
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 10-Q

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

for the quarterly period ended March 31, 2021

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 May 11, 2021, the registrant had 95,471,843 shares of common stock outstanding.

CERECOR INC.

FORM 10-Q

For the Quarter Ended March 31, 2021

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements</u>
a)	<u>Condensed Consolidated Balance Sheets as of March 31, 2021 (Unaudited) and December 31, 2020</u>
b)	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) for the Three Months Ended March 31, 2021 and 2020</u>
d)	<u>Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the Three Months Ended March 31, 2021 and 2020</u>
c)	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three Months Ended March 31, 2021 and 2020</u>
e)	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>
<u>PART II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>
<u>Item 1A.</u>	<u>Risk Factors</u>
<u>Item 6.</u>	<u>Exhibits</u>
<u>SIGNATURES</u>	

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

CERECOR INC. and SUBSIDIARIES

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

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,292	\$ 18,919
Accounts receivable, net	3,130	2,177
Other receivables	2,056	2,208
Inventory, net	—	3
Prepaid expenses and other current assets	2,465	2,660
Restricted cash, current portion	153	38
Total current assets	46,096	26,005
Property and equipment, net	1,530	1,607
Intangible assets, net	1,161	1,585
Goodwill	14,409	14,409
Restricted cash, net of current portion	149	149
Total assets	\$ 63,345	\$ 43,755
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 11,913	\$ 2,574
Accrued expenses and other current liabilities	14,238	11,310
Current liabilities of discontinued operations	209	1,341
Total current liabilities	26,360	15,225
Royalty obligation	2,000	2,000
Deferred tax liability, net	111	90
Other long-term liabilities	1,719	1,878
Total liabilities	30,190	19,193
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 89,104,816 and 75,004,127 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	89	75
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at March 31, 2021 and December 31, 2020; 1,257,143 shares issued and outstanding at March 31, 2021 and December 31, 2020	1	1
Additional paid-in capital	241,535	202,276
Accumulated deficit	(208,470)	(177,790)
Total stockholders' equity	33,155	24,562
Total liabilities and stockholders' equity	\$ 63,345	\$ 43,755

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product revenue, net	\$ 473	\$ 2,754
Total revenues, net	473	2,754
Operating expenses:		
Cost of product sales	77	66
Research and development	25,206	4,768
Acquired in-process research and development	—	25,549
General and administrative	4,911	2,676
Sales and marketing	435	677
Amortization expense	424	431
Total operating expenses	31,053	34,167
	(30,580)	(31,413)
Other income:		
Change in fair value of Investment in Aytu	—	7,080
Other income	—	11
Interest income	17	10
Total other income, net from continuing operations	17	7,101
Loss from continuing operations before taxes	(30,563)	(24,312)
Income tax expense (benefit)	11	(2,157)
Loss from continuing operations	\$ (30,574)	\$ (22,155)
(Loss) income from discontinued operations, net of tax	(106)	1,038
Net loss	\$ (30,680)	\$ (21,117)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	\$ (0.32)	\$ (0.36)
Discontinued operations	(0.00)	0.02
Net loss per share of common stock, basic and diluted	\$ (0.32)	\$ (0.34)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	\$ (1.61)	\$ (1.78)
Discontinued operations	(0.01)	0.08
Net loss per share of preferred stock, basic and diluted	\$ (1.62)	\$ (1.70)

See accompanying notes to the unaudited condensed consolidated financial statements.

CERECOR INC. and SUBSIDIARIES

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

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

	Common stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Three Months Ended March 31, 2020							
Balance, December 31, 2019	44,384,222	\$ 44	2,857,143	\$ 3	\$ 135,239	\$ (114,291)	\$ 20,995
Conversion of preferred stock to common stock	8,000,000	8	(1,600,000)	(2)	(6)	—	—
Issuance of shares related to Aevi Merger	3,893,361	4	—	—	15,492	—	15,496
Issuance of shares pursuant to registered direct offering, net of offering costs	1,306,282	1	—	—	5,135	—	5,136
Issuance of shares pursuant to common stock private placement, net of offering costs	1,951,219	2	—	—	3,886	—	3,888
Exercise of stock options and warrants	25,168	—	—	—	74	—	74
Stock-based compensation	—	—	—	—	1,116	—	1,116
Net loss	—	—	—	—	—	(21,117)	(21,117)
Balance, March 31, 2020	59,560,252	\$ 59	1,257,143	\$ 1	\$ 160,936	\$ (135,408)	\$ 25,588

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	2020
Operating activities		
Net loss	\$ (30,680)	\$ (21,117)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	451	453
Stock-based compensation	1,448	1,116
Acquired in-process research and development, including transaction costs	—	25,549
Deferred taxes	21	21
Change in fair value of Investment in Aytu	—	(7,080)
Change in value of Guarantee	—	(1,755)
Change in fair value of warrant liability and unit purchase option liability	—	(11)
Changes in assets and liabilities:		
Accounts receivable, net	(953)	(696)
Other receivables	152	(1,963)
Inventory, net	3	5
Prepaid expenses and other assets	195	23
Accounts payable	9,339	251
Income taxes payable	—	(551)
Accrued expenses and other liabilities	1,724	(142)
Lease liability, net	(16)	158
Net cash used in operating activities	(18,316)	(5,739)
Investing activities		
Net cash paid in merger with Aevi	—	(1,251)
Purchase of property and equipment	(21)	—
Net cash used in investing activities	(21)	(1,251)
Financing activities		
Proceeds from issuance of common stock and pre-funded warrants in underwritten public offering, net	37,653	—
Proceeds from registered direct offering, net	—	5,136
Proceeds from sale of shares pursuant to common stock private placement, net	—	3,888
Proceeds from exercise of stock options and warrants	172	74
Net cash provided by financing activities	37,825	9,098
Increase in cash, cash equivalents and restricted cash	19,488	2,108
Cash, cash equivalents, and restricted cash at beginning of period	19,106	3,729
Cash, cash equivalents, and restricted cash at end of period	\$ 38,594	\$ 5,837
Supplemental disclosures of cash flow information		
Cash paid for taxes	\$ —	\$ 316
Supplemental disclosures of non-cash activities		
Issuance of common stock in Aevi Merger	\$ —	\$ 15,496

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

	March 31,	
	2021	2020
Cash and cash equivalents	\$ 38,292	\$ 5,659
Restricted cash, current	153	65
Restricted cash, non-current	149	113
Total cash, cash equivalents and restricted cash	<u>\$ 38,594</u>	<u>5,837</u>

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 and orphan diseases. The Company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases.

The Company’s rare disease pipeline includes CERC-801, CERC-802 and CERC-803 (“CERC-800 compounds”), which are in development for therapies for congenital disorders of glycosylation and CERC-006, an oral mTORC1/2 inhibitor in development for the treatment of complex lymphatic malformations. The Company is also developing two monoclonal antibodies, CERC-002 and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for the treatment of severe pediatric-onset Crohn’s disease and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still’s disease (adult onset Still’s disease and systemic juvenile idiopathic arthritis) and multiple myeloma. CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Disease Designation, which makes all four eligible for a priority review voucher (“PRV”) upon approval from the U.S. Food and Drug Administration (“FDA”).

The Company continues to explore strategic alternatives for its non-core assets, including its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, and for its neurology pipeline assets.

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

Liquidity

In January 2021, the Company closed an underwritten public offering of 13,971,889 shares of its common stock and 1,676,923 pre-funded warrants for net proceeds of approximately \$37.7 million (see Note 9 for additional information). As of March 31, 2021, Cerecor had \$8.3 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 three months ended March 31, 2021, Cerecor generated a net loss of \$30.7 million and negative cash flows from operations of \$18.3 million. As of March 31, 2021, Cerecor had an accumulated deficit of \$208.5 million.

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

To mitigate these conditions and to meet the Company’s capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) dilutive and/or non-dilutive financings, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financing and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company’s ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report were issued.

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

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated balance sheet at December 31, 2020 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC").

The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the December 31, 2020 audited consolidated financial statements.

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

Significant Accounting Policies

During the three months ended March 31, 2021, 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, 2020, as filed with the SEC on March 8, 2021.

3. Aytu Divestiture

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

In 2019, the Company closed on an asset purchase agreement to sell the Company's rights, title and interest in assets relating to certain commercialized products (the "Pediatric Portfolio") and the corresponding commercial infrastructure to Aytu BioScience, Inc. ("Aytu"). 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 to Deerfield CSF, LLC ("Deerfield") and certain other liabilities primarily related to contingent consideration and sales returns. Steve Boyd, Chief Investment Officer of Armistice Capital, LLC, a significant stockholder of the Company, serves on each company's board of directors.

Cerecor retains all rights to Millipred®. Pursuant to a transition services agreement entered into between Aytu and Cerecor upon the divestiture close date, Aytu managed Millipred® commercial operations for 18 months (post November 1, 2019). In May 2021, the Company entered into an amended transition services agreement in which Aytu will continue to manage Millipred®'s commercial operations for an additional two months.

Upon the sale of the Pediatric Portfolio to Aytu, the Pediatric Portfolio met all conditions to be classified as discontinued operations. Therefore, the accompanying condensed consolidated financial statements for the three months ended March 31, 2021 and 2020 and as of December 31, 2020 reflect the operations, net of taxes, and related assets and liabilities of the Pediatric Portfolio as discontinued operations. Refer to the "Discontinued Operations" section below for more information, including Cerecor's continuing involvement.

Deerfield Guarantee

As of the closing date of the Aytu Divestiture on November 1, 2019, Aytu assumed the Company's debt obligation to Deerfield and the contingent consideration liability related to future royalties on Avadel Pharmaceuticals PLC's ("Avadel") pediatric products. In conjunction with the closing of this transaction, the Company entered into a guarantee in favor of Deerfield, which guarantees the payment of the assumed liabilities to Deerfield, which included the debt obligation and includes the contingent consideration related to future royalties on Avadel's pediatric products (collectively referred to as the "Guarantee").

Aytu publicly reported that it had paid the \$15.0 million balloon payment to Deerfield before it came due in June 2020 and the fixed monthly payments to Deerfield ended in January 2021, thus satisfying the debt obligation. 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 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 a payment under the Guarantee upon demand by Deerfield 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. The remaining minimum commitments payable as most recently publicly reported by Aytu was \$7.3 million as of June 30, 2020, which represents Cerecor's estimated maximum potential future payments under the Guarantee.

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 Aytu Divestiture as the difference between (i) the estimated fair value of the assumed payments using Cerecor's estimated cost of debt and (ii) the estimated fair value of the assumed payments 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 and comprehensive loss. We considered key drivers of cost of debt both at Aytu and Cerecor, including but not limited to, recent financings, cash position, operating cash flows and trends and Aytu's ability to meet its financial commitments. Based on these facts, the Company concluded that the expected credit loss of the Guarantee was de minimis as of March 31, 2021.

Discontinued Operations

The following tables summarizes the liabilities of the discontinued operations as of March 31, 2021 and December 31, 2020 (in thousands):

	March 31, 2021	December 31, 2020
Liabilities		
Current liabilities:		
Accrued expenses and other current liabilities	\$ 209	\$ 1,342
Total current liabilities of discontinued operations	\$ 209	\$ 1,342

Aytu assumed sales returns of the Pediatric Portfolio made after the closing date of November 1, 2019 related 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 March 31, 2021, the Company estimated future returns on sales of the Pediatric Portfolio made prior to the transaction close date to be \$0.2 million, which was recognized within 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 comprehensive loss and is shown within product revenue, net in the table summarizing the results of discontinued operations below. In future periods, as additional information becomes available, 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, 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 the second quarter of 2022.

The following table summarizes the results of discontinued operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Product revenue, net	\$ (5)	\$ (717)
Operating expenses:		
Sales and marketing	101	—
Total operating expenses	101	—
Other income:		
Change in value of Guarantee	—	1,755
Total other income	—	1,755
(Loss) income from discontinued operations, net of tax	\$ (106)	\$ 1,038

There were no non-cash operating items from discontinued operations for the three months ended March 31, 2021 and no non-cash investing items from the discontinued operations for the three months ended March 31, 2021 and 2020. The significant non-cash operating item from the discontinued operations for the three months ended March 31, 2020 is contained below (in thousands).

