adjusted upwards.

8.5.5 Reports and Royalty Payments. Within (***) after the end of each Contract Quarter during the Term, KKC will deliver to AEVI a report setting forth for the previous Contract Quarter the following information on a Licensed Product-by-Licensed Product and country-by-country basis: (a) the gross sales and Royalty-Bearing Sales of each Licensed Product, (b) the number of units sold by KKC or its Affiliate, (c) the Sublicensing Royalty received by KKC, (d) the basis for any adjustments to the royalty payable for the sale of each Licensed Product, (e) the royalty due hereunder for the sales of each Licensed Product, and (f)

the applicable exchange rate as determined pursuant to Section 8.6.2. The total royalty due for the sale of Licensed Products during such Contract Quarter will be remitted at the time such report is made but no later than (***) after the end of each Contract Quarter during the Term. Along with such reports, KKC will also provide the Sales Tracking Methodologies used to determine Royalty-Bearing Sales outside the Field in the Territory.

8.6 Payment Provisions Generally.

8.6.1 Taxes and Withholding. If Applicable Laws require withholding of income taxes or other taxes imposed upon payments set forth in Article 8, the paying Party will make such withholding payments as required and subtract such withholding payments from the payments set forth in Article 8. The paying Party will submit appropriate proof of payment of the withholding taxes to the payee Party within a reasonable period of time. At the request of the payee Party, the paying Party will, at the payee Party's cost, give the payee Party such reasonable assistance, which will include the provision of appropriate certificates of such deductions made together with other supporting documentation as may be required by the relevant tax authority, to enable the payee Party to claim exemption from such withholding or other tax imposed or obtain a repayment thereof or reduction thereof and will upon request provide such additional documentation from time to time as is reasonably required to confirm the payment of tax.

8.6.2 Payment and Currency Exchange. All amounts payable and calculations hereunder will be in United States dollars and will be paid by bank wire transfer in immediately available funds to such bank account as may be designated in writing by the payee Party from time to time. Whenever for the purposes of calculating the Profit or royalties payable under Section 8.4 or 8.5, conversion from any foreign currency will be required, all amounts will first be calculated in the currency in which the activity was paid or sale was recorded and then converted into United States dollars by applying the rate of exchange quoted in the New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter.

8.6.3 Overdue Payments. If any payment due under this Agreement (other than payments that are the subject of a good faith dispute between the Parties) is overdue by more than thirty (30) days, the paying Party will pay interest to the payee Party at a rate per annum equal to the lesser of the prime rate of interest, as reported by New York edition of The Wall Street Journal on the last Business Day of the paying Party of the applicable Contract Quarter, or the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date such payments are due.

8.6.4 Financial Matters Relating to Existing In-Licenses.

(a) All amounts payable in respect of Profit-Share Products under the KKC In-Licenses will be paid directly by KKC or its Related Parties to the KKC Licensor, AEVI will reimburse KKC such amounts as defined in Section 1.85(a), and any such amounts reimbursed by AEVI will be treated as Allowable Expenses.

(b) (**), for the supply of the Licensed Product, and the entry into such contract triggers any payment obligation by KKC to Lonza, then AEVI will reimburse KKC any and all such payments that KKC makes to Lonza, provided that any such reimbursement obligations of AEVI will not exceed (**). Such payment to Lonza will be first payable within (**) of signature of a manufacturing agreement with such Third Party or grant of sublicense to such contract manufacturer and will continue for the duration of such manufacture by such Third Party or sublicense. No payment made by AEVI under this Section 8.6.4(b) will be included in Allowable Expenses.

(c) Notwithstanding anything to the contrary in Section 8.6.4(b), if AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date, AEVI may deduct (**) of the upfront payments (but not annual fees) and milestone payments made by AEVI to Lonza pursuant to such agreement from the initial license fee and milestone payments payable to KKC by AEVI under Sections 8.1 and 8.3, (**).

(d) If AEVI has entered into the AEVI Lonza License Agreement prior to the Effective Date and AEVI has an obligation to pay an annual fee to Lonza pursuant to such agreement for conducting the process development or Manufacture of the Licensed Product using a contract manufacturer that is not Lonza, as between the Parties, AEVI will (**). For clarity, no portion of (**) will be subject to the deduction set forth in Section 8.6.4(c) or will be included in Allowable Expenses.

8.6.5 Record-Keeping. Each Party will keep, and will cause their respective Related Parties to keep, books and accounts of record in connection this Agreement in sufficient detail to permit accurate determination of all figures necessary for any and all financial calculations required by this Agreement, including without limitation all elements of Allowable Expense, Developments Costs, Net Sales, Royalty-Bearing Sales, and Profit. Each Party will maintain, and will cause their respective Related Parties to maintain, such records for a period of at least five (5) years after the end of the Contract Year in which they were generated.

8.6.6 Audits. Upon thirty (30) days' prior written notice from a Party (the "**Requesting Party**"), the Party receiving the written notice (the "**Audited Party**") will permit an independent certified public accounting firm of nationally recognized standing selected by the Requesting Party and reasonably acceptable to the Audited Party, to examine, at the Requesting Party's sole expense, the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the amounts reporting or payable by the Audited Party to the Requesting Party. An examination by a Requesting Party under this Section 8.6.6 will occur not more than once in any Contract Year and will be limited to the pertinent books and records for any Contract Year ended not more than five (5) years before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination will be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm will provide both the Audited Party and the Requesting Party a written report

disclosing any discrepancies in the reports submitted by the Audited Party or, as applicable, the amounts payable under this Agreement, and in each case, the specific details concerning any discrepancies. No other information will be provided to the Requesting Party.

8.6.7 Underpayments/Overpayments. If such accounting firm concludes that additional amounts were due to the Requesting Party, the Audited Party will make such payments as is necessary for the Requesting Party to have been paid the correct amount due under this Agreement for the audited periods. If such underpayment exceeds five percent (5%) of the amounts that were to be paid, the Audited Party also will reimburse the Requesting Party for all Out-of-Pocket Costs incurred in conducting the audit. If such accounting firm correctly concludes that the Audited Party overpaid amounts due to the Requesting Party, the Requesting Party will refund such overpayments to the Audited Party within sixty (60) days of the date the Requesting Party receives such accountant's report so correctly concluding.

8.6.8 Confidentiality. All financial information of a Party that is subject to review under this Section 8.6 will be deemed to be Confidential Information of such Audited Party subject to the provisions of Article 10, and the Requesting Party will not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than verifying payments to be made by the Audited Party to the Requesting Party hereunder.

8.7 Adjustment of FTE Rates. Effective upon each anniversary of the Effective Date, the FTE Rates will increase by the percentage increase, if any, in the Consumer Price Index published by the United States Bureau of Labor Statistics during the most recent preceding one (1) year period for which final data is available, and such increase will be effective for the then-current and all subsequent FTE Costs hereunder unless and until further modified under this Section 8.7. In addition, within sixty (60) days after the third anniversary of the Effective Date and every three (3) years thereafter, each Party will have the right to require the other Party to conduct a salary survey in respect of FTEs and provide the result of such survey. In addition, a Party may conduct a salary survey at its own discretion in respect of FTEs and provide such survey to the other Party. Following receipt of such survey from each Party, the Parties may agree in writing to adjust one or more of the FTE Rates.

Article 9.

INTELLECTUAL PROPERTY

9.1 Ownership of and Rights to Intellectual Property.

9.1.1 AEVI Technology. As between the Parties, AEVI is and will remain the sole owner of the AEVI Technology.

9.1.2 KKC Technology. As between the Parties, KKC is and will remain the sole owner of the KKC Technology. AEVI acknowledges that certain of the KKC Patent Rights have been licensed to KKC from the KKC Licensors pursuant to the KKC In-Licenses.

9.1.3 Joint Inventions. The Parties will jointly own all Joint Inventions, and each will have an undivided interest in the Joint Inventions subject to the licenses granted under this Agreement.

9.1.4 Inventorship. For purposes of determining whether an invention is solely invented by AEVI or solely invented by KKC, or a Joint Invention, questions of inventorship will be resolved in accordance with United States patent laws.

9.2 Filing, Prosecution and Maintenance of Patent Rights.

9.2.1 KKC Patent Rights. This Section 9.2 will not apply to the KKC Patent Rights over which KKC has no right to control the filing, prosecution or maintenance thereof, and, for purposes of this Section 9.2, the KKC Patent Rights over which KKC has the right to control the filing, prosecution and maintenance thereof, including those described in clauses (a) and (c) of Section 1.52, but excluding those described in clause (b) of Section 1.52, are referred to as the “***KKC Managed Patent Rights***.”

(a) As between KKC and AEVI, KKC, through counsel of its choosing, will control (but not be obligated to control) the prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of the KKC Patent Rights in the Territory. AEVI will provide all reasonable assistance required to prosecute the KKC Patent Rights in the Territory. AEVI will have the right to review and comment upon any substantive communications received from the applicable patent offices with respect to the KKC Managed Patent Rights, including, but not limited to, official actions, examination reports, documents relating to patentability and/or amendment or cancellation of the claims, and documents related to patent term adjustment and patent term extension. KKC will consider all comments received from AEVI with respect to the KKC Managed Patent Rights and will comply with all reasonable requests. In addition, AEVI will have the right to review and comment upon any substantive communications that KKC plans to make to an applicable patent office in the Territory with respect to the KKC Managed Patent Rights, including, but not limited to, draft responses to official actions, draft responses to examination reports, drafts relating to amendment or cancellation of the claims, and drafts relating to patent term adjustment and/or extension. KKC will provide AEVI with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. KKC will consider all comments received from AEVI and will comply with all reasonable requests. In addition to the above, KKC will keep AEVI reasonably informed with respect to all such prosecution and maintenance activities to which KKC has access, including written communications with patent office officials, and consult with AEVI regarding such matters, including the planned abandonment of claims thereof.

