UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

or

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

For the transition period from to .

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware	**33-0728374**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

2100 Powell Street, Suite 900
Emeryville, CA 94608
(510) 848-5100
(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)

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

Title of each class:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	DVAX	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration 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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 2, 2020, the registrant had outstanding 110,172,859 shares of common stock.

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DYNAVAX TECHNOLOGIES CORPORATION

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about the direct and indirect impact of the ongoing COVID-19 global pandemic on our business and operations, including sales of HEPLISAV-B®, our ability to successfully commercialize HEPLISAV-B, our anticipated market opportunity and level of sales of HEPLISAV-B, our ability to manufacture sufficient supply of HEPLISAV-B to meet future demand, our business, collaboration and regulatory strategy, our ability to successfully develop and commercialize other vaccines containing our novel adjuvant CpG 1018, including any potential vaccine for COVID-19, our ability to manufacture sufficient supply of CpG 1018 to meet potential future demand in connection with new vaccines, including any potential COVID-19 vaccine, and to meet regulatory requirements, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, liquidity and cash needs, as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," or "intend," or the negative of these terms or other variations or comparable terminology.

Actual results may vary materially from those in our forward-looking statements as a result of various factors that are identified in "Item 1A—Risk Factors" and "Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this document. No assurance can be given that the risk factors described in this Quarterly Report on Form 10-Q are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.

This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners. References herein to "we," "our," "us," "Dynavax" or the "Company" refer to Dynavax Technologies Corporation and, where appropriate, its subsidiary Dynavax GmbH.

ITEM 1. FINANCIAL STATEMENTS

Dynavax Technologies Corporation
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)

	September 30, 2020 (unaudited)	December 31, 2019 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 32,688	$ 39,884
Marketable securities available-for-sale	144,473	111,171
Accounts and other receivables, net	35,023	8,886
Inventories, net	59,033	41,332
Prepaid expenses and other current assets	18,786	7,380
Total current assets	290,003	208,653
Property and equipment, net	30,379	32,022
Intangible assets, net	-	2,500
Operating lease right-of-use assets	27,353	30,252
Goodwill	2,196	2,081
Restricted cash	226	216
Other assets	3,238	3,344
Total assets	$ 353,395	$ 279,068
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,273	$ 9,278
Accrued research and development	2,939	4,120
Accrued liabilities	17,192	14,802
Warrant liability	10,660	14,860
Deferred revenue	21,712	-
Other current liabilities	8,849	9,987
Total current liabilities	66,625	53,047
Long-term debt, net of debt discount of $1,172 and $1,394 at September 30, 2020 and December 31, 2019, respectively	179,733	178,601
Long-term portion of lease liabilities	35,519	37,845
Other long-term liabilities	2,234	1,285
Total liabilities	284,111	270,778
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock: $0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:	-	-
Series B Convertible Preferred stock– 4 shares and 5 shares at September 30, 2020 and December 31, 2019, respectively	-	-
Common stock: $0.001 par value; 278,000 shares and 139,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 110,173 shares and 83,871 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	110	84
Additional paid-in capital	1,348,793	1,229,417
Accumulated other comprehensive loss	(1,022)	(2,387)
Accumulated deficit	(1,278,597)	(1,218,824)
Total stockholders' equity	69,284	8,290
Total liabilities and stockholders' equity	$ 353,395	$ 279,068

See accompanying notes.

Dynavax Technologies Corporation
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product revenue, net	$ 13,276	$ 10,158	$ 26,195	$ 24,086
Other revenue	138	417	806	563
Total revenues	13,414	10,575	27,001	24,649
Operating expenses:				
Cost of sales - product	4,031	3,824	7,352	7,765
Cost of sales - amortization of intangible assets	-	2,324	2,500	6,894
Research and development	8,521	12,660	19,058	50,062
Selling, general and administrative	21,538	18,459	61,418	54,668
Gain on sale of assets (Note 5)	(6,851)	-	(6,851)	-
Restructuring	-	3,937	-	12,714
Total operating expenses	27,239	41,204	83,477	132,103
Loss from operations	(13,825)	(30,629)	(56,476)	(107,454)
Other income (expense):				
Interest income	269	890	1,190	2,604
Interest expense	(4,794)	(4,779)	(14,257)	(12,111)
Sublease income	1,926	891	5,779	891
Change in fair value of warrant liability (Note 11)	21,245	-	4,200	-
Other	(420)	168	(209)	226
Net income (loss)	4,401	(33,459)	(59,773)	(115,844)
Preferred stock deemed dividend	-	(3,267)	-	(3,267)
Net income (loss) allocable to common stockholders	$ 4,401	$ (36,726)	$ (59,773)	$ (119,111)
Basic net income (loss) per share allocable to common stockholders	$ 0.04	$ (0.49)	$ (0.61)	$ (1.75)
Weighted average shares used to compute basic net income (loss) per share allocable to common stockholders	109,816	75,106	97,589	68,032
Diluted net loss per share allocable to common stockholders	$ (0.15)	$ (0.49)	$ (0.65)	$ (1.75)
Weighted average shares used to compute diluted net loss per share allocable to common stockholders	111,973	75,106	98,577	68,032

Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 4,401	$ (33,459)	$ (59,773)	$ (115,844)
Other comprehensive income (loss), net of tax:				
Reclassification of realized gain on available-for-sale securities recognized in interest income	(108)	-	(21)	-
Change in unrealized gain on marketable securities available-for-sale	(75)	(71)	30	105
Foreign currency translation adjustments	1,256	(1,034)	1,356	(1,178)
Total other comprehensive income (loss)	1,073	(1,105)	1,365	(1,073)
Total comprehensive income (loss)	$ 5,474	$ (34,564)	$ (58,408)	$ (116,917)

See accompanying notes.

Dynavax Technologies Corporation
Condensed Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months Ended September 30, 2020	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at June 30, 2020	109,503	$ 109	4	$ -	$ 1,343,279	$ (2,095)	$ (1,282,998)	$ 58,295
Issuance of common stock upon exercise of stock options and restricted stock awards, net	457	1	-	-	212	-	-	213
Issuance of common stock under Employee Stock Purchase Plan	104	-	-	-	361	-	-	361
Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (see Note 11)	109	-	-	-	839	-	-	839
Stock compensation expense	-	-	-	-	4,102	-	-	4,102
Total other comprehensive income	-	-	-	-	-	1,073	-	1,073
Net income	-	-	-	-	-	-	4,401	4,401
Balances at September 30, 2020	110,173	$ 110	4	$ -	$ 1,348,793	$ (1,022)	$ (1,278,597)	$ 69,284
Nine Months Ended September 30, 2020								
Balances at December 31, 2019	83,871	$ 84	5	$ -	$ 1,229,417	$ (2,387)	$ (1,218,824)	$ 8,290
Conversion of preferred stock	700	1	(1)	-	-	-	-	1
Issuance of common stock upon exercise of stock options and restricted stock awards, net	1,192	1	-	-	223	-	-	224
Issuance of common stock under Employee Stock Purchase Plan	195	-	-	-	672	-	-	672
Issuance of common stock, net of issuance costs, in conjunction with an underwritten public offering and an At Market Sales Agreement (see Note 11)	24,215	24	-	-	108,513	-	-	108,537
Stock compensation expense	-	-	-	-	9,968	-	-	9,968
Total other comprehensive income	-	-	-	-	-	1,365	-	1,365
Net loss	-	-	-	-	-	-	(59,773)	(59,773)
Balances at September 30, 2020	110,173	$ 110	4	$ -	$ 1,348,793	$ (1,022)	$ (1,278,597)	$ 69,284

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months Ended September 30, 2019	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at June 30, 2019	65,155	$ 65	-	$ -	$ 1,161,115	$ (1,983)	$ (1,148,609)	$ 10,588
Issuance of common stock upon exercise of stock options and restricted stock awards, net	138	-	-	-	-	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	47	-	-	-	158	-	-	158
Issuance of common stock, net of issuance costs, in conjunction with an underwritten public offering (see Note 11)	18,525	19	-	-	46,146	-	-	46,165
Issuance of Series B convertible preferred stock, net of issuance costs in conjunction with an underwritten public offering (see Note 11)	-	-	5	-	12,061	-	-	12,061
Stock compensation expense	-	-	-	-	4,748	-	-	4,748
Total other comprehensive loss	-	-	-	-	-	(1,105)	-	(1,105)
Net loss	-	-	-	-	-	-	(33,459)	(33,459)
Balances at September 30, 2019	83,865	$ 84	5	$ -	$ 1,224,228	$ (3,088)	$ (1,182,068)	$ 39,156
Nine Months Ended September 30, 2019								
Balances at December 31, 2018	62,862	$ 63	-	$ -	$ 1,131,241	$ (2,015)	$ (1,066,224)	$ 63,065
Issuance of common stock upon exercise of stock options and restricted stock awards, net	969	1	-	-	1	-	-	2
Issuance of common stock under Employee Stock Purchase Plan	122	-	-	-	565	-	-	565
Issuance of common stock, net of issuance costs, in conjunction with an underwritten public offering and an At Market Sales Agreement (see Note 11)	19,912	20			60,093			60,113
Issuance of Series B convertible preferred stock, net of issuance costs in conjunction with an underwritten public offering (see Note 11)	-	-	5	-	12,061	-	-	12,061
Stock compensation expense	-	-	-	-	20,267	-	-	20,267
Total other comprehensive loss	-	-	-	-	-	(1,073)	-	(1,073)
Net loss	-	-	-	-	-	-	(115,844)	(115,844)
Balances at September 30, 2019	83,865	$ 84	5	$ -	$ 1,224,228	$ (3,088)	$ (1,182,068)	$ 39,156

See accompanying notes.