	Three Months Ended March 31,	
	2021	2020
Change in value of Guarantee	—	\$ (1,755)

4. Revenue

The Company generates substantially all of its revenue from sales of Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, which is considered a prescription drug. The Company sells its prescription drug in the United States primarily through wholesale distributors and specialty contracted pharmacies. Wholesale distributors account for substantially all of the Company's net product revenues and trade receivables. The Company also earns revenue from sales of its prescription drug directly to retail pharmacies. For the three months ended March 31, 2021, the Company's three largest customers accounted for approximately 67%, 18%, and 15% of the Company's total net product revenues from sale of prescription drugs from continuing operations.

The Company has a license and supply agreement for the Millipred® product with a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which expires on September 30, 2023. As part of a prior amendment to extend the contract to its current term, Cerecor agreed to pay Teva fifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a \$0.5 million quarterly minimum payment, which was set to begin on April 1, 2021. In May 2021, the Company and Teva entered into an amendment in which the net profit split will be delayed until July 1, 2021. Dr. Sol Barer is the Chairman of Cerecor's board of directors and also serves as the Chairman of Teva's board of directors.

Revenue from sales of prescription drugs was \$0.5 million and \$2.8 million for the three months ended March 31, 2021 and 2020, respectively. During the first quarter of 2021, the Company's inventory on hand became short-dated (which the Company considers inventory within six months of expiration) due to manufacturing delays. The Company recorded a full allowance of \$2.9 million for returns on the sale of short-dated inventory given the high likelihood of return. The Company received the delayed inventory lot in April 2021.

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 outstanding as of March 31, 2021 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. 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. In April 2021, Armistice Capital Master Fund Ltd. (an affiliate of Armistice Capital, LLC and collectively "Armistice"), which is a significant

stockholder of the Company and whose chief investment officer, Steven Boyd, currently serves on the Board, converted the remaining 1,257,143 shares of convertible preferred stock into 6,285,715 shares of Cerecor's common stock. Refer to Note 9 for more information.

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. The weighted average number of common shares outstanding as of March 31, 2021 includes the weighted average effect of the pre-funded warrants issued in connection with the January 2021 underwritten public offering, the exercise of which requires nominal consideration for the delivery of the shares of common stock (refer to Note 9 for more information).

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

The following table sets forth the computation of basic and diluted net (loss) income per share of common stock and preferred stock for the three months ended March 31, 2021 and 2020 (in thousands, except share and per share amounts):

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

	Three Months Ended March 31, 2020			
	Common stock		Preferred stock	
	Continuing Operations	Discontinued Operations	Continuing Operations	Discontinued Operations
Numerator:				
Allocation of undistributed net loss	\$ (19,205)	\$ 900	\$ (2,950)	\$ 138
Denominator:				
Weighted average shares	53,934,760	53,934,760	1,657,143	1,657,143
Basic and diluted net loss per share	<u>\$ (0.36)</u>	<u>\$ 0.02</u>	<u>\$ (1.78)</u>	<u>\$ 0.08</u>

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three months ended March 31, 2021 and 2020, as they could have been anti-dilutive:

	Three Months Ended March 31,	
	2021	2020
Stock options	12,944,891	7,712,680
Warrants on common stock ¹	4,002,380	4,024,708
Restricted Stock Units	155,833	267,500
Underwriters' unit purchase option	—	40,000

¹ The above table excludes 1,676,923 pre-funded warrants. See the "Q1 2021 Financing" in Note 9 for more information.

6. Asset Acquisition

Aevi Merger

In the first quarter of 2020, the Company consummated its merger with Aevi Genomic Medicine Inc. ("Aevi"), in which Cerecor acquired the rights to CERC-002, CERC-006 and CERC-007 (the "Merger" or the "Aevi Merger").

The Merger consideration included (i) stock valued at approximately \$15.5 million, resulting in the issuance of approximately 3.9 million shares of Cerecor common stock to Aevi stockholders, (ii) forgiveness of \$4.1 million the Company had loaned Aevi prior to the Merger closing, (iii) contingent value rights for up to an additional \$6.5 million in subsequent payments based on certain development milestones (discussed further in Note 13), and (iv) transaction costs of \$1.5 million.

The Company recorded this transaction as an asset purchase as opposed to a business combination because management concluded that substantially all the value received was related to one group of similar identifiable assets, which was the in-process research and development ("IPR&D") for two early phase therapies. The Company considered these pipeline 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 \$25.5 million (consisting primarily of \$24.0 million IPR&D, \$0.3 million of cash and \$0.9 million of assembled workforce) was immediately recognized as acquired in-process research and development expense in the Company's consolidated statement of operations and comprehensive loss because the IPR&D asset has no alternate use due to the stage of development. The assembled workforce asset was recorded to intangible assets and will be amortized over an estimated useful life of two years.

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 (in thousands):

	March 31, 2021		
	Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	\$ 37,008	\$ —	\$ —
	December 31, 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*	\$ 17,503	\$ —	\$ —

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

As of March 31, 2021 and December 31, 2020, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities. The carrying amounts reported in the accompanying condensed consolidated financial statements approximate their respective fair values because of the short-term nature of these accounts.

No changes in valuation techniques or inputs occurred during the three months ended March 31, 2021 and 2020. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the three months ended March 31, 2021 and 2020.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of March 31, 2021 and December 31, 2020 consisted of the following (in thousands):

	As of	
	March 31, 2021	December 31, 2020
Research and development	\$ 7,393	\$ 4,939
Compensation and benefits	1,697	3,119
General and administrative	966	771
Sales and marketing	93	31
Sales returns and allowances	3,630	1,794
Medicaid rebates	83	119
Lease liability, current	357	426
Other	19	111
Total accrued expenses and other current liabilities	\$ 14,238	\$ 11,310

The \$2.5 million increase in the research and development accrual as of March 31, 2021 was driven by an increase in manufacturing activities for CERC-002 to support the program's clinical development.

During the first quarter of 2021, the Company's inventory on hand became short-dated (which the Company considers inventory within six months of expiration) due to manufacturing delays. The Company records a full allowance for the returns on the sale of short-dated inventory given the high likelihood of return, which was the main driver of the increase in sales returns and allowances as of March 31, 2021.

9. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock, common stock and preferred stock. At March 31, 2021, the total number of shares of capital stock the Company was authorized to issue was 205,000,000 of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of \$0.001 per share.

Common Stock

Q1 2021 Financing

In January 2021, the Company closed an underwritten public offering of 13,971,889 shares of its common stock and 1,676,923 pre-funded warrants for net proceeds of \$37.7 million. Armistice, which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, currently serves on the Board, participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC (collectively, "Nantahala"), which beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering and, therefore, were considered a related party pursuant to the Company's written related person transaction policy, purchased 1,400,000 shares of common stock, on the same terms as all other investors.

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

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

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

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

2020 Financings

On June 11, 2020, the Company closed an underwritten public offering of 15,180,000 shares of its common stock for net proceeds of approximately \$5.4 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.

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.

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 approximately 3.9 million shares of common stock.

Common Stock Warrants

At March 31, 2021, the following common stock warrants were outstanding:

Number of shares underlying warrants	Exercise price per share	Expiration date
2,380	\$ 8.68	May 2022
4,000,000	\$ 12.50	June 2024
1,676,923	\$ 0.001	—
5,679,303		

Convertible Preferred Stock

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. During the first quarter of 2020, Armistice converted 1,600,000 shares of Series B Convertible Preferred Stock into 8,000,000 shares of Cerecor’s common stock. In April 2021, Armistice converted the remaining 1,257,143 shares of Series B Convertible Preferred Stock into 6,285,715 shares of Cerecor’s common 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 Armistice. The transactions were 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 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, which it has since converted into 14,285,715 shares of Cerecor common 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”).

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 March 31, 2021, there were 2,728,771 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 months ended March 31, 2021 and 2020 was as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 298	\$ 382
General and administrative	1,045	680
Sales and marketing	105	55
Total stock-based compensation	<u>\$ 1,448</u>	<u>\$ 1,117</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 three months ended March 31, 2021 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, 2020	8,830,674	\$ 3.95	\$ 2.36	7.7
Granted	3,467,817	\$ 3.35	\$ 2.22	
Exercised	(128,800)	\$ 1.34	\$ 1.00	
Forfeited	(224,800)	\$ 3.77	\$ 2.40	
Balance at March 31, 2021	<u>11,944,891</u>	<u>\$ 3.81</u>	<u>\$ 2.34</u>	<u>8.2</u>
Exercisable at March 31, 2021	<u>3,914,889</u>	<u>\$ 4.39</u>	<u>\$ 2.53</u>	<u>6.0</u>

In March 2021, the Company granted its newly appointed Chief Financial Officer options with service-based vesting conditions to purchase 0.5 million shares of common stock as an inducement option grant, pursuant to NASDAQ Listing Rule 5635(c)(4). In January 2021, the Company granted 2.7 million options with service-based vesting conditions to its employees as part of its annual stock option award.

In March 2020, our Chief Executive Officer entered into an amended employment agreement in which his salary in cash was reduced to \$5,568 (the "Reduction"), which represents the minimum exempt annual salary. In consideration for the Reduction, on a quarterly basis, the Company grants stock options, which vest immediately, 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 the foregone salary.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of March 31, 2021, the aggregate intrinsic value of options outstanding was \$1.6 million. The aggregate intrinsic value of options currently exercisable as of March 31, 2021 was \$0.7 million. There were 1,137,239 options that vested during the three months ended March 31, 2021 with a weighted average exercise price of \$3.96 per share. The total grant date fair value of shares which vested during the three months ended March 31, 2021 was \$2.8 million.

The Company recognized stock-based compensation expense of \$1.3 million related to stock options with service-based vesting conditions for the three months ended March 31, 2021. At March 31, 2021, there was \$16.1 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 3.1 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options with service-based vesting conditions granted under the Black-Scholes valuation model for the three months ended March 31, 2021:

Service-based options	
Expected annual dividend yield	—%
Expected stock price volatility	73.0% - 75.6%
Expected term of option (in years)	5.0 - 6.25
Risk-free interest rate	0.36% - 1.12%

Stock options with market-based vesting conditions

The following table summarizes the Company's market-based option activity for the three months ended March 31, 2021 (in thousands except, for share amounts):

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (1)
Balance at December 31, 2020	1,000,000	\$ 3.29	9.5	\$ 65
Granted	—	\$ —		
Balance at March 31, 2021	1,000,000	\$ 3.29	9.2	\$ —
Exercisable at March 31, 2021	1,000,000			\$ 255

(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.

In the second quarter of 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 \$2.51. 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 has 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 has an exercise price of the 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 \$0.1 million related to stock options with market-based vesting conditions for the three months ended March 31, 2021.

In the first quarter of 2021, the second tranche of 250,000 shares and the third tranche of 250,000 shares both vested upon the Company's stock price reaching a 50% and 75% premium to the stock price on June 18, 2020, respectively.

Restricted Stock Units

The Company measures the fair value of the restricted stock units using the stock price on the date of the grant. The restricted shares typically vest annually over a four-year period beginning on the first anniversary of the award. The following table summarizes the Company's restricted stock unit ("RSU") activity for the three months ended March 31, 2021:

	RSUs Outstanding	
	Number of shares	Weighted average grant date fair value
Unvested RSUs at December 31, 2020	155,833	\$ 4.91
Vested	—	—
Unvested RSUs at March 31, 2021	155,833	\$ 4.91

The Company recognized expense of less than \$6 thousand related to RSUs for the three months ended March 31, 2021.

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 500,000 on January 1, 2021. As of March 31, 2021, 1,925,308 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of \$34 thousand for the three months ended March 31, 2021.

11. Income Taxes

The Company recognized minimal income tax expense for the three months ended March 31, 2021 and an income tax benefit of \$2.2 million for the three months ended March 31, 2020. The tax benefit recognized for the three months ended March 31, 2020 was a result of a tax law change signed into law as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which allowed the Company to carry back certain losses for taxes paid in fiscal year 2017. Due to the full valuation allowance against the Company's deferred tax assets and the current year losses, minimal tax expense was recognized for the three months ended March 31, 2021.

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 office located in Rockville, Maryland is \$161,671, subject to annual 2.5% increases over the term of the lease. The applicable lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company 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 under the Chesterbrook Lease is \$280,185. The lease expires in November 2021.

The weighted average remaining term of the operating leases at March 31, 2021 was 7.7 years.

Supplemental balance sheet information related to the leased property is as follows (in thousands):

	As of	
	March 31, 2021	December 31, 2020
Property and equipment, net	\$ 846	\$ 917
Accrued expenses and other current liabilities	\$ 357	\$ 426
Other long-term liabilities	1,018	1,038
Total operating lease liabilities	\$ 1,375	\$ 1,464

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 7.4% to determine the present value of the lease payments.