(b) If KKC determines in its sole discretion to abandon or not maintain any KKC Managed Patent Rights, in one or more country(ies) or in the entire Territory, then KKC will provide AEVI with at least sixty (60) days prior written notice of such determination to abandon or cease maintenance (or such other longer period of time reasonably necessary to allow AEVI to assume such responsibilities). If KKC provides such a notification, then AEVI will have the right (but not the obligation), to control the prosecution and maintenance of any such KKC Managed

Patent Rights in its sole discretion and at AEVI's sole cost and expense by providing KKC with notice thereof within such sixty (60) day period. In the event that AEVI so elects to control the prosecution and maintenance of any KKC Managed Patent Rights, then in the concerned country(ies) or in the entire Territory, as applicable, KKC will provide all reasonable assistance required to prosecute such KKC Managed Patent Rights in the concerned country(ies) or in the entire Territory, at AEVI's sole cost and expense, including allowing AEVI to exercise all rights of KKC under the KKC In-License with LJL relevant to prosecution and maintenance of the KKC Managed Patent Rights. KKC will have the right to review and comment upon any substantive communications and filings made by AEVI with respect to the prosecution of such KKC Managed Patent Rights before they are sent to any patent offices in the entire Territory. AEVI will provide KKC with a copy of each such communication or filing reasonably in advance of submitting such communication or filing to the relevant patent authority. With respect to all such prosecution and maintenance AEVI will keep KKC reasonably informed with respect to such activities (including by providing KKC with access to all filings and correspondence with and from any patent offices or officials upon request by KKC), and consult with KKC regarding such matters, including the abandonment of claims thereof

(c) Notwithstanding anything to the contrary in this Agreement (including Section 9.3.1(a)), the following terms and conditions will apply with respect to the KKC Patent Rights: (i) with respect to those KKC Patent Rights solely owned by LJL, LJL and KKC will have the joint right to control the filing, prosecution and maintenance of such KKC Patent Rights, including the extension of the patent term(s) of such KKC Patent Rights, and if both LJL and KKC determine in their sole discretion to abandon or not maintain such KKC Patent Rights, then AEVI will have the right, subject to Section 9.3.1(a) and the other applicable terms and conditions of this Agreement, to control the prosecution and maintenance of any such KKC Patent(s) and KKC will request LJL to provide all reasonable assistance required to prosecute and maintain such KKC Patent Rights; and (ii) with respect to those KKC Patent Rights jointly owned by LJL, on the one hand, and KKC and/or its Affiliates, on the other hand, in the event that both KKC and AEVI determine in their sole discretion to abandon or not maintain any such KKC Patent(s), then (A) LJL will have the right to control the filing, prosecution and maintenance (including, without limitation, the extension of the patent term(s)) of such KKC Patents, and (B) all rights and licenses granted to KKC under the LJL Agreement (and therefore the sublicense to AEVI under this Agreement) in and to such KKC Patent(s) will immediately terminate.

(d) Notwithstanding anything to the contrary in this Agreement, to the extent that KKC does not have the right to control or participate in the prosecution or maintenance of Patent Rights under a KKC In-License, no right to prosecute or maintain such Patent Rights are granted to AEVI by this Agreement.

(e) All information, if any, exchanged between the Parties or between KKC's outside patent counsel and AEVI regarding preparation, filing, prosecution or maintenance of the KKC Patent Rights will be deemed Confidential Information of KKC. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution and maintenance of the KKC Patent Rights, the interests of the Parties as licensor and licensee are to obtain the

strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the KKC Patent Rights including without limitation, privilege under the common interest doctrine and similar or related doctrines.

9.2.2 Joint Inventions. With respect to any potentially patentable Joint Invention, the Parties will meet and agree upon which Party will lead (in a joint effort with the other Party) the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of patent applications covering such Joint Invention (any such patent application and any patents issuing therefrom a “**Joint Patent**”) in any jurisdiction. Joint Patents are included within both the KKC Technology and AEVI Technology and within the licenses granted to each Party hereunder. The Party that leads prosecution of a patent application in the Joint Patents (the “**Prosecuting Party**”) will provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patents in the particular jurisdictions, and such other Party will provide the Prosecuting Party reasonable assistance in such efforts, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. The Prosecuting Party will provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and will provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party will no longer be obligated to pay any costs for filing, prosecution or maintenance thereof; (ii) the disclaiming Party will, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration and (iii) if such assignment is effected, any such Joint Patent would thereafter be deemed a patent of AEVI in the case of assignment to AEVI, or a patent of KKC in the case of assignment to KKC.

9.2.3 New Inventions. AEVI will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all AEVI Inventions, and KKC will retain ownership of, and be entitled to file patents (in its sole discretion) in its name, on all KKC Inventions. All the foregoing will be included in the license granted by each Party to the other Party in Article 7. Each Party will disclose any such inventions or improvements to the other Party within (***) of filing a patent application claiming the Invention.

9.2.4 Cooperation. Each Party hereby agrees: (a) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party’s authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution as contemplated by this Agreement; (b) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights that are subject to this Agreement; and (c) to endeavor in good faith to coordinate

its efforts with the other Party to minimize or avoid interference with the prosecution and maintenance of the other Party's patent applications that are subject to this Agreement.

9.2.5 Patent Costs. KKC will bear all of the costs and expenses of filing, prosecuting and maintaining the KKC Patent Rights, and AEVI will bear all of the costs and expenses of filing, prosecuting and maintaining the AEVI Patent Rights. The costs and expenses of filing, prosecuting and maintaining the Joint Patents shall be borne solely by AEVI for costs and expenses incurred inside the Territory.

9.3 Enforcement of Patent Rights.

9.3.1 Notification. Each Party will promptly report in writing to the other Party during the Term any (a) known or suspected infringement by a Third Party of any KKC Patent Rights, AEVI Patent Rights or Patent Rights covering Joint Inventions or (b) unauthorized use or misappropriation by a Third Party of any Confidential Information, including KKC Know-How or AEVI Know-How, of which it becomes aware, and will provide the other Party with all available evidence supporting such infringement or unauthorized use or misappropriation.

9.3.2 Rights to Enforce. KKC will have the right, but not the obligation, to take any reasonable measures it deems appropriate to: (a) stop infringing activities described in Section 9.3.1 in respect of the KKC Technology in the Territory including initiating or prosecuting an infringement or other appropriate suit or action against the alleged infringer, but not granting adequate rights and licenses necessary for continuing such activities by the alleged infringer or (b) defend the KKC Technology in the Territory against any declaratory judgment, opposition, patentability or invalidity actions ("**Defensive Actions**"). KKC may request that AEVI grant such adequate rights and licenses; provided that AEVI will have no obligation to grant any such rights or licenses; and provided further that upon making such request, AEVI will have the right to participate in all negotiations with the alleged infringer concerning such adequate rights and licenses. Before KKC takes any action to stop the infringing activity against an alleged infringer of the KKC Technology in the Territory, KKC will consult in good faith with AEVI concerning the alleged infringement, including selection of counsel, litigation strategy, litigation risks, the damage being caused to KKC and/or AEVI and any other matter relevant to enforcement of the KKC Technology against the alleged infringer in the Territory. In particular, KKC will consider in good faith a request from AEVI to not take any actions to enforce the KKC Technology against the alleged infringer in the Territory and only take such actions, in light of such request from AEVI, if KKC is suffering material harm from the infringement in the Territory. Subject to the provisions of the LJL Agreement, in the event that KKC elects to not take action or cease action with respect to the KKC Managed Patent Rights pursuant to this Section 9.3.2 with respect to the Territory, including declining or ceasing to defend Defensive Actions, KKC will so notify AEVI in writing of its intention (***) prior to any deadlines by which an action must be taken to establish, preserve or maintain any enforcement rights or defend or continue to defend the Defensive Action, and, subject to Section 9.3.4, AEVI will have the right, but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer or defend the Defensive Action, in which event, upon AEVI's request, KKC will exercise its rights under the LJL Agreement to the extent

necessary for the enforcement or defense of KKC Managed Patent Rights that are subject to the LJI Agreement.

9.3.3 Procedures; Expenses and Recoveries. The Party having the right to initiate any infringement suit or defend a Defensive Action under Section 9.3.2 (the “**Controlling Party**”) will have the sole and exclusive right to select counsel for and control any such suit or Defensive Action. The expenses of the suit or the Defensive Action, including attorneys’ fees and court costs and the reasonable Out-of-Pocket Costs the other Party (the “**Cooperating Party**”) in rendering assistance requested by the Controlling Party (“**Enforcement Expense**”), will be borne (**). If required under Applicable Law in order for the Controlling Party to initiate and/or maintain such suit or to defend the Defensive Action, or if either Party is unable to initiate or prosecute such suit or defend the Defensive Action solely in its own name or it is otherwise advisable to obtain an effective legal remedy, in each case, the other Party will join as a party to the suit or Defensive Action and will execute and cause its Affiliates to execute all documents necessary for the Controlling Party to initiate litigation to prosecute and maintain such action or defend the Defensive Action. In addition, at the Controlling Party’s request, the Cooperating Party will provide reasonable assistance to the Controlling Party in connection with an infringement suit (**). The Cooperating Party will have the right to participate and be represented in any such suit by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with such suit, any damages, license fees, royalties or other compensation (including any amount received in settlement of such litigation) (“**Recoveries**”) in the Territory, such amounts will be allocated as follows:

(**).