The components of lease expense for the three months ended March 31, 2021 and 2020 were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Operating lease cost*	\$ 95	\$ 55

*Includes short-term leases, which are immaterial.

The following table shows a maturity analysis of the operating lease liabilities as of March 31, 2021 (in thousands):

	Undiscounted Cash Flows	
April 1, 2021 through December 31, 2021	\$	314
2022		174
2023		178
2024		183
2025		187
2026		192
Thereafter		621
Total lease payments	\$	1,849
Less implied interest		(474)
Total	\$	1,375

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.

Karbinal Royalty Make-Whole Provision

In 2018, in connection with the acquisition of Avadel's pediatric products, the Company entered into a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc. ("TRIS"). As part of the Karbinal Agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2033. The Company was required to pay TRIS a royalty make whole payment ("Make-Whole Payments") of \$30 for each unit under the 70,000 units annual minimum sales commitment through 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 the TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

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. 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 purchases inventory on an ad-hoc basis.

As part of a prior amendment to extend the contract to its current term, Cerecor agreed to pay Tevafifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a \$0.5 million quarterly minimum payment, which was set to begin on April 1, 2021. In May 2021, the Company and Teva entered into an amendment in which the net profit split will be delayed until July 1, 2021. Dr. Sol Barer is the Chairman of Cerecor's board of directors and also serves as the Chairman of Teva's board of directors.

Possible Future Milestone Proceeds for Out-Licensed Compounds

CERC-611 License Assignment

In August 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, which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, currently serves on the Board. 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 in 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 releases 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 and from additional potential future payments due to Lilly upon achievement of certain development and commercialization milestones.

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.

Possible Future Milestone Payments for In-Licensed Compounds

General

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

CERC-002 KKC License Agreement

On March 25, 2021, the Company entered into a license agreement with Kyowa Kirin Co., Ltd. (“KKC”) for exclusive worldwide rights to develop, manufacture and commercialize CERC-002, KKC’s first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody for all indications (the “KKC License Agreement”). The KKC License Agreement replaces the Amended and Restated Clinical Development and Option Agreement between the Company and KKC dated May 28, 2020.

Under the KKC License Agreement, the Company paid KKC an upfront license fee equal to \$0.0 million. The Company will also pay KKC milestone payments based on achievement of certain success-based regulatory milestones that equal, for each of three separate indications of CERC-002, mid-teen millions of dollars or less depending on the territory to which the regulatory milestone achievement relates. In addition, the Company will pay KKC (a) royalties during a country-by-country royalty term agreement equal to mid-teens percentage of the net sales of CERC-002 by the Company, (b) sales milestone payments aggregating up to \$75 million tied to achievement of annual net sales targets, and (c) a double digit percentage (less than 30%) of the payments that the Company receives from sublicensing of its rights under the KKC License Agreement, subject to certain exclusions. Subject to the option described below that allows, upon exercise, KKC to develop, manufacture and commercialize CERC-002 in Japan, the Company will be responsible for the development and commercialization of CERC-002 in all indications worldwide.

The Company granted KKC an option to exclude Japan from the scope of the worldwide rights granted to the Company such that, upon exercise of the option, KKC can develop, manufacture and commercialize CERC-002 in Japan. Upon exercise of the Option, KKC will be required to (a) reimburse the Company for a pre-agreed percentage of certain of its costs incurred to develop CERC-002 as a condition to KKC accessing the Company’s data that would be required to be included in an application for marketing authorization, (b) pay the Company for its services (such as transfer of data and regulatory support), (c) pay for all further development of CERC-002 in Japan and (d) pay any royalty due to the Company’s licensors on sales of CERC-002 in Japan. KKC will also have the right to purchase CERC-002 from the Company for use in Japan. No other amounts would be payable by KKC to the Company such as license fees, royalties and milestone payments. The option will expire if KKC does not exercise it within a set number of days after the FDA accepts for filing a Biologics License Application for a pre-defined indication of CERC-002.

The Company recognized the upfront license fee of \$10.0 million within research and development expenses for the three months ended March 31, 2021 and made the payment in April 2021. The Company has not recognized any liabilities related to the milestones outlined in the KKC License Agreement as of March 31, 2021. The Company will continue to monitor the milestones at each reporting period.

CERC-006 Astellas License Agreement

The Company has an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly owned subsidiary of Astellas Pharma, Inc. (“Astellas”), for the worldwide development and commercialization of the novel, second generation mTORC1/2 inhibitor (which we refer to as CERC-006). Under the terms of the license agreement, the Company paid Astellas an upfront license fee of \$0.5 million and Astellas will be eligible to receive milestone payments of up to \$5.5 million based upon the achievement of specified development and regulatory milestones. Upon commercialization, Astellas will be entitled to a tiered, single-digit royalty on worldwide annual net sales. Cerecor is fully responsible for the development and commercialization of the program.

For the three months ended March 31, 2021, the Company accrued a \$0.5 million milestone payment due to Astellas upon confirmation from the FDA that an initial signal finding study may proceed in the United States given the Company concluded it was probable the Company will begin such study in 2021. The Company will continue to monitor the remaining milestones at each reporting period.

CERC-007 AstraZeneca License Agreement

The Company has an exclusive global license to develop and commercialize a Phase 2-ready fully human, anti-IL-18 monoclonal antibody (which we refer to as CERC-007) from Medimmune Limited, a subsidiary of AstraZeneca plc (“AstraZeneca”). Up to \$162 million may be due to AstraZeneca upon achievement of certain development and sales-related milestones, in addition to a tiered low double-digit royalty on global annual product sales. Cerecor is fully responsible for the development and commercialization of the program.

For the year ended December 31, 2020, Cerecor recognized a \$1.5 million milestone payment to AstraZeneca within research and development expenses, which was due upon initiation of the first proof-of-concept study which uses CERC-007. The Company made such payment in the first quarter of 2021. The Company will continue to monitor the remaining milestones at each reporting period.

Related Party and Acquisition Related Contingent Liabilities

CERC-006 Royalty Agreement with Certain Related Parties

Prior to Cerecor entering into the Aevi Merger, in July 2019, Aevi entered into a royalty agreement with Mike Cola, Cerecor's 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, Cerecor's current Chief Scientific Officer (collectively, the "Investors") in exchange for a one-time aggregate payment of \$ 2.0 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' 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 Aevi Merger and it is recorded as a royalty obligation within the Company's accompanying condensed consolidated balance sheet as of March 31, 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

A portion of the consideration for the Aevi Merger includes two future contingent development milestones worth up to an additional \$6.5 million. The first milestone is the enrollment of a patient in a Phase 2 study related to CERC-002 for use in pediatric onset Crohn's disease, CERC-006 (any indication) or CERC-007 (any indication) 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 March 31, 2021, 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

In September 2018, the Company acquired Ichorion Therapeutics, Inc. including acquiring three compounds for inherited metabolic disorders known as CDGs (CERC-801, CERC-802 and CERC-803) and one other preclinical compound. Consideration for the transaction included shares of Cerecor common stock and three future contingent development milestones for the acquired compounds worth up to an additional \$15.0 million. 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 March 31, 2021, no contingent consideration related to the development milestone has been recognized. The Company will continue to monitor the development milestones at each reporting period.

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

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "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 8, 2021, 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, 2020 appearing in our Annual Report on Form 10-K filed with the SEC on March 8, 2021.

Overview

Cerecor Inc. (the "Company" or "Cerecor" or "we") is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases. The Company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases.

The Company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are in development for therapies for congenital disorders of glycosylation and CERC-006, an oral mTORC1/2 inhibitor in development for the treatment of complex lymphatic malformations. The Company is also developing two monoclonal antibodies, CERC-002 and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for the treatment of severe pediatric-onset Crohn's disease and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease and systemic juvenile idiopathic arthritis) and multiple myeloma. CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Designation, which makes all four eligible for a priority review voucher ("PRV") upon approval from the U.S. Food and Drug Administration ("FDA").

The Company continues to explore strategic alternatives for its commercialized product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, and for its non-core neurology pipeline assets.

Management's primary evaluation of the success of the Company is the ability to progress its pipeline assets forward towards commercialization or opportunistically out-licensing rights to indications or geographies. This success depends not only on the operational execution of the programs, but also the ability to secure sufficient funding to support the programs. We believe the ability to achieve the anticipated milestones (as presented in the Research and Development Updates milestone chart below), represents our most immediate evaluation points.

We have made significant progress in 2021 toward our key goal of advancing the pipeline as highlighted by the successful CERC-002 COVID-19 ARDS Phase 2 proof-of-concept data release and subsequent receipt of fast-track designation ("FTD"), completion of the first cohort of the CERC-007 Multiple Myeloma Phase 1b trial, obtaining FTD for CERC-803 and enrollment of the first patient in the CERC-007 AOSD Phase 1b open-label proof-of-concept trial. We also believe that the expanded license agreement with Kyowa Kirin Co. ("KKC") will allow us to explore CERC-002 in other indications and to enhance the pipeline asset's potential for business development opportunities. Finally, the financing executed in January for net proceeds of \$37.7 million provided cash runway for the development of our pipeline.

We expect COVID-19 to continue to present both challenges and opportunities to our business. However, there were no recent developments impacting the Company related to COVID-19.

Recent Developments

Research and Development Updates

On March 25, 2021, the Company entered into an expanded license agreement with KKC for exclusive worldwide rights to develop, manufacture and commercialize CERC-002, KKC's first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody for all indications. KKC has an option to retain the rights in Japan. The Company paid a \$10.0 million upfront license fee to KKC in April 2021. KKC is also eligible to receive additional payments based on achievement of regulatory and commercial milestones, as well as royalties, and a share of sublicensing income.

In May 2021, the Company announced that it dosed its first patient in a Phase 1b open-label dose-escalation clinical trial of CERC-007 in patients with adult onset Still's disease ("AOSD"). The Phase 1b clinical trial is a global multi-center, open label trial of CERC-007 that will enroll approximately 12 subjects with active AOSD. The primary objective of the study is to determine the safety and tolerability of CERC-007 in AOSD patients. Key secondary endpoints include assessing pharmacokinetic profile of CERC-007 and determining the effect of CERC-007 on systemic clinical manifestations and systemic markers of inflammation in subjects with AOSD.

In May 2021, the Company announced the FDA had granted FTD to CERC-002 for treatment of hospitalized patients with COVID-19. FTD is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the provision is to help facilitate development and expedite the review of drugs to treat serious or life-threatening conditions so that an approved product can reach the market expeditiously. Sponsors of drugs that receive FTD have the opportunity for more frequent interactions with the FDA review team throughout the development program. Under FTD, a Biologic License Application ("BLA") for CERC-002 is eligible for both rolling submission and priority review.

The following chart summarizes key information about our clinical-stage 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	COVID-19 ARDS					Received FTD**
		CERC-002	Anti-LIGHT mAb	Severe Pediatric Onset Crohn's					Initial Data 2Q 2021
		CERC-007	Anti-IL-18 mAb	AOSD					Initial Data 3Q 2021
Oncology	Blood Cancers	CERC-007	Anti-IL-18 mAb	Multiple Myeloma					Top Line Data 2H 2021
Rare Genetic Disorders	Complex Lymphatic Malformations	CERC-006 ⁺	Dual mTOR inhibitor	Complex Lymphatic Malformations					Initial Data 3Q 2021
	Congenital Disorders of Glycosylation	CERC-801 ⁺ ‡	D-Galactose replacement	PGM1-CDG					Pivotal Trial Data 2H 2021
		CERC-802 ⁺ ‡	D-Mannose replacement	MPI-CDG					Pivotal Trial Data 2H 2021
		CERC-803 ⁺ ‡	L-Fucose replacement	LAD-II (SLC35C1-CDG)					Pivotal Trial Data 2H 2021

⁺ Orphan Drug Designation, Rare Pediatric Disease Designation; Eligibility for Priority Review Voucher upon approval

[‡] Fast Track Designation

*The anticipated milestones 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.

**The Company continues dialogue with the FDA to discuss the path to a potential Emergency Use Authorization (EUA) for treatment of COVID-19 ARDS.