9.3.4 LJI Enforcement Rights. The Parties acknowledge and agree that in the event that (**), LJI will have the right but not the obligation under the LJI Agreement to bring, defend, or maintain any appropriate suit or action involving such infringement or Defensive Action at its own cost and expense against alleged infringers and to defend such KKC Patent Rights from Defensive Actions. Subject to the foregoing, if LJI finds it necessary or reasonably desirable to join AEVI and/or KKC into such suit or action, AEVI and/or KKC will execute all papers and perform such other acts as may be reasonably required, and AEVI and/or KKC, at their respective options, may be represented by respective counsel(s) of their own choice, provided that (a) (**), and (b) if any amount is recovered on any such action or suit, whether by judgment or settlement (any such settlement requiring the consent of KKC), the balance of any such recovery will be paid to or retained (**) (including, for clarity, the LJI (**) set forth on Schedule 1.48) in respect of the applicable KKC Patent Right(s) and Licensed Product(s), after reimbursement for the reasonable attorneys’ fees incurred with respect to such suit or action by LJI, KKC and AEVI.

9.4 Claimed Infringement of Third Party Rights.

9.4.1 Notice. In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of such Party’s respective Related Parties, claiming infringement of such Third Party’s Patent Rights or unauthorized use or misappropriation of such Third Party’s Know-How, based upon an assertion

or claim arising out of the Development, Manufacture or Commercialization of a Licensed Product (each, an “**Infringement Claim**”), such Party will promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served. Each Party agrees to make available to the other Party its advice and counsel regarding the technical merits of any such claim at no cost to the other Party and to offer reasonable assistance to the other Party at no cost to the other Party.

9.4.2 Right to Defend. AEVI will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product in the Field in the Territory. KKC will have the right, but not the obligation, to defend any Infringement Claim brought against either Party or any of its Related Parties arising out of the Development, Manufacture or Commercialization of a Licensed Product outside the Field.

(a) Procedure. The Party having the obligation or first right to defend an Infringement Claim in which either Party is named as defendant will be referred to as the “**Defending Party**.” The Defending Party will have the sole and exclusive right to select counsel for any Infringement Claim; provided that it will consult with the other Party with respect to selection of counsel for such defense. The Defending Party will keep the other Party informed, and will from time to time consult with the other Party regarding the status of any such claims and will provide the other Party with copies of all documents filed in, and all written communications relating to, any suit brought in connection with such claims. The other Party will also have the right to participate and be represented in any such claim or related suit, at its own expense. The other Party will have the sole and exclusive right to control the defense of an Infringement Claim in the event the Defending Party fails to exercise its right to assume such defense within (***) following written notice from the other Party of such Infringement Claim. No Party will settle any claims or suits involving rights of another Party without obtaining the prior written consent of such other Party, which consent will not be unreasonably withheld. Any recoveries by the Defending Party of attorneys’ fees or costs in defense of a claim in the Territory under this Section 9.4, and any sanctions awarded to Defending Party and against a party asserting a claim in the Territory being defended under this Section 9.4, will be (***). The costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim in the Territory will be treated as Allowable Expense in the Territory. The costs and expenses and damages incurred by the Parties in connection with defense of such Infringement Claim outside the Field will be allocated between the Parties as follows: (***). AEVI and KKC will have the right to take action to invalidate Third Party’s patents which would be infringed by the activity under this Agreement. The cost and expenses of such action will be shared in the same way as set forth above.

9.4.3 Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTION 12.10, THE FOREGOING STATES THE ENTIRE RESPONSIBILITY OF KKC AND AEVI, AND THE SOLE AND EXCLUSIVE REMEDY OF KKC OR AEVI, AS THE CASE MAY BE, IN THE CASE OF ANY CLAIMED INFRINGEMENT OF ANY THIRD PARTY PATENT RIGHTS OR UNAUTHORIZED USE OR MISAPPROPRIATION OF ANY THIRD PARTY’S KNOW-HOW.

9.5 Third Party Technology. If either Party reasonably determines that any Third Party Technology is reasonably necessary for the Development, Manufacture, or Commercialization of a Licensed Product in the Field, then such Party will notify the other Party. The Parties will determine which Party will negotiate the most favorable license. The chosen Party will obtain a license to such Third Party Technology with the right to sublicense to the other Party. Subject to the foregoing, the terms and conditions involved in obtaining such rights will be determined at such chosen Party's sole discretion. If such chosen Party elects not to obtain rights to such Third Party Technology, or is unsuccessful in obtaining such Third Party Technology, then the other Party will have the right (but not the obligation) to negotiate and obtain rights from such Third Party at its sole discretion and expense. Notwithstanding anything to the contrary in this Section 9.5, AEVI will pay to a Third Party any and all royalties and other payments pursuant to any agreement under which a Party acquires rights to intellectual property that would otherwise block the Development and/or Commercialization of a Profit-Share Product in the Field in the Territory. Any such payments will be included in Third Party Technology Costs and, for clarity, will be included in Allowable Expenses for the applicable Profit-Share Product. The costs outside the Field will be borne solely by KKC, provided that such costs will be subject to royalties reduction to AEVI in accordance with Section 8.5.2. Notwithstanding the foregoing, with respect to any lump sum payment under any such agreement that is made with respect to a license covering countries or jurisdictions in the Territory, the Parties will negotiate and decide in good faith the allocation of the payment based on the scope and territory of the acquired rights.

9.6 Other Infringement Resolutions.

9.6.1 Notice of Third Party Applications. In the event of a dispute or potential dispute that has not ripened into a demand, claim or suit of the type described Sections 9.3 or 9.4, the same principles governing control of the resolution of the dispute, consent to settlements of the dispute, and implementation of the settlement of the dispute (including sharing in and allocating the payment or receipt of damages, license fees, royalties and other compensation) will apply. Notwithstanding anything herein to the contrary, within (***) after Regulatory Approval is achieved with respect to a BLA for a Licensed Product in the Territory (or such shorter time as the Parties agree in the case of a Licensed Product in the Territory that does not earn reference product exclusivity under the PHS Act), the Parties will consult as to potential strategies with respect to unexpired Patent Rights Controlled by either Party that potentially could be asserted if an unlicensed person engaged in the making, using, offering to sell, selling, or importing into the United States of a product described in a Biosimilar Application filed by a Third Party applicant (a "**Section 351(k) Applicant**").

9.6.2 Cooperation and Enforcement. If either Party who is the reference product sponsor of the Licensed Product within the meaning of section 351(l)(1)(A) of the PHS Act ("**Reference Product Sponsor**") receives notice of a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product and related manufacturing information in accordance with section 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with section 351(l)(8)(A) of the PHS Act, then such Party will provide notice to the other Party, and the Parties will discuss and cooperate with each other in

determining the Reference Product Sponsor's course of action with regard to (a) engaging in the information exchange provisions of the Biologics Price Competition and Innovation Act of 2009, Section 351(k) of the Public Health Service Act, as may be amended, supplemented, or replaced (the "**BPCIA**"), including providing a list of patents that relate to the relevant Licensed Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under Section 351(l)(6) of the BPCIA. In the event that the Parties do not agree with respect to the exercise of any such rights, KKC will make the final determination with respect thereto, including without limitation with respect to (a), (b) and (c) above. If any patent litigation commences with respect to a Biosimilar Application filed by a Section 351(k) Applicant that references such Licensed Product, then the provisions of Section 9.3 will thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.

9.7 Product Trademarks.

9.7.1 Product Trademarks in the Territory. AEVI will own the Product Trademarks for each Licensed Product in the Field in the Territory and will be solely responsible for filing and maintaining the Product Trademarks in the Field in the Territory (including payment of costs associated therewith).

9.7.2 Each Party agrees to (a) conduct its business in a manner that will not damage the reputation or integrity of the Trademarks of the other Party, (b) conduct its business in a manner that will not damage in any way the goodwill associated with the Trademarks of the other Party, (c) use the Trademarks of the other Party in a manner that will not cause a negative impact upon the good name of such other Party, and (d) conduct its business in compliance with all applicable trademark Laws.

9.8 Patent Term Extensions. The Parties will use reasonable efforts to obtain all available supplementary protection certificates ("**SPC**") and other extensions of Patent Rights. Each Party will execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties will cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to Patent Rights. The Party first eligible to seek patent term restoration or extension of any such Patent Rights or any SPC related thereto will have the right to do so; provided that if in any country the first Party has an option to extend the patent term for only one of several patents, the first Party will consult with the other Party before making the election. If more than one patent is eligible for extension or patent term restoration, KKC will select in good faith a strategy that will maximize patent protection and commercial value for each Licensed Product. All filings for such extensions and certificates will be made by the Party to whom responsibility for prosecution and maintenance of the Patent Rights are assigned, provided that in the event that the Party to whom such responsibility is assigned elects not to file for an extension or SPC, such Party will (a) inform the other Party of its intention not to file and (b) grant the other Party the right to file for such extension or SPC in the patentee's name, and (c) provide all necessary assistance in connection therewith.

9.9 Patent Marking. AEVI (and its Related Parties) will mark Licensed Products marketed and sold by AEVI (and/or its Related Parties, as applicable) with appropriate numbers of the KKC Patent Rights printed on the appropriate portion of the packaging. Without limiting the foregoing, AEVI shall mark each Licensed Product sold or offered for sale by or on behalf of AEVI with the patent number or numbers of any issued patents encompassed within the KKC Patent Rights solely owned by LJI, if applicable, and AEVI shall ensure that the content, form, location and language of such markings is in accordance with the applicable laws and practices of each jurisdiction in which the Licensed Products are made, used or sold.

Article 10. **CONFIDENTIALITY**

10.1 Confidentiality.

10.1.1 Confidential Information. All Confidential Information disclosed by or on behalf of a Party (together with its Affiliates, the “**Disclosing Party**”) to the other Party (together with its Affiliates, the “**Receiving Party**”) during the Term will be used by the Receiving Party solely in connection with the activities contemplated by this Agreement, will be maintained in confidence by the Receiving Party and will not otherwise be disclosed by the Receiving Party to any other person, firm, or agency, governmental or private (other than a Party’s Affiliates or as set forth in Section 10.1.2), without the prior written consent of the Disclosing Party, except to the extent that the Confidential Information (as determined by competent documentation):

(a) was known or used by the Receiving Party without restriction as to its use or disclosure prior to its date of disclosure to the receiving Party; or

(b) either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party without restriction as to its use or disclosure by sources other than the Disclosing Party rightfully in possession of the Confidential Information; or

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

(d) is independently developed by or for the Receiving Party without reference to or reliance upon the Confidential Information.

All obligations of confidentiality imposed under this Article 10 will expire five (5) years following termination of this Agreement.

10.1.2 Required Disclosures. Section 10.1.1 will not preclude the Receiving Party from disclosing Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and

lawful actions to avoid and/or minimize the degree of such disclosure. If a public disclosure is required by any Applicable Laws, including, without limitation, in a filing with the Securities and Exchange Commission or submission to an exchange on which any securities of a Party is listed, the disclosing Party will provide copies of the disclosure (but shall be permitted to redact or omit portions of any filing, submission or disclosure not relevant to this Agreement) reasonably in advance of such filing or other disclosure, for the non-disclosing Party's prior review and comment and to allow the other Party a reasonable time to object to any such disclosure or to request confidential treatment thereof. The disclosing Party will negotiate in good faith with the applicable Regulatory Authority concerning the confidential treatment request. If the disclosure is substantially similar to prior disclosures made by the Party and for which the obligations of this provision have been satisfied, the disclosing Party need not share such disclosure ahead of it being made.

10.1.3 Permitted Disclosures. KKC and AEVI each agree that they will provide Confidential Information received from the other Party only to their respective directors, officers, employees, consultants, suppliers, sublicensees, collaborators and advisors, and to those of such Party's Related Parties, who have a need to know for such Party's development, manufacture, and commercialization of Licensed Products in accordance with this Agreement, including in connection with Regulatory Filings and obtaining Regulatory Approvals, provided that such Third Parties are bound by confidentiality obligations at least as strict as this Article 10. In addition, each Party may not disclose the terms of this Agreement (to the extent such terms are confidential) to any Third Party except to actual or prospective lenders, investors, acquirers, licensees/sublicensees or strategic partners (including the KKC Licensors and AEVI Licensor) or to a Party's accountants, attorneys and other professional advisors; provided that such disclosures will be subject to continued confidentiality obligations at least as strict as this Article 10.

10.2 Publication Review.

10.2.1 Publications by the Parties. Subject to Section 10.2.2 and except as required by Applicable Law, during the Term, each Party agrees that, unless explicitly authorized in this Agreement, it will not without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed, file patent application, issue any press release, make any public announcement, or issue any scientific or other presentations or publications, with respect to the results of any Development work relating to this Agreement without the opportunity for prior review by the other Party. With respect to any such proposed publications or presentations by one of the Parties, each Party will provide to the other Party for information and review any (a) abstracts, posters and slide presentations that the Party proposes prior to any scientific meetings and the other Party will provide feedback to the publishing Party within ten (10) of its Business Days of its receipt of such abstracts, posters and slide presentations, and (b) primary and final manuscripts and review articles that the Party proposes prior to journal submission and the other Party will provide feedback within fifteen (15) of its Business Days of its receipt of such manuscript or article. Each Party agrees, upon request from the other Party, not to submit any abstract or manuscript for publication or to make any scientific presentation until the other Party is given up to forty-five (45) days from the date of such written request to seek appropriate patent protection for any material in such publication or presentation

which it reasonably believes is patentable. Once such abstracts, manuscripts or presentations have been reviewed by the other Party and have been approved for publication, the same abstracts, manuscripts or presentations do not have to be provided again to the other Party for review for a later submission for publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Parties. The other Party also will have the right to require that its Confidential Information that may be disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation.

10.2.2 Publications by Third Parties. Notwithstanding Section 10.2.1, the Parties understand and agree that any restrictions on scientific or other presentations or publications will not be construed to prohibit the clinical investigators of any clinical trials conducted under this Agreement, from making scholarly publications, manuscripts, abstracts, oral presentations or other disclosures with respect to the results of any Development work, including without limitation clinical data resulting from such clinical trials ("**Publications**"); provided that AEVI will ensure that (a) any such clinical investigator must agree to submit to KKC for its review and comment, a copy of any proposed Publication, abstract or other disclosure resulting from such activities, simultaneous with submission of the same to AEVI and at least forty-five (45) days prior to any such presentation or publication, (b) such publication will not contain any references to, or otherwise disclose any of, the Confidential Information (other than clinical data) without KKC's prior written consent, and (c) at KKC's request, such clinical investigator will, for a reasonable period of up to ninety (90) days from initial delivery to KKC, delay revealing any subject matter included in the clinical data in any publication or disclosure in order to permit the filing of patent applications.

10.3 Public Announcements and Use of Names. Except for public disclosures (a) resulting from the issuance of one or more press releases to be mutually-agreed upon by the Parties, (b) otherwise permitted under this Article 10 or (c) required by Applicable Law or by the rules and regulations of any securities exchange on which a Party's securities are traded, neither Party will disclose any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the execution of this Agreement, the subject matter of this Agreement, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party.

Article 11.

TERM AND TERMINATION

11.1 Term

. This Agreement will commence on the Effective Date and will remain in full force and effect for as long as any Licensed Product(s) is Commercialized by either Party and/or its Related Parties, unless terminated earlier pursuant to Section 11.2 or 11.3 (the "**Term**").

11.2 Termination by KKC.

11.2.1 Insolvency. To the extent permitted under Applicable Laws, KKC will have the right to terminate this Agreement in its entirety, at KKC's sole discretion, upon delivery

of written notice to AEVI upon the filing by AEVI in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of AEVI or its assets, upon the proposal by AEVI of a written agreement of composition or extension of its debts, or if AEVI is served by a Third Party (and not by KKC) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by AEVI of an assignment for the benefit of its creditors.

11.2.2 Breach. KKC will have the right to terminate this Agreement in its entirety, at KKC's sole discretion, subject to Section 11.2.4, upon delivery of written notice to AEVI in the event of any material breach (other than a material breach of Sections 6.1 and/or 6.2 or a material breach that is specific to a given country in the Territory) by AEVI of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and KKC's intention to terminate is given by KKC to AEVI; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by KKC (except that in the case of a bona fide dispute over whether or to what extent a payment by AEVI to KKC is due, this Section 11.2.2 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Subject to Section 11.2.4, any such termination of this Agreement will become effective at the end of the applicable cure period, unless AEVI has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, KKC's right of termination will be suspended only if and for so long as AEVI has provided to KKC a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to KKC (such acceptance not to be unreasonably withheld, conditioned, or delayed), and AEVI commits to and carries out such plan as provided to KKC.

11.2.3 Diligence or Country-Specific Breach. In the case of a material breach by AEVI of Sections 6.1 and/or 6.2 or a material breach by AEVI that is specific to a given country in the Territory, subject to Section 11.2.4, KKC will have the right to terminate this Agreement only as to the particular country to which such breach relates and not as to this Agreement in its entirety, upon delivery of written notice to AEVI provided that such breach has not been cured within (***) after written notice of such breach and KKC's intention to terminate is given by KKC to AEVI; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by KKC (except that in the case of a bona fide dispute over whether or to what extent a payment by AEVI to KKC is due, this Section 11.2.3 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Subject to Section 11.2.4, any such termination of this Agreement will become effective at the end of the applicable cure period, unless AEVI has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, KKC's right of termination will be suspended only if and for so long as AEVI has provided to KKC a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to KKC

(such acceptance not to be unreasonably withheld, conditioned, or delayed), and AEVI commits to and carries out such plan as provided to KKC.

11.2.4 Termination for Patent Challenge. If AEVI or any of its Affiliates directly claim, or cause a Third Party to claim, or knowingly supports (other than as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or in response to a subpoena or court or administrative law request or order), including by providing information, documents, and/or funding, a claim (a) to the validity, scope, enforceability or patentability of any of the KKC Patent Rights in any formal legal or administrative action or proceeding, or (b) that no Earned Royalties, Sublicense Royalties, Net Receipts, milestone payments, Patent Costs or other payments (as such capitalized terms are defined under the LJI Agreement) are due or required to be paid to LJI under the LJI Agreement because the applicable KKC Patents licensed by LJI to KKC under the LJI Agreement covering or claiming a Licensed Product are invalid or unenforceable except where such KKC Patent Rights have been found to be unpatentable, invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal is taken or can be taken, or have been admitted or determined to be invalid or unenforceable through reissue, re-examination, disclaimer or similar formal proceeding, or where a pending application within the KKC Patent Rights has been abandoned or finally rejected (in each case, other than pursuant to a claim by KKC, AEVI or their respective Affiliates or by a Third Party caused by any of the foregoing entities) in any Challenge, then (x) if and to the extent permitted by Applicable Law, (***) during and after the pendency of such Challenges from the date KKC, AEVI, or any of their respective Affiliates first institute or make such challenges. In such event, notwithstanding anything to the contrary in this Agreement, (i) AEVI will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of KKC or any of its Affiliates (in which case, KKC will be responsible for (***)), and (ii) KKC will not be obligated to (***) in case such Challenges are initiated or conducted solely by or on behalf of AEVI or any of its Affiliates (in which case, AEVI (***)). (***) under this Section 11.2.4 (x) may be exercised at any time after AEVI (or any of its Affiliates) may have Challenged or knowingly supports (other than in response to a subpoena or court order) a Challenge to the validity, enforceability or patentability of any of the KKC Patent Rights. If a sublicensee of AEVI Challenges the validity, scope or enforceability of or otherwise opposes any of the KKC Patent Rights under which such sublicensee is sublicensed, then AEVI will, upon written notice from KKC, promptly terminate such sublicense. “**Challenge**” under this Section 11.2.3 will refer to a legal action or filing with a patent authority or tribunal or a court that could, if successful, result in a holding of invalidity, unenforceability, or unpatentability of a patent or application within the KKC Patent Rights.