Our Strategy

Our strategy for increasing stockholder value includes:

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

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

Product Revenue, net

Net product revenue was \$0.5 million for the three months ended March 31, 2021, as compared to \$2.8 million for the three months ended March 31, 2020. During the first quarter of 2021, the Company's inventory on hand became short-dated (which the Company considers to be within six months of expiration), due to manufacturing delays. The Company recorded a full allowance of \$2.9 million for returns on the sale of short-dated inventory given the high likelihood of return. This led to a minimal amount of net sales being recognized in the first quarter of 2021, which drove the decrease as compared to the three months ended March 31, 2020. The Company received the delayed inventory lot in April 2021. Therefore, we expect net revenues of Millipred® to return to levels consistent with prior periods over 2021, however we continue to explore strategic alternatives for our non-core assets, which includes Millipred®. Accordingly, our ability to increase revenue in the future will depend on developing and commercializing our current clinical pipeline of product candidates.

Cost of Product Sales

Cost of product sales was \$0.1 million for the three months ended March 31, 2021, which was consistent with the cost of product sales for the three months ended March 31, 2020.

The Company has a license and supply agreement for the Millipred® product with a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which expires on September 30, 2023. As part of a prior amendment to extend the contract to its current term, Cerecor agreed pay Teva fifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a \$0.5 million quarterly minimum payment, which was set to begin April 1, 2021. In May 2021, the Company and Teva entered into an amendment in which the net profit split will be delayed until July 1, 2021. Dr. Sol Barer is the Chairman of Cerecor's board of directors and also serves as the Chairman of Teva's board of directors. Beginning in the third quarter of 2021, we expect cost of product sales to increase as compared to historic periods.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Preclinical expenses	\$ 2,234	\$ 1,277
Clinical expenses	5,440	570
CMC expenses	4,734	1,193
License and milestone expenses	10,500	—
Internal expenses:		
Salaries, benefits and related costs	1,937	1,313
Stock-based compensation expense	298	382
Other	63	33
	<u>\$ 25,206</u>	<u>\$ 4,768</u>

Research and development expenses increased \$20.4 million for the three months ended March 31, 2021 compared to the same period in 2020. The Company's merger with Aevi Genomic Medicine Inc. ("Aevi") (the "Aevi Merger" or the "Merger"), which closed in February 2020, was a transformative event as it significantly broadened our pipeline by adding the rights to three new

assets, as well as bringing in critical leadership to guide the Company and development of the expanded pipeline. Given the timing of the Merger, the first half of 2020 was spent integrating and initiating the additional programs. Therefore, a main driver of the increase was due to a full quarter of expanded development activities for the three months ended March 31, 2021 (compared to preliminary activities for the prior year period).

In addition, the increase was driven by a \$10.0 million upfront license fee, which was recorded in March of 2021 and paid in April 2021, related to the expanded indication license agreement for CERC-002 entered into with KKC in March 2021. Furthermore, clinical expenses increased \$4.9 million primarily due to costs incurred to advance the pipeline, most notably the CERC-800 compounds and CERC-007. Chemistry, Manufacturing, and Controls (“CMC”) expenses increased \$3.5 million due to additional spending on manufacturing to support development of the progressing pipeline. Preclinical expenses increased \$1.0 million due to an increase in non-clinical toxicity studies and biomarker studies to support clinical development.

We expect research and development expense to continue to outpace historic periods, as the Company advances its maturing pipeline in anticipation of multiple clinical data readouts over the next twelve months.

Acquired In-Process Research and Development Expenses

In the first quarter of 2020, the Company consummated its merger with Aevi, resulting in the Company acquiring \$25.5 million of in-process research and development (“IPR&D”). The fair value of the IPR&D was immediately recognized as acquired in-process research and development expense given such asset has no other alternate use due to the stage of development. There was no acquired in-process research and development for the three months ended March 31, 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Salaries, benefits and related costs	\$ 920	\$ 1,012
Legal, consulting and other professional expenses	2,592	784
Stock-based compensation expense	1,045	706
Other	354	174
	<u>\$ 4,911</u>	<u>\$ 2,676</u>

General and administrative expenses were \$4.9 million for the three months ended March 31, 2021, which represents a \$2.2 million increase from the prior year period. The increase was largely driven by a \$1.8 million increase in legal, consulting and other professional expenses. The largest drivers was higher legal costs in the current quarter, including costs to execute the KKC expanded indication license agreement and to advance other business development activities.

Stock-based compensation expense increased \$0.3 million as a result of increased headcount in the first quarter of 2021 (inclusive of a full quarter of expense for the executive leadership team, as opposed to a partial period in the prior year due to timing of the Aevi Merger) and as a result of service-based options granted to employees in January 2021 as part of its annual stock option award.

We expect general and administrative expenses to continue to increase compared to historic periods as a result of the increased infrastructure to support the Company’s expanded research and development efforts.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Salaries, benefits and related costs	\$ 189	\$ 134
Stock-based compensation expense	105	55
Advertising and marketing expense	129	481
Other	12	7
	<u>\$ 435</u>	<u>\$ 677</u>

Sales and marketing expenses consist of expenses related to initiatives to support the go-to-market strategy of our pipeline assets. For the three months ended March 31, 2020, we incurred costs related to market research projects for multiple programs and indications that did not repeat in the current year, thus driving the \$0.2 million decrease.

Amortization Expense

The following table summarizes our amortization expense for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Amortization of intangible assets	\$ 424	\$ 431

Amortization expense relates to the amortization of the assembled workforces acquired as part of previous acquisitions and mergers and was consistent for the three months ended March 31, 2021 and 2020. In 2020, as a result of the asset acquisition accounting treatment of the Aevi Merger, the Company recorded an assembled workforce intangible asset of \$0.9 million, which was assigned a two-year useful life.

Other Income, Net

The following table summarizes our other income, net for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Change in fair value of Investment in Aytu (as defined below)	\$ —	\$ 7,080
Change in other income	—	11
Interest income, net	17	10
	<u>\$ 17</u>	<u>\$ 7,101</u>

Other income, net decreased \$7.1 million for the three months ended March 31, 2021, as compared to the prior year. For the three months ended March 31, 2020, other income, net was mainly comprised of a \$7.1 million gain on change in the fair value of the Company's investment in Aytu. As consideration of the Company's divestiture of certain commercialized products to Aytu BioScience, Inc. ("Aytu") in 2019 (the "Aytu Divestiture"), the Company received 9,805,845 shares of Aytu Series G Preferred Stock (the "Investment in Aytu"), which was remeasured at fair value each reporting period. As of March 31, 2020, the Investment in Aytu was \$14.7 million, representing a change in fair value of \$7.1 million from the prior reporting period (driven by a significant increase in Aytu's stock price from December 31, 2019 to March 31, 2020). The Company subsequently converted such shares into common stock and sold that common stock for net proceeds of approximately \$12.8 million in April 2020.

Income Tax Expense (Benefit)

The following table summarizes our income tax expense (benefit) for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Income tax expense (benefit)	\$ 11	\$ (2,157)

The Company recognized minimal income tax expense for the three months ended March 31, 2021 compared to an income tax benefit of \$2.2 million for the three months ended March 31, 2020. The tax benefit recognized for the three months ended March 31, 2020 was a result of a tax law change signed into law as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), which allowed the Company to carry back certain losses for taxes paid in fiscal year 2017. Due to the full valuation allowance against the Company’s deferred tax assets and current year losses, minimal tax expense was recognized for the three months ended March 31, 2021.

Liquidity and Capital Resources

In January 2021, the Company closed an underwritten public offering of 13,971,889 shares of its common stock and 1,676,923 pre-funded warrants for net proceeds of approximately \$37.7 million. As of March 31, 2021, Cerecor had \$38.3 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 three months ended March 31, 2021, Cerecor generated a net loss of \$30.7 million and negative cash flows from operations of \$18.3 million. As of March 31, 2021, Cerecor had an accumulated deficit of \$208.5 million.

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

To mitigate these conditions and to meet the Company’s capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) dilutive and/or non-dilutive, (ii) federal and/or private grants, (iii) other out-licensing or strategic alliances/collaborations of its current pipeline assets, and (iv) out-licensing or sale of its non-core assets. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financings and other potential options to raise additional funds, management has concluded that substantial doubt exists with respect to the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued.

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

Uses of Liquidity

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

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (18,316)	\$ (5,739)
Investing activities	(21)	(1,251)
Financing activities	37,825	9,098
Net increase in cash and cash equivalents	\$ 19,488	\$ 2,108

Net cash used in operating activities

Net cash used in operating activities was \$18.3 million for the three months ended March 31, 2021 and consisted primarily of a net loss of \$30.7 million, which was primarily driven by research and development activities as the Company continued to fund its pipeline of development assets. The three months ended March 31, 2020 included a one-time non-cash acquired IPR&D expense of \$25.5 million recorded in connection with the Aevi Merger, while the three months ended March 31, 2021 did not include a similar offset to cash used in operating activities. Additionally, the three months ended March 31, 2021 included a full quarter of development of the expanded pipeline from the Aevi Merger compared to a partial quarter in the prior year (in which the focus was integration as opposed to pipeline development). Changes in net liabilities increased by \$10.4 million, mainly driven by a \$9.3 million increase in accounts payable and \$1.7 million increase in accrued expenses, partially offset by increased accounts receivable of \$1.0 million. Accounts payable as of March 31, 2021 included the \$10.0 million upfront license fee related to the expanded KKC license agreement for CERC-002, which was entered into March 2021. The Company subsequently paid the \$10.0 million fee in April 2021.

Net cash used in operating activities was \$5.7 million for the three months ended March 31, 2020 and consisted primarily of a net loss of \$21.1 million, which was driven by research and development activities, and non-cash adjustments to reconcile net loss to net cash used in operating activities including a \$7.1 million gain related to the change in fair value of the Investment in Aytu and a \$1.8 million gain related to the change in the 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 \$1.1 million.

Net cash used in investing activities

Net cash used in investing activities was minimal for the three months ended March 31, 2021 and consisted primarily of the purchase of property and equipment.

Net cash used in investing activities was \$1.3 million for the three months ended March 31, 2020 and consisted primarily of transaction costs incurred as part of the Aevi Merger, partially offset by the cash acquired as part of the Merger.

Net cash provided by financing activities

Net cash provided by financing activities was \$37.8 million for the three months ended March 31, 2021 and consisted primarily of net proceeds of \$37.7 million from an underwritten public offering of 13,971,889 shares of common stock and 1,676,923 pre-funded warrants. Armistice Capital Master Fund Ltd. (an affiliate of Armistice Capital, LLC and collectively “Armistice”), which is a significant stockholder of the Company and whose chief investment officer, Steven Boyd, currently serves on the Board, participated in the offering by purchasing 2,500,000 shares of common stock, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC (collectively, “Nantahala”), which beneficially owned greater than 5% of the Company’s outstanding common stock at the time of the offering and, therefore, were considered a related party pursuant to the Company’s written related person transaction policy, purchased 1,400,000 shares of common stock, on the same terms as all other investors. Nantahala also purchased the pre-funded warrants to purchase up to an aggregate of 1,676,923 shares of common stock at a purchase price of \$2.599, which represents the per share public offering price for the common stock less the \$0.001 per share exercise price for each pre-funded warrant.

Net cash provided by financing activities was \$9.1 million for the three months ended March 31, 2020 and consisted primarily of net proceeds of \$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 Company and net proceeds of \$3.9 million from a private placement of equity securities with Armistice during March 2020.

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, 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, 2020 filed with the

SEC on March 8, 2021. There have been no material changes to our critical accounting policies during the three months ended March 31, 2021.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 8, 2021, which could materially affect our business, financial condition, or future results. Our risk factors as of the date of this Quarterly Report on Form 10-Q have not changed materially from those described in the Form 10-K referenced above. The risks described in the Form 10-K referenced above are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, or future results of operations and the trading price of our common stock.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1*+	License Agreement, dated March 25, 2021, by and between Cerecor Inc. and Kyowa Hakko Kirin Co., Ltd
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets as of March 31, 2021 and December 31, 2020; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three Months Ended March 31, 2021 and 2020; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three Months Ended March 31, 2021 and 2020; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the Three Months Ended March 31, 2021 and 2020; and (v) Notes to Unaudited Financial Statements.
104	Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

* Certain portions of this exhibit have been omitted pursuant to 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: May 13, 2021

/s/ Schond L. Greenway

Schond L. Greenway

Chief Financial Officer

(on behalf of the registrant and as the registrant's principal financial 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.**

LICENSE AGREEMENT

by and between

KYOWA KIRIN CO., LTD.

and

AEVI GENOMIC MEDICINE, LLC

<u>ARTICLE 1. DEFINITIONS</u>	1
<u>ARTICLE 2. GOVERNANCE AFTER ELECTION OF THE JAPAN OPTION</u>	14
<u>ARTICLE 3. DEVELOPMENT</u>	16
<u>ARTICLE 4. COMMERCIALIZATION</u>	19
<u>ARTICLE 5. DILIGENCE</u>	21
<u>ARTICLE 6. LICENSES</u>	22
<u>ARTICLE 7. FINANCIAL PROVISIONS</u>	25
<u>ARTICLE 8. INTELLECTUAL PROPERTY</u>	30
<u>ARTICLE 9. CONFIDENTIALITY</u>	38
<u>ARTICLE 10. TERM AND TERMINATION</u>	41
<u>ARTICLE 11. REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION</u>	49
<u>ARTICLE 12. MISCELLANEOUS PROVISIONS</u>	55

Schedules

Schedule 1.14 – Amino Acid Sequence of Anti-Light mAb
Schedule 1.53 – KKC In-Licenses
Schedule 1.57 – KKC Patent Rights

LICENSE AGREEMENT

This License Agreement (this “**Agreement**”), dated as of March 25, 2021 (the “**Effective Date**”), is made 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 (“**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 the Anti-LIGHT mAb (as defined in Section 1.14) and granted AEVI certain options to enter into various license agreements; and

WHEREAS, the Parties have decided to supersede the Clinical Development and Option Agreement and such options with 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 “AEVI Business Day” means a day on which banking institutions in New York, New York are open for business other than Saturday or Sunday.