11.2.5 Dispute. If AEVI reasonably and in good faith disagrees as to whether KKC has a basis for terminating this Agreement pursuant to Section 11.2.2, AEVI may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by KKC pursuant to Section 11.2.2 will be effective unless and until KKC’s right to terminate this Agreement under Section 11.2.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other

Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.2.6 Abandonment. If AEVI, in its discretion, decides to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, AEVI will promptly notify KKC in writing of its intent to do so. KKC will have the right to terminate this Agreement immediately upon receipt of such notice.

11.3 Termination by AEVI.

11.3.1 Insolvency. To the extent permitted under Applicable Law, AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, upon delivery of written notice to KKC upon the filing by KKC in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of KKC or its assets, upon the proposal by KKC of a written agreement of composition or extension of its debts, or if KKC is served by a Third Party (and not by AEVI) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by KKC of an assignment for the benefit of its creditors.

11.3.2 Breach. AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, subject to Section 11.3.4, upon delivery of written notice to KKC in the event of a material breach by KKC of this Agreement, provided that such breach has not been cured within (***) after written notice of such breach and AEVI's intention to terminate is given by AEVI to KKC; provided, however, that if such breach relates to the failure to make a payment when due, such breach must be cured within (***) after written notice thereof is given by AEVI (except that in the case of a bona fide dispute over whether or to what extent a payment by KKC to AEVI is due, this Section 11.3.2 will not be triggered provided that KKC will pay the amount in dispute into escrow until such dispute is resolved). Such termination will be effective upon expiration of the applicable time period set forth in this Section 11.3.2. Subject to Section 11.3.4, any such termination of this Agreement will become effective at the end of the applicable cure period, unless KKC has cured any such breach or default prior to the expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then, AEVI's right of termination will be suspended only if and for so long as KKC has provided to AEVI a written plan that is reasonably calculated to effect a cure within (***) thereafter and such plan is acceptable to AEVI (such acceptance not to be unreasonably withheld, conditioned, or delayed), and KKC commits to and carries out such plan as provided to AEVI.

11.3.3 Convenience. (***), such termination to be effective at the end of such notice period, AEVI may terminate this Agreement as to such Licensed Product and/or such jurisdiction for any reason or no reason, including if AEVI, in its reasonable discretion, decides to cease all of its Development and/or Commercialization efforts with respect to such Licensed Product in such jurisdiction.

11.3.4 Dispute. If KKC reasonably and in good faith disagrees as to whether AEVI has a basis for terminating this Agreement pursuant to Section 11.3.2, KKC may contest the allegation in accordance with Section 13.2. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. No termination by AEVI pursuant to Section 11.3.2 will be effective unless and until KKC's right to terminate this Agreement under Section 11.3.2 has been finally determined by arbitration in accordance with Section 13.2. Any payments that are owed one Party to the other Party pursuant to this Agreement affected by such dispute may be paid into escrow pending resolution of the dispute, and then paid or refunded to the appropriate party as determined pursuant to Section 13.2.

11.3.5 No obligation to KKC. In any termination pursuant to this Section 11.3, KKC has no obligation for further Development, Manufacture and/or Commercialization of the Licensed Product. AEVI shall be responsible for all negotiations with BARDA for the abandonment, and KKC will not take over from AEVI any Development, Manufacture and /or Commercialization for Licensed Product requested by BARDA.

11.4 Consequences of Termination. Upon termination of this Agreement in its entirety or with respect to a country in the Territory (in which event the following will apply only with respect to such country):

11.4.1 Reversion. All rights and licenses granted to AEVI in Article 7 will terminate, all rights of AEVI under the KKC Technology will revert to KKC, and AEVI and its Affiliates will cease all use of the KKC Technology. Except as set forth in Sections 11.4.2 through 11.4.9, all rights and licenses granted to KKC in Article 7 will terminate, all rights of KKC under the AEVI Technology will revert to AEVI, and KKC and its Affiliates will cease all use of the AEVI Technology.

11.4.2 Regulatory Filings. AEVI will assign, and hereby does assign effective as of the effective date of such termination, to KKC all Regulatory Filings (including all INDs and NDAs) and Regulatory Approvals and all other documents necessary to further Develop, Manufacture, and Commercialize the Licensed Products, as they exist as of the date of such termination, (and all of AEVI's right, title and interest therein and thereto). AEVI will provide to KKC one (1) copy of the foregoing documents and Regulatory Filings, all documents and filings contained in or referenced in any such Regulatory Filings, together with the raw and summarized data for any preclinical and clinical studies of the Licensed Product. For clarity, KKC will have the right to use the foregoing material information, materials and data developed by AEVI solely in connection with KKC's development, manufacture and commercialization of Licensed Products. KKC will have the right to seek specific performance of AEVI's obligations referenced in this Section 11.4.2 and/or in the event of failure to obtain assignment, AEVI hereby consents and grants to KKC the right to access and reference (without any further action required on the part of AEVI, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose. Without limiting the foregoing in this paragraph, to the extent applicable, AEVI's obligations

under this Section 11.4.2 will continue with respect to all countries in the Territory for which there is a failure to obtain assignment of all regulatory filings and Regulatory Approvals.

11.4.3 Know-How Transfer. AEVI will provide to KKC all data and information generated during the Term necessary for the development and/or commercialization of the relevant Licensed Products and assign (or, if applicable, cause its Affiliate to assign) to KKC all of AEVI's (and such Affiliate's) entire right, title and interest in and to all such data and information. AEVI will provide to KKC the tangible embodiments of all other Know-How Controlled by AEVI and its Affiliates in existence as of the effective date of such termination relating to the Development, Manufacturing, and Commercialization of the Licensed Products, including without limitation AEVI's manufacturing processes, techniques and trade secrets necessary for and used in the manufacture of such Licensed Products as of the effective date of such termination and all Know-How specifically relating to any composition, formulation, method of use or manufacture of such Licensed Products. AEVI will grant, and hereby does grant effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide right and license under such Know-How for developing, making, using, importing, selling and offering for sale Licensed Products. AEVI will reasonably cooperate with KKC to assist KKC with understanding and using the Know How provided to KKC under this Section 11.4.3. If AEVI has decided to abandon all of its Development and/or Commercialization efforts with respect to the Licensed Product, and this Agreement is terminated pursuant to Section 11.2.5, AEVI will provide to KKC all technology resulting from such abandoned Development and/or Commercialization efforts. KKC will have a royalty-free, irrevocable, world-wide, unlimited license to such abandoned Development and/or Commercialization efforts including the right to sublicense and to contract with Third Parties for further Development and/or Commercialization.

11.4.4 Trademarks. To the extent that AEVI owns any trademark(s) (including without limitation any Product Trademarks) and/or domain names that pertain specifically to an Licensed Product that KKC believes would be necessary for the Commercialization of a Licensed Product (as then currently marketed, but not including any marks that include, in whole or part, any corporate name or logo of AEVI), AEVI will assign (or, if applicable, cause its Affiliate to assign), and hereby does assign effective as of the effective date of such termination, to KKC all of AEVI's (and such Affiliate's) right, title and interest in and to any registered or unregistered trademark, trademark application, trade name or internet domain name in each country.

11.4.5 Termination License. AEVI will grant, and hereby grants effective as of the effective date of such termination, to KKC a non-exclusive, irrevocable, royalty-free, transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license under any Patent Rights owned solely by AEVI or its Affiliates as of the effective date of termination to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products. AEVI will grant to KKC, under any Patent Rights that AEVI's Controls but does not own at the time of termination, to the full extent permitted under the agreement(s) of AEVI covering such Patent

Rights, a non-exclusive, irrevocable, royalty-free (as to AEVI), transferable, sublicensable, worldwide (excluding the countries of the Territory to which AEVI retains its rights) right and license, to the extent that such Patent Rights cover or claim the composition of matter, use, or manufacture of Licensed Products and for the sole purpose of developing, manufacturing, and commercializing Licensed Products; provided that KKC enters into a written agreement with AEVI with respect to each such Patent Right that (a) ensures compliance with the applicable contract between AEVI and its licensor including KKC agreeing to all provisions thereof that must be imposed on sublicensees, (b) requires KKC to pay all amounts payable to its licensor by AEVI related to KKC's exercise or enjoyment of such rights including milestones, royalties and patent expenses and (c) indemnifies AEVI for any breach of such agreement between KKC and AEVI.

11.4.6 Continued Supply. If AEVI has any inventory of any Licensed Products suitable for use in clinical trials, AEVI will offer to sell such Licensed Products to KKC at (***) (but KKC will be under no obligation to purchase the foregoing inventory of Licensed Products unless it agrees to do so in writing at such time); provided, however, that, in the event of a termination pursuant to Section 11.3.3, (***). If AEVI has the capability in place as of the effective date of such termination to commercially Manufacture and supply to KKC all or part of KKC's requirements of the applicable Licensed Products, if KKC so elects in its sole discretion, AEVI will use Commercially Reasonable Efforts to supply to KKC (**) as much of KKC's requirements of such Licensed Products (and to develop a reasonable inventory level) during such period, (**) for such Licensed Products, under terms and conditions as may be mutually agreed between the Parties. If KKC, despite its best efforts, is unable to Manufacture, or to secure a supply of, such Licensed Products in an amount sufficient to meet its requirements (**), AEVI will continue to supply such Licensed Products to KKC to the extent necessary to meet KKC's requirements, so long as KKC continues to use its best efforts to develop the capabilities necessary to Manufacture such Licensed Products and/or to secure a supply of such Licensed Products.

11.4.7 Transfer of Manufacturing Technology. In the event, at the time of such termination, (a) AEVI manufactures the Licensed Products at its own facility, AEVI will conduct manufacturing technology transfer to KKC, and (b) if AEVI engages a Third Party to manufacture and supply the Licensed Products, AEVI will, at KKC's election, either (i) have such Third Party conduct manufacturing technology transfer to KKC or (ii) will use reasonable efforts to assist in the transfer of such supply arrangements to KKC.