1.4 “AEVI In-License” means the License Agreement between The Children’s Hospital of Philadelphia and Medgenics Medical Israel Ltd. (**).

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 or the Clinical Development and Option 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 the Licence Agreement between AEVI and Lonza (**).

1.8 “AEVI’s Net Sales” means the Net Sales of AEVI and its Affiliates for all the Indications of Licensed Products excluding, for the avoidance of doubt, the Net Sales of Sublicensees of AEVI or its Affiliates.

1.9 “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.

1.10 “AEVI’s Sublicensee Milestone Payment” means a milestone payment received by AEVI or any of its Affiliates under a Sublicense for achievement of a Milestone Event by the applicable Sublicensee of AEVI or any of its Affiliates.

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 “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.

1.14 “Anti-LIGHT mAb” means the fully human monoclonal antibody targeting LIGHT (TNFSF14) consisting of the amino acid sequence set forth on Schedule 1.14.

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

1.16 “BARDA” means the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services.

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 “CHOP” means The Children’s Hospital of Philadelphia.

1.24 “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. When used as a verb, “Commercialize” will mean to engage in Commercialization.

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 “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 (***) of the oral disclosure requesting that such information be treated as Confidential Information hereunder, (c) all information that is manifestly confidential, whether or not marked as such and (d) all of the foregoing disclosed under the Clinical Development and Option Agreement.

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

1.28 “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, 2021. Each Contract Year, except the first Contract Year, will be divided into four (4) Contract Quarters.

1.29 “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.

1.30 “Crohn’s Disease Study” means the clinical study of the Licensed Product defined in the protocol No. MDGN-002-CD-101 and listed on clinicaltrials.gov at NCT03169894.

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 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 or any of its Affiliates in accordance with this Agreement and attributable to, or reasonably allocable to, the Development of the Licensed Products in the Field in the Territory, 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 CMC activities, costs of clinical studies for Indications in the Field and 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). 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 written comprehensive plan for (a) 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 (b) the preparation and submission of related Regulatory Approval Applications in the Territory.

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 any and all diseases and conditions in humans.

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 the 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 7.7.

1.46 “Governmental Entity” means any supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, institutes, bureaus, commissions, councils, or other government entities.

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 “Indication” means a separate and distinct disease, disorder, illness or health condition for which separate clinical trial(s) and a separate BLA approval for the Licensed Products are required. By way of example, (a) all indications for treatment of suspected or confirmed COVID-19 are considered the same Indication whereas (b) an indication for treatment of suspected or confirmed COVID-19 is a different and separate Indication from an Indication for treatment of pediatric onset inflammatory bowel disease.

1.49 “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.

1.50 “Japan Option Development Costs” means the Development Costs incurred by AEVI and its Affiliates and reasonably allocable to Development of the data and information that would be required to be included in a Regulatory Approval Application including pre-clinical data, safety data, chemistry, manufacturing and control information and data from proof-of-concept clinical trials and Phase 3 Clinical Trials but excluding the following Development Costs: (a) Development Costs for Phase 3 Clinical Trials the data from which KKC and its Related Parties do not and will not include in any IND or Regulatory Approval Application; (b) Development Costs incurred by AEVI and/or its Affiliates 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 AEVI or its Related Parties for Development activities; and (c) on a dollar-for-dollar basis, Development Costs incurred by AEVI and/or its Affiliates after the Effective Date and funded or reimbursed by any Governmental Entity (such as BARDA), charitable organization or any Sublicensee of AEVI or any of its Affiliates.

1.51 “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.

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

1.53 “KKC In-Licenses” means the Third Party agreements listed on Schedule 1.53.

1.54 “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.

1.55 “KKC Know-How” means Know-How that is (a) Controlled by KKC on the Effective Date (including all such Know-How to which KKC had rights under the Clinical Development and Option Agreement) 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.

1.56 “KKC Licensor” means LJI, BMS, 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.

1.57 “KKC Patent Rights” means (a) the United States and foreign patents and patent applications listed on Schedule 1.57 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 1.57 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.

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

1.59 “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.

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

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

1.62 “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.

1.63 “LJI Agreement” means License Agreement between La Jolla Institute for Immunology and Kyowa Kirin Co., Ltd. (***) (including the LIGHT Addendum between La Jolla Institute for Immunology and Kyowa Kirin Co., Ltd. attached thereto).

1.64 “Lonza” means Lonza Sales AG and its Affiliates.

1.65 “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.

1.66 “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 3.4.2) 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.

1.67 “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.

1.68 “Net Sales” means the gross invoiced sales by AEVI or any of its Related Parties to Third Parties for Licensed Products sold, less deductions, consistent with the applicable Accounting Standards used in the applicable reporting period for the selling 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 the selling 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 to Third Parties. 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 or among AEVI and any of its Related Parties, whether or not value is exchanged therefor, will not be booked as sales.

1.69 **"NMPA"** means the National Medical Products Administration of China and any successor agency having substantially the same functions.

1.70 **"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.

1.71 **"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).

1.72 **"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.

1.73 **"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.

1.74 **"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.

1.75 **"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, the EMA and the NMPA.

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.

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 Term” means, on a country-by-country basis, the period of time commencing on the date of the First Commercial Sale of the first Licensed Product in such country and extending until the later of (a) (***) from the date of the First Commercial Sale of such Product in such country; (b) the expiration in such country of the last Valid Claim of the last to expire KKC Patent Rights; and (c) expiration of the Data Exclusivity Period in such country.

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

1.83 “Sublicense” means (a) a grant by AEVI or any of its Affiliates to a Third Party of the right to Develop or Commercialize a Licensed Product in any jurisdiction, (b) a covenant not sue granted by AEVI or any of its Affiliates to a Third Party in respect of such Third Party’s Commercialization of Licensed Product, (c) the grant of an option to receive or negotiate for either or both of the rights in clauses (a) or (b) by AEVI or any of its Affiliates, or (d) a grant by KKC or any of its Affiliates to a Third Party of the right to Develop or Commercialize a Licensed Product in Japan after KKC’s exercise of the Japan Option.

1.84 “Sublicensee” means any Third Party granted a Sublicense by a Party or any of its Affiliates.

1.85 “Sublicense Income” means income received by AEVI or its Affiliates in consideration for the grant of a Sublicense such as license issue fees, milestone payments, royalties on the Commercialization of Licensed Products and the like but specifically excludes (a) amounts received by AEVI or any of its Affiliates as payment for manufacture or supply of any Licensed Product by AEVI or any of its Affiliates up to (***)%; provided that, for clarity, amounts so received in excess of (***)% for such manufacture or supply shall be

included as Sublicense Income, (b) AEVI's Sublicensee Milestone Payments, (c) payments received for funding research and development services pursuant to a written research and development or funding agreement between AEVI and/or any of its Affiliates, on the one hand, and any Governmental Entity (such as BARDA), charitable organization or Sublicensee of AEVI or any of its Affiliates up to the fair market value of such services, (d) proceeds received for the sale or issuance of any debt or equity security of AEVI or any of its Affiliates up to the Fair Market Value of such 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 securities will be included in the calculation of Sublicense Income] and (e) reimbursements of documented out-of-pocket patent expenses incurred by AEVI or any of its Affiliates on a pass-through basis for reimbursement of patent prosecution or patent maintenance expenses.

1.86 "Territory" means, (a) prior to the effectiveness of the Japan Option or following the expiration of the Japan Option Period without KKC making the Japan Option, worldwide, and (b) following the effectiveness of the Japan Option, worldwide except for Japan.

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

1.90 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 Indemnities</i> "	11.10.2
" <i>AEVI Study Report</i> "	5.3.4
" <i>Agreement</i> "	Preamble
" <i>BARDA Contract</i> "	6.8
" <i>BPCIA</i> "	8.6.2
" <i>Challenge</i> "	10.2.4
" <i>Clinical Development and Option Agreement</i> "	Introduction
" <i>Controlling Party</i> "	8.3.4
" <i>Cooperating Party</i> "	8.3.4
" <i>Defending Party</i> "	8.4.2(a)
" <i>Defensive Actions</i> "	8.3.2

“ <i>Disclosing Party</i> ”	9.1.1
“ <i>Effective Date</i> ”	Preamble
“ <i>Enforcement Expense</i> ”	8.3.4
“ <i>Global Clinical Study</i> ”	3.2.3
“ <i>ICC</i> ”	12.2.2(a)
“ <i>Indemnatee</i> ”	11.10.3
“ <i>Infringement Claim</i> ”	8.4.1
“ <i>IP</i> ”	10.7
“ <i>Japan Option</i> ”	6.5
“ <i>Japan Option Period</i> ”	6.5
“ <i>Joint Steering Committee</i> ” or “ <i>JSC</i> ”	2.1.1
“ <i>Joint Patent</i> ”	8.2.2
“ <i>KKC</i> ”	Preamble
“ <i>KKC Indemnities</i> ”	11.10.1
“ <i>KKC Managed Patent Rights</i> ”	8.2.1
“ <i>Losses</i> ”	11.10.1
“ <i>Milestone Event</i> ”	7.3.1
“ <i>Milestone Payment</i> ”	7.3.1
“ <i>Option Exercise Notice</i> ”	6.5.2
“ <i>Party</i> ” or “ <i>Parties</i> ”	Preamble
“ <i>Phase 3 Clinical Trial</i> ”	3.3.3
“ <i>Prosecuting Party</i> ”	8.2.2
“ <i>Publications</i> ”	9.3
“ <i>Receiving Party</i> ”	9.1.1
“ <i>Recoveries</i> ”	8.3.4
“ <i>Reference Product Sponsor</i> ”	8.6.2
“ <i>Sales Milestone</i> ”	7.4.1
“ <i>Sales Milestone Payment</i> ”	7.4.1
“ <i>Section 351(k) Applicant</i> ”	8.6.1
“ <i>SPC</i> ”	8.8
“ <i>Supply Agreement</i> ”	4.2.2
“ <i>Term</i> ”	10.1
“ <i>Third Party Claim</i> ”	11.10.1

ARTICLE 2. GOVERNANCE AFTER ELECTION OF THE JAPAN OPTION

2.1 Joint Steering Committee.

2.1.1 Establishment of JSC. Within (***) after the KKC exercises the Japan Option, the Parties will establish a committee to facilitate the Development and Commercialization of Licensed Products in Japan by KKC and in the rest of the world by AEVI (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 9. 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 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 those being pursued by AEVI;

(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.

2.1.2 **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 3. DEVELOPMENT

3.1 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.

3.2 AEVI Development Plans.

3.2.1 **COVID-19 Development Plan.** AEVI will provide KKC with a copy of its initial Development Plan for Development of the Licensed Product for treatment of patients in the United States with acute respiratory distress syndrome associated with COVID-19 within (***) after AEVI is permitted by the FDA to proceed with its next clinical trial investigating such treatment based on the protocol submitted by AEVI to the FDA.

3.2.2 **Updates.** No later than (***) and annually thereafter, AEVI will provide an updated Development Plan for the following Contract Year to KKC for informational purposes. Each Development Plan will contain the specific Development objectives to be achieved by AEVI during the next Contract Year and the projected timeline for performing such Development activities. AEVI will use its Commercially Reasonable Efforts to perform the activities set forth in each Development Plan.