11.4.8 Continuing Obligations. Neither Party will be relieved of any obligation that accrued prior to the effective date of such termination. All amounts due or payable to KKC that were accrued prior to the effective date of termination will remain due and payable. Except as otherwise expressly provided herein, no additional amounts will be payable based on events occurring after the effective date of termination; provided that the foregoing will not be deemed to limit either Party's indemnification obligations under this Agreement for acts or omissions incurring prior to the effective date of such termination that are the subject of such indemnification even if the indemnification amount cannot be accrued or determined as of the effective date of such termination.

11.4.9 Retention of Payments. KKC will have the right to retain all amounts previously paid to KKC by AEVI.

11.4.10 No Compensation. KKC will not owe any compensation to AEVI for the research, development, manufacture, or commercialization of any Licensed Products in the event of any termination of the Agreement by KKC, without prejudice to any rights that either Party may have to bring a claim for damages arising out of this Agreement and the termination thereof or any other amounts payable with respect to activities conducted prior to the effective date of such termination.

11.4.11 Costs. Any costs and expenses incurred by AEVI in connection with the assignments and transfers made by AEVI under this Section 11.4 will be borne by AEVI.

11.5 Return of Confidential Information. Upon the termination of this Agreement, each Party will promptly return to the other Party, delete or destroy (with written notification of such destruction) all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only.

11.6 Effect of Termination; Survival. The termination of this Agreement will not relieve the Parties of any obligation accruing prior to such termination. The provisions of Article 10 (Confidentiality), Article 12 (Representations and Warranties; Indemnification) and Article 13 (Miscellaneous Provisions) and Sections 7.4.3 (Effect of Termination on Sublicenses), 7.7 (Obligation under the BARDA Contract), 9.2.2 (Joint Inventions) and 11.3.5 (No obligation to KKC) will survive any termination of this Agreement. Except as set forth in this Article 11 or as otherwise set forth in this Agreement, upon termination of this Agreement all other rights and obligations cease. Any termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

11.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by either Party, including without limitation Article 7, are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "**IP**"). The Parties agree that each Party, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. In the event of termination of a Party pursuant to Section 11.2.1 or 11.3.1, the terminated Party hereby grants to the other Party and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of intellectual property, which, if not already in such other Party's possession, will be promptly delivered to it upon such other Party's written request therefor. The term "embodiments of intellectual property" includes all tangible, electronic or other embodiments of rights and licenses hereunder, including all Licensed Products, all Regulatory Approval Applications and Regulatory Approvals and rights of reference therein, and all Information related to Licensed Products, KKC Technology and

AEVI Technology, as applicable. The terminated Party will not interfere with the exercise by the other Party or its Affiliates of rights and licenses to IP and embodiments of intellectual property licensed hereunder in accordance with this Agreement and agrees to assist such other Party and Affiliates of such other Party to obtain the IP and embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for such other Party or Affiliates of such other Party to exercise such rights and licenses in accordance with this Agreement. The Parties acknowledge and agree that milestone payments made under Section 8.3 do not constitute royalties within the meaning of U.S. Bankruptcy Code §365(n) or relate to licenses of intellectual property hereunder.

11.8 No Limitation of Remedies. Except as herein expressly provided, notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination nor prejudice either Party's right to obtain performance of any obligation. Each Party will be free, pursuant to Section 13.2, to seek (without restriction as to the number of times it may seek) damages, costs and remedies that may be available under Applicable Law or in equity and will be entitled to offset the amount of any damages and costs obtained in a final determination under Section 13.2 of monetary damages or costs (as permitted by this Agreement) against the other Party against any amounts otherwise due to such other Party under this Agreement. It is understood and agreed that either Party will be entitled to seek specific performance as a remedy to enforce the provisions of this Article 11, in addition to any other remedy to which such Party may be entitled by Applicable Law. Nothing in this Article 11 will be deemed to limit any remedy to which either Party may be entitled by Applicable Law.

Article 12.

REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION

12.1 Mutual Representations and Warranties. Each Party represents, warrants and covenants to the other Party that as of the Effective Date of this Agreement:

(a) Corporate Existence and Authority. It is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Authorized Execution; Binding Obligation.

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

(ii) This Agreement has been duly executed and delivered by it and constitutes a legal, valid, and binding obligation enforceable against it in accordance with this Agreement's terms, except as the same may be limited by applicable bankruptcy, insolvency,

reorganization, moratorium or other laws relating to or affecting creditors' rights generally and by general equity principles, including judicial principles affecting the availability of injunction and specific performance.

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

(d) All Consents and Approvals Obtained. Except with respect to any consent required from Lonza or Sanofi, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all governmental authorities and other persons or entities required to be obtained or provided by such Party in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those government approvals, if any, not required at the time of execution of this Agreement.

(e) Compliance with Law. It will at all times comply with Applicable Laws in all material respects. Neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered services relating to the Licensed Products: (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be debarred by the FDA (or subject to a similar sanction of a Regulatory Authority) or (ii) has ever been under indictment for a crime for which a person or entity could be so debarred.

12.2 KKC Representations and Warranties. KKC represents and warrants to AEVI that as of the Effective Date:

(a) KKC Controls the KKC Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The KKC Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by KKC as of the Effective Date that are necessary or useful to Develop, Manufacture and Commercialize the Licensed Product. KKC has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(b) To the knowledge of KKC, there is no actual or threatened infringement of the KKC Patent Rights in the Field by any Third Party that would adversely affect AEVI's rights under this Agreement.

(c) To the knowledge of KKC, the KKC Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by KKC or any of its Affiliates relating to the KKC Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and KKC is not aware of any reasonable basis for a claim alleging that (i) the KKC Patent Rights are invalid or unenforceable, (ii) the KKC Patent Rights or the licensing or exploiting of the KKC Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party, or (iii) any

Third Party other than a KKC Licenser has any right, title, or interest in, to, and under any KKC Patent Rights.

(d) To the knowledge of KKC, KKC is not in default, and to KKC's knowledge, none of the KKC Licensors is in default, with respect to a material obligation under, and neither such party has claimed or has grounds upon which to claim that the other party is in default with respect to a material obligation under, any KKC In-Licenses, and KKC has not waived or allowed to lapse any of its rights under any KKC In-Licenses, and no such rights have lapsed or otherwise expired or been terminated.

(e) There are no claims, judgments or settlements against or owed by KKC or its Affiliates or pending or threatened claims or litigation relating to the KKC Technology.

12.3 KKC Covenants. KKC covenants that during the Term:

(a) KKC will use Commercially Reasonable Efforts to fulfill its obligations under the KKC In-Licenses to the extent such obligations have not been delegated to AEVI and to the extent that failure to do so would materially adversely affect AEVI or its rights hereunder.

(b) KKC will not assign, transfer, convey or otherwise encumber its right, title and interest in the KKC Technology in a manner that conflicts with any rights granted to AEVI hereunder.

(c) KKC will not enter into any subsequent agreement with any KKC Licenser that modifies or amends any KKC In-Licenses in any way that would materially adversely affect AEVI's rights or economic interest under this Agreement without AEVI's prior written consent.

(d) KKC will not terminate any KKC In-Licenses in whole or in part, directly or indirectly, without AEVI's prior written consent if such termination would materially affect AEVI's license granted hereunder; for clarity KKC may (i) terminate any KKC In-Licenses by acquiring all of the intellectual property licensed thereunder, or (ii) terminate its obligation to make royalty and milestone payments by making a lump-sum payment, and KKC will promptly notify AEVI after the occurrence of each such event.

(e) KKC will furnish AEVI with copies of all notices received by KKC relating to any alleged breach or default by KKC under any KKC In-Licenses within (***) after KKC's receipt thereof and, if KKC cannot or chooses not to cure or otherwise resolve any such alleged breach or default, KKC will so notify AEVI within (***) thereafter.

12.4 AEVI Representations and Warranties. AEVI represents and warrants to KKC that as of the Effective Date:

(a) AEVI Controls the AEVI Patent Rights existing as of the Effective Date and is entitled to grant the rights and licenses specified herein. The AEVI Technology existing as of the Effective Date constitute all of the Patent Rights, Know-How and Inventions Controlled by AEVI as of the Effective Date that are necessary or useful to Develop, Manufacture and

Commercialize the Licensed Product. AEVI has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

(b) To the knowledge of AEVI, there is no actual or threatened infringement of the AEVI Patent Rights in the Field by any Third Party that would adversely affect KKC's rights under this Agreement.

(c) To the knowledge of AEVI, the AEVI Patent Rights existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part; there are no claims, judgments or settlements against or amounts with respect thereto owed by AEVI or any of its Affiliates relating to the AEVI Patent Rights; and no claim or litigation has been brought or threatened by any Third Party alleging, and AEVI is not aware of any reasonable basis for a claim alleging that (i) the AEVI Patent Rights are invalid or unenforceable, (ii) the AEVI Patent Rights or the licensing or exploiting of the AEVI Patent Rights violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party or (iii) any Third Party other than the AEVI Licensor has any right, title, or interest in, to, and under any AEVI Patent Rights.

(d) To the knowledge of AEVI, the Development activities set forth in the initial Development Plan do not infringe any third party intellectual property rights.

(e) There are no claims, judgments or settlements against or owed by AEVI or its Affiliates or pending or threatened claims or litigation relating to the AEVI Technology.

12.5 AEVI Covenants. AEVI covenants that during the Term:

(a) AEVI will not engage in any activities that use the KKC Technology in a manner that is outside the scope of the rights granted to it hereunder.

(b) All of AEVI's activities related to its use of the KKC Technology, and the research, Development and Commercialization of the Licensed Products, pursuant to this Agreement will comply with all Applicable Laws.