3.2.3 **Global Clinical Study or Study in Japan.** Until the expiration of the Japan Option or if KKC exercises the Japan Option, then thereafter, if AEVI plans to conduct a Global Clinical Study in various countries in the Territory (including Japan) or a clinical study of the Licensed Product in Japan, at KKC's request AEVI will in good faith discuss with KKC including sites in Japan for such Global Clinical Study in order for KKC to consider exercising the Japan Option and join such Global Clinical Study or other clinical study in Japan. In order for AEVI to include such sites in the Global Clinical Trial or if KKC exercises the Japan Option, such discussions must result in a mutually satisfactory amendment to this Agreement that addresses all relevant matters related to Japan 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 (i) the services of AEVI and its Affiliates (such as transfer of AEVI Know-How and regulatory support to obtain Regulatory Approval in Japan) and (ii) further Development of the Licensed Product in Japan. 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.

3.3 KKC Development Plans.

3.3.1 Initial Development Plan. Within (***) after KKC exercises the Japan Option, KKC will provide AEVI with a copy of its initial Development Plan for Development of the Licensed Product in Japan.

3.3.2 Updates. No later than (***) prior to the beginning of the Contract Year that begins after the Contract Year in which KKC provided its initial Development Plan under Section 3.3.1 KKC will provide an updated Development Plan to AEVI for informational purposes, except that if KKC's proposed Development Plan in Japan is likely to, in the reasonable judgment of AEVI, present a substantial and identifiable risk to the Development or Commercialization of the Licensed Product outside of Japan, then the Parties must agree to changes to KKC's proposed Development Plan that eliminate or reduce the risk to a level acceptable to AEVI before KKC may proceed with such Development Plan. Each Development Plan will contain the specific Development objectives to be achieved by AEVI during the next Contract Year and the projected timeline for performing such Development activities. AEVI will use its Commercially Reasonable Efforts to perform the activities set forth in each Development Plan.

3.3.3 Development Event Notices. KKC will inform AEVI 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 Japan; and (b) receipt of the first Regulatory Approval for any Licensed Product in Japan. 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.

3.4 Development Responsibilities for Licensed Products in the Field in the Territory. Without limiting the generality of Section 3.1, AEVI will be responsible for Development activities for Licensed Product for the Field for Territory as follows:

3.4.1 Regulatory Matters.

(a) Strategy. AEVI will develop a regulatory strategy for the Licensed Product for such Indications in the Field in the Territory as AEVI determines in its discretion.

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 such countries in the Territory that AEVI determines to so file a Regulatory Approval Application (e.g., use of ICH eCTD format).

(b) Communications with Regulatory Authorities. Prior to KKC's exercise of the Japan Option, AEVI will be responsible for all communications with Regulatory Authorities concerning the Licensed Product in the Field in the Territory; provided that (a) AEVI will keep KKC informed of any planned or actual material communications with any Regulatory Authority regarding Development of the Licensed Product in Japan and (b) AEVI will disclose to KKC any and all material correspondence between AEVI and any Regulatory Authority in Japan and minutes concerning the Development of the Licensed Product in the Field in Japan received from any Regulatory Authority in Japan within (***) after receipt or transmission thereof.

(c) Regulatory Approvals. AEVI will be responsible for preparing and filing Regulatory Approval Applications for the Licensed Products in the Field for the Territory as AEVI determines in its discretion. 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. If KKC makes the Japan Option, KKC will cooperate with AEVI to provide all reasonable assistance and take all actions reasonably requested by AEVI that are necessary or desirable to enable AEVI 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.

3.4.2 Clinical Development. AEVI will develop a clinical development strategy for Licensed Product in the Field in the Territory as AEVI determines in its discretion. 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 as AEVI determines in its discretion.

3.4.3 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.

3.4.4 Preclinical Development. If deemed necessary by AEVI, AEVI will develop a preclinical strategy for the Field in the Territory.

3.5 Drug Safety.

3.5.1 Responsibility Before Exercise of the Japan Option. Prior to exercise of the Japan Option and if the Japan Option expires, then thereafter, AEVI will hold and manage a safety database and will lead safety monitoring and reporting for the Licensed Product.

3.5.2 Pharmacovigilance Agreement. Subject to KKC exercising the Japan Option, the Parties shall 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. In such case, AEVI will be responsible for holding and maintaining the global database for the Licensed Product and KKC will be responsible for pharmacovigilance activities in Japan.

3.6 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. Until expiration of the Japan Option Period or after KKC's exercise of the Japan Option, KKC will have the right, no more than once per Calendar Year and on at least (***) prior notice, to inspect during normal business hours and upon reasonable notice 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 to KKC in accordance with this Agreement will be maintained in confidence by KKC in accordance with Article 9.

3.7 Know-How Transfer. In order to facilitate Development of Licensed Products, from time to time during the Term, KKC will disclose or transfer to AEVI any applicable KKC Know-How 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 KKC Know-How delivered by KKC to AEVI or any of its Affiliates will remain the sole property of KKC.

ARTICLE 4. COMMERCIALIZATION

4.1 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 on sales of Licensed Products in the Field in the Territory.

4.2 Manufacturing and Supply.

4.2.1 For the Account of AEVI and its Related Parties. AEVI will develop a manufacturing and supply strategy for the Licensed Product in the Field in the Territory as AEVI determines in its discretion. 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. For the avoidance of doubt, in the event AEVI's Related Parties manufacture and supply the Licensed Products, it is necessary to obtain Sanofi's prior written consent.

4.2.2 Supply by AEVI. Following KKC's exercise of the Japan Option, AEVI will Manufacture and supply all of KKC's requirements of Licensed Product for Commercialization and/or Development in Japan. AEVI will supply KKC with unlabeled Licensed Product (vial or any other formulation) for clinical trials conducted in Japan and unlabeled Licensed Product (vial or any other formulation) for Commercialization in Japan, in each case (***). AEVI will ship all Licensed Product FCA (INCOTERMS 2020) AEVI's point of distribution. The Parties will use Commercially Reasonable Efforts to complete within (***), after the date on which KKC exercises the Japan Option 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**") and a quality agreement related to the Supply Agreement.

4.3 Medical Affairs Activities. AEVI will be solely responsible for Medical Affairs Activities with the Licensed Products in the Field in the Territory. Following KKC's exercise of the Japan Option, KKC will be solely responsible for Medical Affairs Activities with the Licensed Products in Japan. 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 that are beyond the scope of the Product Labels and Inserts.

4.4 Cross Territory Sales.

4.4.1 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 following exercise of the Japan Option, 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 in Japan. 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.

4.4.2 AEVI Restrictions. Following exercise of the Japan Option, AEVI will not Commercialize or authorize the Commercialization of any Licensed Product in Japan. Following exercise of the Japan Option, 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 in Japan. Without limiting the generality of the foregoing, following exercise of the Japan Option, 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 in Japan. Following exercise of the Japan Option, 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 5. DILIGENCE

5.1 Diligence in Development. AEVI will use Commercially Reasonable Efforts to Develop the Licensed Product in the Field in the Territory and to obtain Regulatory Approvals for the Licensed Product in the Field in France, Germany, Italy, Spain, the United Kingdom, the United States and China. AEVI shall use Commercially Reasonable Efforts to complete the Crohn's Disease Study.

5.2 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 material reasons, and in such cases AEVI will not be liable for a breach of the diligence obligation set forth in this Section 5.2 in respect of such country.

5.3 Reporting. AEVI will provide the following reports and notice to KKC:

5.3.1 the Development Plan updates required by Section 3.2.2;

5.3.2 no later than April 15 of each Contract Year beginning in 2022, AEVI shall provide to KKC a written report summarizing (a) the status of its Development (including the status of any Regulatory Approval process) activities in the Field in the Territory as of March 31 of such Contract Year as compared to the most recently provided Development Plan and (b) its 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 for the twelve month period ending March 31.

5.3.3 no later than September 30 of the Contract Year that follows the Contract Year in which the First Commercial Sale in any country occurs and annually thereafter, AEVI shall provide to KKC a sales forecast for the next Contract Year.

5.3.4 until expiration of the Japan Option Period, no later than (***) after AEVI receives top-line data for any proof-of-concept study of a Licensed Product, receives a substantially final clinical study report for any proof-of-concept study of a Licensed Product or substantially finalizes a protocol synopsis for a Phase 3 Clinical Trial of a Licensed Product (each, an "***AEVI Study Report***"), AEVI will provide each AEVI Study Report to KKC; and

5.3.5 AEVI will provided KKC notice or (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 each case within (***) after the occurrence thereof.

ARTICLE 6. LICENSES

6.1 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 12.3) license, with the right to grant Sublicenses solely as provided in Section 6.4, to:

6.1.1 Develop Licensed Products in the Field in the Territory;

6.1.2 Manufacture or have Manufactured (subject to Section 6.4.6) Licensed Products; and

6.1.3 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.

6.2 License Grants to KKC. Subject to the terms and conditions of this Agreement, following the exercise of the Japan Option, AEVI grants KKC, under the AEVI Technology, a non-exclusive, royalty-free (except as to the AEVI In-License as set forth in Section 7.6.4(b)) license, with the right to sublicense solely as provided in Sections 6.4.1, to:

6.2.1 Develop, have Developed, Manufacture, have Manufactured, use, offer for sale, sell, have sold and otherwise Commercialize and have Commercialized Licensed Products in Japan; and

6.2.2 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 in Japan.

6.3 Rights of Reference. Upon KKC exercising the Japan Option, 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 6.1 or 6.2, as applicable.

6.4 Sublicenses.

6.4.1 AEVI's Right to Sublicense. Subject to the penultimate sentence of this Section 6.4.1, AEVI may sublicense the rights granted to it under Section 6.1 to its Related Parties or Third Parties at any time. AEVI will remain responsible for the performance of its

Sublicensees under this Agreement, including for all payments due hereunder. AEVI will provide KKC with notice of each permitted Sublicense. In addition, AEVI will provide a copy of any such Sublicense to KKC after execution of such Sublicense. All such notices of Sublicenses provided by AEVI under this Section 6.4.1 will be deemed to be Confidential Information of AEVI subject to the provisions of Article 9 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 and licensed to KKC may be subject to Sanofi's written consent. If Sanofi's written consent to sublicensing is so required, both Parties shall cooperate with each other to obtain such consent.

6.4.2 Terms of Sublicenses by AEVI. Each Sublicense granted by AEVI pursuant to Section 6.4.1 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 of KKC that include the right to Commercialize any Licensed Product(s) will contain a requirement that such Sublicensee comply with the confidentiality and non-use provisions of Article 9 with respect to both Parties' Confidential Information.

6.4.3 KKC's Right to Sublicense. KKC may sublicense the rights granted to it under Section 6.1 to its Related Parties or Third Parties at any time, other than rights under the AEVI In-License which sublicensing by KKC requires the consent of CHOP. KKC will remain responsible for the performance of its Sublicensees under this Agreement, including for all payments due hereunder. KKC will provide AEVI with notice of each permitted Sublicense. In addition, KKC will provide a copy of any such Sublicense to AEVI after execution of such Sublicense. All such notices of Sublicenses provided by KKC under this Section 6.4.1 will be deemed to be Confidential Information of KKC subject to the provisions of Article 9 whether or not so marked.

6.4.4 Terms of Sublicenses by KKC. Each Sublicense granted by KKC pursuant to Section 6.4.3 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 a requirement that such Sublicensee comply with the confidentiality and non-use provisions of Article 9 with respect to both Parties' Confidential Information.

6.4.5 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 sublicensing Party.

6.4.6 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 responsibilities under 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 9 and intellectual property provisions that will such Party to comply with Article 8.

6.5 Japan Option

6.5.1 Option Grant. Subject to the terms and conditions of this Agreement, AEVI hereby grants to KKC an exclusive option to remove Japan from the Territory and to obtain an exclusive license to Develop and Commercialize Licensed Products in Japan in accordance with the terms and conditions as described in Section 6.5.2 (the "**Japan Option**").