(c) AEVI will not assign, transfer, convey or otherwise encumber its right, title and interest in the AEVI Technology in a manner that conflicts with any rights granted to KKC hereunder.

12.6 Mutual Covenants. Each Party hereby covenants to the other Party that during the Term:

(a) All employees and officers of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their Inventions, whether or not patentable, if any, to such Party as the sole owner thereof, and under the obligation to maintain as confidential the Confidential Information of such Party.

(b) Such Party will perform its activities pursuant to this Agreement in compliance with good clinical practices and good manufacturing practices, in each case as applicable under the Applicable Laws and regulations of the country and the state and local government wherein such activities are conducted, and also with the standards in the pharmaceutical industry for the development and commercialization of pharmaceutical products.

(c) Such Party will not employ (or, to its knowledge, use any contractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or, to its knowledge, any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority), in the conduct of its activities under this Agreement, and each contractor or consultant used by such Party in connection with the conduct of clinical trials under this Agreement will be subject to a covenant that is the same or substantially the same as the foregoing covenant.

(d) Such Party will not practice or exploit the intellectual property licensed to such Party under this Agreement except to the extent expressly permitted under the terms and conditions of this Agreement.

(e) Such Party will not grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to the other Party hereunder.

12.7 Consequences of Partial Termination of an In-License. In the event that a portion, but not all of KKC's rights under the KKC In-Licenses terminate, then AEVI will owe no further obligations to KKC under this Agreement with respect to such terminated rights.

12.8 Warranty Disclaimer. The Parties acknowledge and agree that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) will be construed as representing an estimate or projection of either (a) the extent to which Licensed Products will be successfully Developed or Commercialized or (b) the anticipated sales or the actual value of any Licensed Product. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT IT WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT(S). EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

12.9 No Consequential Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING WITHOUT LIMITATION LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.9 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR TO LIMIT A PARTY'S LIABILITY FOR BREACHES OF ITS OBLIGATION REGARDING CONFIDENTIALITY UNDER Article 10.

12.10 Indemnification and Insurance.

12.10.1 Indemnification by AEVI. AEVI will indemnify, hold harmless, and defend KKC, its Affiliates, and their respective directors, officers, employees and agents ("**KKC Indemnitees**") from and against any and all damages, losses, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments of any kind (collectively, "**Losses**") arising out of any Third Party claim (including any claim from BARDA), suit or proceeding, whether for money or equitable relief (each, a "**Third Party Claim**"), arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by AEVI in this Agreement, or any breach or violation of any covenant or agreement of AEVI or a Related Party in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of AEVI or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by AEVI or its Affiliate or sublicensee (including a sublicensed contract manufacturer) of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by AEVI or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from AEVI's exercise in accordance with the terms of this Agreement of any intellectual property rights granted by KKC hereunder. Furthermore, AEVI will have no obligation to indemnify the KKC Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any matter for which KKC must indemnify AEVI under this Agreement. In addition, AEVI will indemnify, hold harmless, and defend (i) LJI and its directors, officers, employees, and agents from and against any and all Losses (including costs of investigation and court costs) arising at any time from or in any manner connected with, directly or indirectly, any activity of AEVI involving the KKC Patent Rights solely owned by LJI or any information furnished under the LJI Agreement, including the use, handling, storage, distribution, containment, sale and/or disposition of any product (whether or not a Licensed Product), or provision of any service, related to or derived directly or indirectly from or using any KKC Patent Rights solely owned by LJI; and (ii) the KKC Indemnitees from and against any and all Losses arising out of any Third Party Claims related to, directly or indirectly, any activities performed by or on behalf of AEVI or AEVI's Third Party contract manufacturer in connection with the exercise of rights under the KKC Technology licensed under the KKC In-License with Lonza, if, pursuant to Section 7.4.1, KKC sublicenses its rights under such KKC Technology to AEVI or AEVI's Third Party contract manufacturer for the Manufacture of Licensed Products by AEVI or such contract manufacturer.

12.10.2 Indemnification by KKC. KKC will indemnify, hold harmless, and defend AEVI, its Affiliates and their respective directors, officers, employees and agents (“**AEVI Indemnitees**”) from and against any and all Losses arising out of Third Party Claims arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by KKC in this Agreement, or any breach or violation of any covenant or agreement of KKC in or pursuant to this Agreement, (b) the negligence or willful misconduct by or of KKC or any of its Related Parties, and their respective directors, officers, employees and agents, (c) the practice by KKC or its Affiliate or sublicensee of any license or sublicense granted to it under Article 7, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by KKC or any of its Related Parties. This indemnification excludes Losses arising out of Third Party Infringement Claims resulting from KKC’s exercise in accordance with the terms of this Agreement of any intellectual property rights granted by AEVI hereunder. Furthermore, KKC will have no obligation to indemnify the AEVI Indemnitees to the extent that the Losses arise out of or result from, directly or indirectly, any matter for which AEVI must indemnify KKC.

12.10.3 Indemnification Procedure. In the event of any such claim against any AEVI Indemnitee or KKC Indemnitee (individually, an “**Indemnitee**”), the indemnified Party will promptly notify the other Party in writing of the claim and the indemnifying Party will manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnitee will cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party will not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party’s written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Section 12.10.1 or Section 12.10.2 may apply, the indemnifying Party will promptly notify the Indemnitees, which will then have the right to be represented in any such action or proceeding by separate counsel at their expense; provided that the indemnifying Party will be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. If the indemnifying Party does not assume the defense of such claim as described in this Section 12.10.3, above, the Indemnitee may defend such claim but will have no obligation to do so. The defending Party will not settle or compromise such claim without the prior written consent of the other Party, and will not settle or compromise such claim in any manner which would have an adverse effect on such other Party’s interests, without the prior written consent of such other Party, which consent, in each case, will not be unreasonably withheld, conditioned, or delayed.

12.10.4 Insurance. Each Party will use its Commercially Reasonable Efforts to maintain insurance, including product liability insurance, with respect to its activities hereunder. Such insurance will be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time in order to fulfill the obligation under Section 12.10.1 or 12.10.2, including, but not limited to, the indemnification against any Losses involving any actual or alleged death or bodily injury arising out of or resulting from the Development, Manufacture or Commercialization of any Licensed Product.

Article 13.
MISCELLANEOUS PROVISIONS

13.1 Governing Law

. This Agreement will be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York, New York, U.S.A., notwithstanding the provisions governing conflict of laws of any jurisdiction to the contrary.

13.2 Dispute Resolution.

13.2.1 With respect to any disputes between the Parties concerning this Agreement, the dispute will be submitted to escalating levels of AEVI and KKC senior management for review. If the dispute cannot be resolved despite such escalation, then the matter will be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, by the Executive Officers will be final and binding on the Parties. If the Executive Officers are unable to resolve such dispute within such thirty (30) day period, each Party may submit such dispute for arbitration pursuant to Section 13.2.2.

13.2.2 Arbitration.

(a) If any dispute will arise between KKC and AEVI in connection with or relating to this Agreement, then such dispute will be resolved exclusively by and through an arbitration proceeding to be conducted under the auspices of, and pursuant to, the Commercial Rules of the International Chamber of Commerce (together with any successor organization thereto, the “**ICC**”) in New York, New York, U.S.A. Such arbitration proceeding will be conducted in the English language applying the law provided in Section 13.1 and in such an expedited manner as is then permitted by the ICC’s commercial arbitration rules. The Parties also agree to take reasonable discovery, with reasonableness to be determined by the arbitrators. Each of the foregoing agreements to arbitrate all disputes and the results, determinations, findings, judgments and awards rendered through such arbitration will be final, non-appealable and legally binding on KKC and AEVI and may be entered and enforced by any court or tribunal of competent jurisdiction. Notwithstanding anything to the contrary in this Section 13.2, a Party may seek injunctive relief in any court of competent jurisdiction.

(b) Any arbitration proceeding will be initiated by written notice from either KKC or AEVI to the other Party. The arbitration will be conducted before a panel of three (3) arbitrators. Each of KKC and AEVI will have the right to select one (1) arbitrator. The third arbitrator will be selected by the mutual agreement of the arbitrators appointed by the Parties. The Party initiating the arbitration proceeding will appoint its arbitrator within ten (10) days following service of the demand for arbitration to the other Party, who will in turn appoint its arbitrator within thirty (30) days of receiving service of the demand. The two appointed arbitrators will agree upon an arbitrator within thirty (30) days of the date of the appointment by the parties of the second arbitrator. If either Party or their appointees fail to appoint an arbitrator within the specified time period, the ICC will exercise its powers pursuant to Article 9 of the ICC

Rules of Arbitration to appoint such arbitrator. The ICC's appointment will be binding on the Parties. Each arbitrator will be an attorney in good standing in the Bar of New York and experienced in commercial disputes involving pharmaceutical companies. Time is of the essence of this arbitration procedure, and KKC and AEVI will instruct the arbitrators to render their decision within ninety (90) days of the arbitration's completion. The cost of the arbitration (including, without limitation, reasonable attorneys' fees, expenses and disbursements) will be borne as the arbitrators will decide; otherwise such costs (including, without limitation, the prevailing Party's reasonable attorneys' and accountants' fees, expenses and disbursements) will be borne by the Party against which the judgment of the arbitrator is to be enforced.

13.3 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party. Notwithstanding the foregoing, (a) KKC may monetize the value of its payments under this Agreement by assigning to a Third Party the right to receive payments and the right to receive payment reports from AEVI; provided that KKC gives thirty (30) days prior written notice to AEVI, and (b) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or pursuant to a Change of Control (but subject to the consent of Sanofi, to the extent required under Applicable Law, in respect of the KKC Technology licensed under the KKC In-License with Sanofi in the case of assignment by AEVI). The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned to such assignee.