6.5.2 Option Exercise. KKC may exercise the Option by giving AEVI written notice (the "**Option Exercise Notice**") at any time beginning on the Effective Date and ending at 5:00PM United States Eastern Time on the date that is (***) that FDA accepted a BLA for (***) Indication of a Licensed Product filed by AEVI or any of its Related Parties (the "**Japan Option Period**"). If KKC exercise the Japan Option prior to the expiration of the Japan Option Period in accordance with the terms of this Section 6.5, then the Territory will no longer include Japan. As conditions to AEVI transferring any AEVI Technology to KKC for its use Japan, the Parties must enter into an agreement in form and substance acceptable to both Parties that obligates KKC to (i) pay AEVI an amount equal to (***%**) of the Japan Option Development Costs for the Licensed Products through the end of the Contract Quarter in which KKC exercises the Japan Option, (ii) pay for AEVI for its services (such as transfer of AEVI Know-How and regulatory support to obtain Regulatory Approval in Japan) and (iii) pay for all further Development Costs for the Licensed Product in Japan. For the avoidance of doubt, if KKC fails to exercise the Japan Option prior to the expiration of the Japan Option Period in accordance with the terms of this Section 6.5, KKC will have no rights to Develop, Manufacture or have Manufactured, or Commercialize Licensed Products in the Field in Japan, and Japan will remain part of the Territory during the Term.

6.6 In-Licenses.

6.6.1 KKC In-Licenses. All licenses and other rights granted to AEVI by KKC under this Article 6 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 6.1 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 LJL. AEVI agrees to be bound by the pertinent sections of Sections 1, 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 LJL Agreement to the same extent that KKC is bound thereby.

6.6.2 AEVI In-Licenses. All licenses and other rights granted to KKC by AEVI under this Article 6 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 licensed from CHOP. 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.

6.7 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.

6.8 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 7. FINANCIAL PROVISIONS

7.1 Initial License Fee. Within (***) after the Effective Date, AEVI will pay to KKC an initial license fee of Ten Million dollars (\$10,000,000).

7.2 Development Costs. Subject to Section 6.5, AEVI and its Related Parties will be solely responsible for payment of the Development Costs they incur in respect of Development of Licensed Products.

7.3 Milestone Events and Milestone Payments.

7.3.1 Milestone Payments. For up to three (3) different and separate Indications, AEVI will pay to KKC the amounts set forth below (each, a “**Milestone Payment**”) no later than thirty (30) days after the earliest date on which AEVI or any of its Related Parties receives written notification that the corresponding milestone event (each, a “**Milestone Event**”) has been achieved with respect to a Licensed Product for a given Indication with the Milestone Payment equal to the amount in the column labeled Payment if Achieved By AEVI or its Affiliates if AEVI or its Affiliate is the person that filed or received approval of the relevant Regulatory Approval Application or in the column labeled Payment if Achieved by AEVI's Sublicensee if its Sublicensee is the person that filed or received approval of the relevant Regulatory Approval Application:

<i>Milestone Event</i>	<i>Payment if Achieved By AEVI or its Affiliates</i>	<i>Payment if Achieved by AEVI's Sublicensee</i>
(**) for a Licensed Product by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event
(**) for a Licensed Product by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event
(**) for a Licensed Product by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event
(**) for a Licensed Product filed with FDA by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event
(**) for a Licensed Product filed with EMA by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event
(**) for a Licensed Product filed with NMPA by AEVI or its Related Party	(**\$)**	The greater of (**\$)** or (**%**) of the AEVI's Sublicensee Milestone Payment received for achievement of this Milestone Event

7.3.2 Repetition of Milestone Payments. For the avoidance of doubt: (a) a Milestone Payment in respect of Licensed Product in a given Indication is paid only once upon the first achievement of such Milestone Event for such Licensed Product in such Indication, (b) each Milestone Payment can be earned a maximum of three times, one per different and separate

Indication, (c) the maximum amount payable under Section 7.3.1 in respect of a Licensed Product in an Indication is \$(***\$***) and (d) the maximum amount payable under Section 7.3.1 is \$(***\$***) (i.e. all Milestone Events achieved for the Licensed Product in three different and separate Indications).

7.4 Sales Milestones.

7.4.1 Sales Milestone Payments. AEVI will pay to KKC the amounts set forth below (each, a “**Sales Milestone Payment**”) no later than (***) after the end of the Calendar Year in which the following sales milestones (each, a “**Sales Milestone**”) have first been achieved with respect to a Licensed Product:

<i>Sales Milestone</i>	<i>Sales Milestone Payment</i>
Aggregate AEVI’s Net Sales in a Calendar Year exceeds (***\$***)	(***\$***)
Aggregate AEVI’s Net Sales in a Calendar Year exceeds (***\$***)	(***\$***)

7.4.2 Other Sales Milestone Payment Arrangements. If both Sales Milestones are first achieved in the same Contract Year, then AEVI shall pay KKC the Sales Milestone Payment equal to (***\$***) (for aggregate AEVI’s Net Sales in a Calendar Year exceeding (***\$***)), and KKC will remain eligible to earn the (***\$***) Sales Milestone Payment based on AEVI’s Net Sales in subsequent Contract Years. For the avoidance of doubt: (a) a Sales Milestone Payment is paid only once upon the first achievement of the associated Sales Milestone, (b) each Sales Milestone Payment can be earned only once, (c) the maximum amount payable under Section 7.4.1 is (***\$***) and (d) only AEVI’s Net Sales, and not the Net Sales of its Sublicensees, are relevant to Section 7.4.1.

7.5 AEVI Royalties; Sublicense Income.

7.5.1 AEVI Royalties. On a country-by-country basis, AEVI will pay to KKC royalties equal to (***) of the Net Sales of AEVI and its Affiliates from such country during the Royalty Term. If there is no Valid Claim and a Data Exclusivity Period does not exist or has expired in such country, the royalties in such country will be reduced for the remainder of the Royalty Term to (**%) of AEVI’s Net Sales. For the avoidance of doubt, no royalty is payable to KKC under this Section 7.5.1 in respect of the Net Sales of Sublicensees of AEVI or any of its Affiliates.

7.5.2 Sublicense Income. AEVI will pay to KKC an amount equal to (**%) of Sublicense Income during the Term.

7.5.3 Reports and Royalty Payments. Within (***) after the end of each Contract Quarter during the Term, AEVI will deliver to KKC 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 Net Sales (with AEVI’s Net Sales and the Net Sales of Sublicensees of AEVI and any of its Affiliates reported separately) of each Licensed Product, (b) the number of units sold by AEVI and its Affiliates, (c) the Sublicense Income

received by AEVI and its Affiliates, (d) the basis for any adjustments to the royalty payable for the sale of each Licensed Product, (e) the royalty due under Section 7.5, and (f) the applicable exchange rate as determined pursuant to Section 7.6.2. 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.

7.6 Payment Provisions Generally.

7.6.1 Taxes and Withholding. If Applicable Laws require withholding of income taxes or other taxes imposed upon payments set forth in Article 7, the paying Party will make such withholding payments as required and subtract such withholding payments from the payments set forth in Article 7. 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.

7.6.2 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 7.5, 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.

7.6.3 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.

7.6.4 Financial Matters Relating to Third Party Technology as of the Effective Date.

(a) All amounts payable in respect of Licensed Product and/or this Agreement under the KKC In-Licenses will be paid directly by KKC or its Related Parties to the KKC Licensor, provided that AEVI will reimburse KKC, within (***) after receipt of invoice therefor, in the amount of (***) of:

(i) the payments stipulated in (***) in respect of sales of Licensed Product by AEVI and its Affiliates and Sublicensees; and

(ii) payments stipulated in (**) in respect of sales of Licensed Product by AEVI and its Affiliates and Sublicensees.

(b) All amounts payable in respect of Licensed Product and/or this Agreement under the AEVI In-License will be paid directly by AEVI or its Affiliates or Sublicensees to CHOP, provided that KKC will reimburse AEVI, within (**) after receipt of invoice therefor, in the amount of (**) in respect of sales of Licensed Product in Japan by KKC and its Affiliates and Sublicensees after KKC exercises the Japan Option (with the royalty rate to be based on annual worldwide sales of the Licensed Product as required by the AEVI In-License).

(c) AEVI is solely responsible for payments due to Lonza under the AEVI Lonza License Agreement. The allocation of costs for Third Party Technology acquired or licensed after the Effective Date is set forth in Section 8.5.

7.6.5 Record-Keeping. AEVI will keep, and will cause its Related Parties to keep, books and accounts of record in connection with this Agreement in sufficient detail to permit accurate determination of all figures necessary for any and all financial calculations required by this Agreement, including Development Costs, Net Sales and Sublicense Income. AEVI will maintain, and will cause its 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.

7.6.6 Audits. Upon thirty (30) days' prior written notice from KKC, AEVI will permit an independent certified public accounting firm of nationally recognized standing selected by KKC and reasonably acceptable to AEVI, to examine, at KKC's sole expense, the relevant books and records of AEVI and its Affiliates as may be reasonably necessary to verify the amounts reporting or payable by AEVI to KKC. An examination by KKC under this Section 7.6.6 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 AEVI's facility(ies) where such books and records are normally kept and such examination will be conducted during AEVI's normal business hours. AEVI may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to AEVI's facilities or records. Upon completion of the audit, the accounting firm will provide both AEVI and KKC a written report disclosing any discrepancies in the reports submitted by AEVI 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 KKC.

7.6.7 Underpayments/Overpayments. If such accounting firm concludes that additional amounts were due to KKC, AEVI will make such payments as is necessary for KKC 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, AEVI also will reimburse KKC for all Out-of-Pocket Costs incurred in conducting the audit. If such accounting firm correctly concludes that AEVI overpaid amounts due to KKC, KKC will refund such

overpayments to AEVI within sixty (60) days of the date KKC receives such accountant's report so correctly concluding.

7.6.8 Confidentiality. All financial information of a Party that is subject to review under this Section 7.6 will be deemed to be Confidential Information of AEVI subject to the provisions of Article 9, and KKC 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 AEVI to KKC hereunder.

7.7 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 7.7.

ARTICLE 8. INTELLECTUAL PROPERTY

8.1 Ownership of and Rights to Intellectual Property.

8.1.1 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.

8.1.2 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.

8.1.3 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.

8.1.4 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.

8.2 Filing, Prosecution and Maintenance of Patent Rights.

8.2.1 KKC Patent Rights. This Section 8.2 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 8.2, 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 1.57, but excluding those described in clause (b) of Section 1.57, 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 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.

(c) Notwithstanding anything to the contrary in this Agreement (including Section 8.3.1(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 8.3.1(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.

(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.

8.2.2 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.

8.2.3 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. 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.

8.2.4 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.

8.2.5 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.

8.3 Enforcement of Patent Rights.

8.3.1 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.

8.3.2 Rights to Enforce in the Territory. AEVI will have the right, but not the obligation, to take any reasonable measures it deems appropriate to: (a) stop infringing activities described in Section 8.3.1 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**”). AEVI may request that KKC grant such adequate rights and licenses; provided that KKC will have no obligation to grant any such rights or licenses; and provided further that upon making such request, KKC will have the right to participate in all negotiations with the alleged infringer concerning such adequate rights and licenses. Before AEVI takes any action to stop the infringing activity against an alleged infringer of the KKC Technology in the Territory, AEVI will consult in good faith with KKC 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 the event that AEVI elects not to take action pursuant to this Section 8.3.2, AEVI shall so notify KKC in writing of its intention (**). Thereafter, the Parties shall consult with one another in an effort to determine whether a reasonably prudent licensee would institute litigation to enforce the KKC Technology in question in light of all relevant business and economic factors (including, but not limited to, the projected cost of such litigation, the likelihood of success on the merits, the probable amount of any damage award, the prospects for satisfaction of any judgment against the alleged infringer, the possibility of counterclaims against the Parties or likely patent challenges, the impact of any possible adverse outcome on the Parties and the effect any publicity might have on the Parties’ respective reputations and goodwill). If, after such process, it is unanimously determined that a suit should be filed and AEVI does not file suit or commence settlement negotiations forthwith against the infringer, then KKC shall have the right, at its own expense, to enforce the KKC Technology in question on behalf of itself and AEVI and KKC shall have the right, but not the obligation, to take any such reasonable measures to stop such infringing activities by such alleged infringer.

8.3.3 KKC Rights to Enforce in Japan. Solely in the event that KKC elects the Japan Option, 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 8.3.1 in respect of the KKC Technology in Japan 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 in Japan or (b) defend the KKC Technology in Japan against any declaratory judgment, opposition, patentability or invalidity actions.

8.3.4 Procedures; Expenses and Recoveries. The Party having the right to initiate any infringement suit or defend a Defensive Action under Section 8.3.2 (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**") (***). 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 (***).

8.3.5 **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 1.53) 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.

8.4 Claimed Infringement of Third Party Rights.

8.4.1 **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.

8.4.2 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. Solely in the event that KKC elects the Japan Option, 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 in the Field in Japan.

(a) Procedure. The Party having the 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 shall bear the expense of defending the Infringement Claim. 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. 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.

8.4.3 Limitations. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN SECTION 11.9, 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.

8.5 Third Party Technology Acquired or Licensed After the Effective Date. If a Party reasonably determines that any Third Party Technology not already the subject of this Agreement is reasonably necessary for the Development, Manufacture, or Commercialization of a Licensed Product in the Field in such Party’s territory, then such Party will notify the other Party. Unless such Third Party Technology is specific only to Japan, AEVI will control the negotiations to obtain a license to such Third Party Technology with a right to sublicense to KKC but otherwise on terms and conditions determined at AEVI’s sole discretion. If such Third Party Technology is specific only to Japan, KKC will control the negotiations to obtain a license to such Third Party Technology on terms and conditions determined at KKC’s sole discretion. If AEVI elects not to obtain rights to such Third Party Technology for Japan, or is unsuccessful in obtaining a license to such Third Party Technology for Japan, then KKC will have the right (but not the obligation) to negotiate and obtain rights from such Third Party Technology at its sole discretion and expense and on such terms and conditions determined at KKC’s sole discretion. AEVI shall (***) and allocable to the activities of AEVI and its Related Parties in the Territory. KKC (***) and allocable to the activities of KKC and its Related Parties in Japan following KKC’s exercise of the Japan Option. Notwithstanding the foregoing, with respect to any lump sum payment (such as license fees and milestone payments) under any such agreement that is

made with respect to a license covering countries or jurisdictions both AEVI's territory and Japan, the Parties will negotiate and decide in good faith the allocation of the payment based on the scope and territory of the acquired rights.

8.6 Other Infringement Resolutions.

8.6.1 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 8.3 or 8.4, 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***").

8.6.2 Cooperation and Enforcement. If AEVI or any of its Related Parties 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 AEVI will provide notice to KKC, and the Parties will discuss and cooperate with each other in determining AEVI'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, AEVI 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 8.3 will thereafter apply as if such Section 351(k) Applicant were an infringer or suspected infringer.

8.7 Product Trademarks.

8.7.1 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).

8.7.2 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.

8.8 Patent Term Extensions. KKC will use reasonable efforts to obtain all available supplementary protection certificates (“*SPC*”) and other extensions of Patent Rights. KKC will execute such authorizations and other documents and take such other actions as may be reasonably requested by AEVI 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. KKC will have the right to seek patent term restoration or extension of any KKC Patent Rights or any SPC related thereto; provided that if in any country KKC has an option to extend the patent term for only one of several patents, KKC will consult with AEVI 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.

8.9 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 9. CONFIDENTIALITY

9.1 Confidentiality.

9.1.1 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, agency, government or private entity (other than a Party’s Affiliates or as

set forth in Section 9.1.2), 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 9 will expire five (5) years following termination of this Agreement.

9.1.2 Required Disclosures. Section 9.1.1 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, except that AEVI shall not be required to provide prior written notice of confidential disclosures to Regulatory Authorities. 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.

9.1.3 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 9. 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 9.

9.2 Publications by the Parties. Following the KKC's exercise of the Japan Option and subject to Section 9.3:

9.2.1 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;

9.2.2 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;

9.2.3 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.

9.3 Publications by Third Parties. Following the KKC's exercise of the Japan Option and notwithstanding Section 9.2, 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.

9.4 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 9 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, any of the terms of this Agreement, or any amendment hereto without the prior written consent of the other Party.

ARTICLE 10. TERM AND TERMINATION

10.1 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 10.2 or 10.3 (the "**Term**").

10.2 Termination by KKC.

10.2.1 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.

10.2.2 Breach. KKC will have the right to terminate this Agreement in its entirety, at KKC's sole discretion, subject to Section 10.2.4, upon delivery of written notice to AEVI in the event of any material breach (other than a material breach of Sections 5.1 and/or 5.2 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 10.2.2 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Subject to Section 10.2.4, 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.

10.2.3 Diligence or Country-Specific Breach. In the case of a material breach by AEVI of Sections 5.1 and/or 5.2 or a material breach by AEVI that is specific to a given country in the Territory, subject to Section 10.2.4, 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 sixty (60) days 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 thirty (30) days 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 10.2.3 will not be triggered provided that AEVI will pay the amount in dispute into escrow until such dispute is resolved). Subject to Section 10.2.4, 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 six (6) months 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.

10.2.4 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 10.2.4 (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 or any of its Affiliates Challenges the validity, scope or enforceability of or otherwise opposes any of the KKC Patent Rights under which such Sublicensee is sublicensed, then AEVI or its Affiliate will, upon written notice from KKC, promptly terminate such sublicense. “**Challenge**” under this Section 10.2.3 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.

10.2.5 Dispute. If AEVI reasonably and in good faith disagrees as to whether KKC has a basis for terminating this Agreement pursuant to Sections 10.2.2 or 10.2.3, AEVI may contest the allegation in accordance with Section 12.2. 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 Sections 10.2.2 or 10.2.3 will be effective unless and until KKC’s right to terminate this Agreement under Sections 10.2.2 or 10.2.3 has been finally determined by arbitration in accordance with Section 12.2. 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 12.2.

10.2.6 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.

10.3 Termination by AEVI.

10.3.1 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.

10.3.2 Breach. AEVI will have the right to terminate this Agreement in its entirety, at AEVI's sole discretion, subject to Section 10.3.4, 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 10.3.2 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 10.3.2. Subject to Section 10.3.4, 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.

10.3.3 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.

10.3.4 Dispute. If KKC reasonably and in good faith disagrees as to whether AEVI has a basis for terminating this Agreement pursuant to Section 10.3.2, KKC may contest the allegation in accordance with Section 12.2. 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 10.3.2 will be effective unless and until KKC's right to terminate this Agreement under Section 10.3.2 has been finally determined by arbitration in accordance with Section 12.2. 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 12.2.

10.3.5 No obligation to KKC. In any termination pursuant to this Section 10.3, 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.

10.4 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):

10.4.1 Reversion. All rights and licenses granted to AEVI in Article 6 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.

10.4.2 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 10.4.2 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 10.4.2 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.

10.4.3 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 the cell line(s), master cell bank, working cell bank, cell line(s) for analysis of the Licensed Product, 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 10.4.3. 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 10.2.5, 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.

10.4.4 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.

10.4.5 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.

10.4.6 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 10.3.3, (**). 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.

10.4.7 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 complete manufacturing technology transfer to KKC without limitation the cell line(s), master cell bank, working cell bank and cell line(s) for analysis of the Licensed Product, 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.

10.4.8 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.

10.4.9 Retention of Payments. KKC will have the right to retain all amounts previously paid to KKC by AEVI.

10.4.10 No Compensation. Each Party will not owe any compensation to the other Party for the research, development, manufacture, or commercialization of any Licensed Products in the event of any termination of the Agreement by itself, 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.

10.4.11 Costs. Any costs and expenses incurred by AEVI in connection with the assignments and transfers made by AEVI under this Section 10.4 will be borne by AEVI.

10.5 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.

10.6 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 9 (Confidentiality), Article 11 (Representations and Warranties; Indemnification) and Article 12 (Miscellaneous Provisions) and Sections 6.4.5 (Effect of Termination on Sublicenses), 6.8 (Obligation under the BARDA Contract), 8.2.2 (Joint Inventions) and 10.3.5 (No obligation to KKC) will survive any termination of this Agreement. Except as set forth in this Article 10 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.

10.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by either Party, including without limitation Article 6, 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 10.2.1 or 10.3.1, 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 and Sales Milestone Payments made under Section 7.3 and 7.4, respectively, do not constitute royalties within the meaning of U.S. Bankruptcy Code §365(n) or relate to licenses of intellectual property hereunder.

10.8 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 12.2, 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 12.2 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 10, in addition to any other remedy to which such Party may be entitled by Applicable Law. Nothing in this Article 10 will be deemed to limit any remedy to which either Party may be entitled by Applicable Law.

ARTICLE 11. REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; INDEMNIFICATION

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

(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 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.

11.2 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 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-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.

(f) As a result of AEVI entering into the AEVI Lonza License Agreement, (i) no rights are sublicensed by KKC to AEVI under the Multi Product Licence Agreement between Lonza and Kyowa Kirin Co., Ltd. (***) and (ii) AEVI has no responsibility for any payment due, whether now or in the future, under such agreement.

11.3 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 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.

(f) KKC 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 AEVI hereunder.

11.4 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; provided that this covenant will terminate upon the expiration of the Japan Option Period.

(d) 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; provided that this covenant will terminate upon the expiration of the Japan Option Period.

(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; provided that this covenant will terminate upon the expiration of the Japan Option Period.

(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; provided that this covenant will terminate upon the expiration of the Japan Option Period.

(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; provided that this covenant will terminate upon the expiration of the Japan Option Period.

11.5 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.

11.6 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.

11.7 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.

11.8 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 11.8 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 9.

11.9 Indemnification and Insurance.

11.10.1 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 to each Party from BARDA or Sanofi), 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 6 or under the Clinical Development and Option Agreement, and/or (d) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by AEVI or any of its Related Parties (including any of the foregoing accomplished under the Clinical Development and Option Agreement). 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 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.

11.10.2 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, and/or (c) the Development, Manufacturing and Commercialization of Licensed Products (including product liability) by KKC or any of its Related Parties. 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.

11.10.3 **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 11.10.1 or Section 11.10.2 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 11.10.3, 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.

11.10.4 **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 11.10.1 or 11.10.2, 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 12.

MISCELLANEOUS PROVISIONS

12.1 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.

12.2 Dispute Resolution.

12.2.1 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 12.2.2.

12.2.2 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 12.1 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 12.2, 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 8 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.

12.3 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, such consent not to be unreasonably withheld, delayed or conditioned. 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.

12.4 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, including the Clinical Development and Option Agreement. Any amendment or modification to this Agreement will be made in writing signed by both Parties.

12.5 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 or (b) sent by internationally recognized overnight delivery service 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

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

If to AEVI:

Aevi Genomic Medicine, LLC
1500 Liberty Ridge Drive, Suite 321
Wayne, PA 19087
USA
Attention: Chief Executive Officer

with a copy to:

Troutman Pepper Hamilton Sanders LLP
Two Logan Square
18th & Arch Streets
Philadelphia, Pennsylvania 19103-2799
USA
Attention: Brian M. Katz

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.

12.6 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.

12.7 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.

12.8 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.

12.9 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.

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

12.11 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.

12.12 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).

12.13 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.

12.14 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.

12.15 No Third Party Beneficiaries. Except as expressly set forth in Section 11.10.2, 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.

[Signature Page Follows]

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

KYOWA KIRIN CO., LTD.

AEVI GENOMIC MEDICINE, LLC

By: /s/ Masashi Miyamoto

By: /s/ Michael F. Cola

Name: Masashi Miyamoto

Name: Michael F. Cola

Title: President and Chief Executive Officer

Title: President and CEO

[Signature Page to License Agreement]

SCHEDULE 1.14

AMINO ACID SEQUENCE OF ANTI-LIGHT MAB

(***)

SCHEDULE 1.45

FTE RATES

1. The following table sets forth the FTE Rates for AEVI FTEs:

Title/Role	FTE Rate
(***)	(***\$***)
(***)	(***\$***)
(***)	(***\$***)
(***)	(***\$***)

SCHEDULE 1.53

KKC IN-LICENSES

License Agreement between La Jolla Institute for Immunology and Kyowa Kirin Co., Ltd. (***) (including the LIGHT Addendum between La Jolla Institute for Allergy and Immunology and Kyowa Kirin Co., Ltd., attached thereto). This is the LJI Agreement referred to in Section 1.63.

(***) Agreement between Bristol-Myers Squibb Company and Kyowa Kirin Co., Ltd. (***)

Letters between Kyowa Kirin Co., Ltd. and Sanofi (***), and sublicensing of rights to AEVI.

KKC PATENT RIGHTS

65

**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: May 13, 2021

/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, Schond Greenway, 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: May 13, 2021

/s/ Schond L. Greenway

Schond L. Greenway

Chief Financial Officer

(Registrant's principal financial officer)

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

In connection with the Quarterly Report of Cerecor Inc. (the "Registrant") on Form 10-Q for the period ended March 31, 2021 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, Schond Greenway, Chief Financial Officer of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 13, 2021

/s/ Michael Cola

Michael Cola

Chief Executive Officer

(Registrant's principal executive officer)

Date: May 13, 2021

/s/ Schond L. Greenway

Schond L. Greenway

Chief Financial Officer

(Registrant's principal financial officer)

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