13.4 Entire Agreement; Amendments. This Agreement and the Schedules and Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, except that Article 1 through 10 of the Clinical Development and Option Agreement will govern with respect to matters occurring prior to the Effective Date. Any amendment or modification to this Agreement will be made in writing signed by both Parties.

13.5 Notices. Any consent or notice required to be given or made under this Agreement by one of the Parties to the other will be in writing and (a) delivered by hand, (b) sent by internationally recognized overnight delivery service or (c) sent by facsimile transmission and confirmed by sender by prepaid, registered or certified mail letter, and will be deemed to have been properly served to the addressee upon receipt of such written communication, in any event to the following addresses:

If to KKC:

Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Business Development Department
Facsimile No.: +81-3-5205-7129

with a copy to:

Kyowa Kirin Co., Ltd.
1-9-2, Otemachi
Chiyoda-ku, Tokyo 100-0004
Japan
Attention: Director of Legal Affairs Group, Legal and Intellectual
Property Department
Facsimile No.: +81-3-5205-7130

If to AEVI:

Aevi Genomic Medicine, LLC
435 Devon Park Drive, Bldg 700, Suite 715
Wayne, PA 19087
Attention: Chief Executive Officer
Facsimile No.: +1 (443) 304-8001

with a copy to:

Pepper Hamilton LLP
Two Logan Square
18th & Arch Streets
Philadelphia, Pennsylvania 19103-2799
Attention: Brian M. Katz
Facsimile No.: +1 (215) 981-4750

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) if personally delivered, when delivered; (b) if sent by internationally-recognized overnight courier, on the Business Day of the sender during which the sender delivers the notice to the courier; or (c) if sent by facsimile, when all pages of the notice are successfully transmitted (as shown by a report generated by the sender's facsimile machine) during a Business Day of the sender.

13.6 Force Majeure. The failure of either Party to timely perform any obligation under this Agreement by reason of epidemic, earthquake, riot, civil commotion, fire, act of God, war, terrorist act, strike, flood, or governmental act or restriction, or other cause that is beyond the reasonable control of such Party, will not be deemed to be a breach of this Agreement, but will be excused to the extent and for the duration of such cause, and the affected Party will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and will use

its Commercially Reasonable Efforts to avoid or remove such cause, and will perform its obligation(s) with the utmost dispatch when the cause is removed. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than one hundred eighty (180) days, the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

13.7 Compliance with Export Regulations. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

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

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

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

13.11 Performance by Affiliates. Each Party recognizes that the other Party may perform some or all of its obligations under this Agreement through Affiliates to the extent permitted under this Agreement; *provided, however*, that such other Party will remain responsible for the performance by its Affiliates as if such obligations were performed by such other Party.

13.12 Construction. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including” as used herein means including, without limiting the generality of any description that precedes such term, and will be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import regardless of whether such words are actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after the word “including” but not others). References to “Article”, “Articles”, “Section”, “Sections”, “Exhibit” or “Exhibits” are references to the numbered Article(s), Section(s), or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, (a) references to a particular law, rule or regulation mean such law, rule or regulation as in effect

as of the relevant time, including all rules and regulations thereunder and any successor law, rule or regulation in effect as of the relevant time, and including the then-current amendments thereto; (b) the word “or” has the inclusive meaning that is typically associated with the phrase “and/or”; (c) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (d) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; (e) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; and (f) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits).

13.13 No Implied Waivers; Rights Cumulative. No failure on the part of KKC or AEVI to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

13.14 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one (1) or several provisions of this Agreement will 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.

13.15 No Third Party Beneficiaries. Except as expressly set forth in Section 12.10.2, no person or entity other than AEVI, KKC and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[Remainder of Page Left Blank Intentionally. Schedules Follow.]

Schedule 1.13

AMINO ACID SEQUENCE OF ANTI-LIGHT MAB

(***)

Schedule 1.23

Commercialization Costs

Examples of Commercialization Costs

Commercialization Costs will include, but will not be limited to, the following, in each case attributable to, or reasonably allocable to, Commercialization of Licensed Products in the Field in the Territory:

Detailing costs - costs associated with interactive face-to-face visits by a sales representative with a medical professional who has prescribing authority or is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses.

Distribution costs - costs identifiable to the distribution of a Licensed Product to a customer (and not otherwise deducted from Net Sales), including customer and specialty pharmacy services (including costs associated with establishing and running customer call centers), collection of data about sales to hospitals, clinics and other customers, order entry, billing, shipping, logistics, warehousing, product insurance, freight not paid by customers, credit and collection and other like activities the costs of which are includable in “distribution costs” in accordance with the Accounting Standards.

Early Access Program or EAP costs – costs associated with any program to provide patients with products free of charge. Early access programs include treatment INDs / protocols and compassionate use programs, as applicable. For clarity, an EAP with respect to a Licensed Product may continue to be performed following Regulatory Approval of a Licensed Product and costs may continue to be incurred in accordance with the performance of such EAP after Regulatory Approval.

Patient Assistance Programs – costs associated with establishing and administering patient assistance programs.

Health Care Reform fees - costs for fees paid to the U.S. government as defined in the Patient Protection and Affordable Care Act and similar taxes and governmental fees.

Commercial Operations Costs – costs of the commercial operations team supporting Commercialization of the Licensed Products in the Field, including, without limitation:

(a) **Marketing Expenses**, which includes costs identifiable to the advertising, promotion and marketing of Licensed Products in the Field, and related professional education;

(b) **Advertising**, which includes costs associated with media costs, direct mails, production expenses, agency fees, and medical congresses and meetings;

(c) **Promotion**, which includes costs associated with professional samples, professional literature, promotional material, patient aids, detailing aids, reimbursement of patient assistance programs, public relations and communications expenses, web and social media expenses, patient advocacy support, development of information and data for national accounts, managed care organizations and group purchasing organizations;

(d) **Market Research**, which includes costs associated with market information, focus groups, and market research professional staff and related out-of-pocket costs such as travel, business meals, and training;

(e) **Marketing Management**, which includes the costs of product management and sales promotion management compensation and departmental expenses as well as costs associated with developing overall sales and marketing strategies and planning;

(f) **Reimbursement/Access Services**, which includes costs incurred to manage reimbursement programs, marketing costs (educational material) as well as coupon or co-pay programs;

(g) **Health Policy/Advocacy**, which includes costs associated with advocacy as well as any specific policy lobbying and trade and government relations related expenses; and

(h) **Selling Support**, which includes costs associated with logistics and document support and the operation of the sales/medical science liaison team such as meeting planning.

Medical Affairs Expenses - costs with respect to: medical affairs and other activities associated with clinical studies conducted after Regulatory Approval in the Territory (to the extent not otherwise included within Development Costs); medical and scientific information and response to external inquiries or complaints; pharmacovigilance, investigator initiated research if not covered in the Phase V Clinical Trials, costs of establishing and maintaining patient registries, medical education, Health Economics and Outcomes Research (HECOR, HEMAR), speaker programs, advisory boards, educational grants and fellowships, drug safety, government affairs (including costs associated with compliance with the Sunshine Act and other similar government regulation); and field-based medical science liaisons, medical affairs clinical trial management, MD's in field (separate from medical science liaisons), publications, medical communications and field medical education.

Recall Expenses – costs, to the extent not otherwise covered by KKC's indemnity obligations, associated with notification, retrieval and return of Licensed Products in the Field in the Territory, destruction of such returned Licensed Products in the Field, and distribution of the replacement Licensed Products in the Field.

Selling Costs - costs directly attributable to selling Licensed Product in the Field, including the FTE Costs for sales representatives/medical science liaisons and first line sales managers, exhibits at shows or conventions including samples, charges for space, sales aids and brochures, sales meetings, consultants, call reporting and other Third Party monitoring/tracking services, automobile allowance, meal expenses, travel/housing for meetings, costs of computer and other

equipment of sales representatives/medical science liaisons and other incidental expenses incurred by sales representatives/medical science liaisons in respect of selling the Licensed Product in the Field.

Other Commercialization Costs - any other costs attributable or allocable to Commercialization of Licensed Products in the Field in the Profit Share Territory in accordance with Accounting Standards, to the extent not included in one of the other categories or definitions of costs under this Schedule 1.23.

Schedule 1.43

FTE Rates

1. The following table sets forth the FTE Rates for AEVI FTEs:

(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)

2. The following table sets forth the FTE Rates for KKC FTEs:

(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)
(***)	(***)

Schedule 1.48

KKC IN-LICENSES

License Agreement between La Jolla Institute for Immunology and Kyowa Hakko Kirin Co., Ltd. (***). This is the LJl Agreement referred to in Section 1.58.

(***) Agreement between Lonza Sales AG and Kyowa Hakko Kirin Co., Ltd. (***)

(***) Agreement between Bristol-Myers Squibb Company and Kyowa Hakko Kirin Co., Ltd. (***)

Letters between Kyowa Hakko Kirin Co., Ltd. and Sanofi (***), and sublicensing of rights to AEVI.

Schedule 1.52

KKC PATENT RIGHTS

[illegible]

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

I, Michael Cola, certify that:

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

Date: August 6, 2020

/s/ Michael Cola

Michael Cola

Chief Executive Officer

(Registrant's principal executive officer)

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

I, Christopher Sullivan, certify that:

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

Date: August 6, 2020

/s/ Christopher Sullivan

Christopher Sullivan

Interim Chief Financial Officer

(Registrant's principal financial officer and principal accounting officer)

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

In connection with the Quarterly Report of Cerecor Inc. (the “Registrant”) on Form 10-Q for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Michael Cola, Chief Executive Officer of the Registrant, and I, Christopher Sullivan, Interim Chief Financial Officer of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: August 6, 2020

/s/ Michael Cola

Michael Cola

Chief Executive Officer

(Registrant’s principal executive officer)

Date: August 6, 2020

/s/ Christopher Sullivan

Christopher Sullivan

Interim Chief Financial Officer

(Registrant’s principal financial officer and principal accounting officer)

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