Dynavax Technologies Corporation
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities		
Net loss	$ (59,773)	$ (115,844)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,166	7,838
Amortization of right-of-use assets	1,906	2,742
Gain on disposal of property and equipment and from lease termination	(76)	-
Amortization of premium (accretion of discounts) on marketable securities	193	(1,293)
Realized gain on available-for-sale securities	(56)	-
Change in fair value of warrant liability	(4,200)	234
Stock compensation expense	9,968	20,267
Cost of sales - amortization of intangible assets	2,500	6,894
Non-cash interest expense	2,129	3,533
Tenant improvements provided by the landlord	908	6,639
Gain on sale of assets	(6,851)	-
Changes in operating assets and liabilities:		
Accounts and other receivables, net	(22,137)	(5,118)
Inventories, net	(17,701)	(20,334)
Prepaid expenses and other current assets	(11,406)	391
Other assets	106	1,467
Accounts payable	(1,433)	3,035
Lease liabilities	(2,131)	(1,340)
Deferred revenue	21,712	-
Accrued liabilities and other liabilities	6,668	(7,351)
Net cash used in operating activities	(76,508)	(98,240)
Investing activities		
Acquisition of technology licenses	(7,000)	(7,000)
Purchases of marketable securities	(171,982)	(181,148)
Proceeds from maturities and redemptions of marketable securities	117,650	141,085
Proceeds from sales of marketable securities	20,902	-
Purchases of property and equipment, net	(3,303)	(20,570)
Proceeds from sale of assets, net of transaction costs	2,859	-
Net cash used in investing activities	(40,874)	(67,633)
Financing activities		
Proceeds from long-term debt, net	-	74,250
Proceeds from issuance of common stock, net	108,537	65,948
Proceeds from issuance of preferred stock, net	-	13,586
Proceeds from exercise of stock options and restricted stock awards, net	224	2
Proceeds from Employee Stock Purchase Plan	672	565
Net cash provided by financing activities	109,433	154,351
Effect of exchange rate changes on cash, cash equivalents and restricted cash	763	(529)
Net decrease in cash, cash equivalents and restricted cash	(7,186)	(12,051)
Cash, cash equivalents and restricted cash at beginning of period	40,100	49,967
Cash, cash equivalents and restricted cash at end of period	$ 32,914	$ 37,916
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 12,149	$ 8,715
Non-cash investing and financing activities:		
Purchases of property and equipment, not yet paid	$ 364	$ 3,135
Proceeds allocated to warrant liability at issuance	$ -	$ 7,360
Right-of-use assets obtained in exchange for operating lease liabilities	$ -	$ 39,104

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. We launched our first product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following United States Food and Drug Administration ("FDA") approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We are also working to develop our novel adjuvant, CpG 1018, as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which we consider necessary to present fairly our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows to be expected for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2019 has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "SEC").

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiary, Dynavax GmbH. All significant intercompany accounts and transactions among these entities have been eliminated from the condensed consolidated financial statements. We operate in one business segment: discovery, development and commercialization of novel vaccines.

Liquidity and Financial Condition

As of September 30, 2020, we had cash, cash equivalents and marketable securities of $177.2 million. As of September 30, 2020, the principal amount of our term loan was $180.9 million, including paid-in-kind interest. The term loan has a maturity date of December 31, 2023, unless earlier prepaid.

The Company has incurred losses and negative cash flows from operations since its inception and expects to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B and development of our CpG 1018 adjuvant. If we cannot generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

We currently anticipate that our cash, cash equivalents and short-term marketable securities as of September 30, 2020, and anticipated revenues from HEPLISAV-B and CpG 1018 will be sufficient to fund our operations for at least the next 12 months from the date of this filing.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. In addition, global financial crises and economic downturns, including those cause by widespread public health crises such as the COVID-19 pandemic, may cause extreme volatility and disruptions in capital and credit markets, and may impact our ability to raise additional capital when needed on acceptable terms, if at all. Adequate financing may not be available to us on acceptable terms, or at all.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management's estimates are based on historical information available as of the date of the condensed consolidated financial statements and various other assumptions we believe are reasonable under the circumstances. However, the worldwide spread of COVID-19 has resulted in a global slowdown of economic activity which is likely to decrease demand for a broad variety of goods and services, while also disrupting sales channels and marketing activities for an unknown period of time until the disease is contained. We are unable to predict the future effect resulting from the COVID-19 pandemic. Actual results could differ materially from management's estimates.

Summary of Significant Accounting Policies

Revenue Recognition

We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Accounting Standards Codification ("ASC") 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net – HEPLISAV-B

We sell HEPLISAV-B to a limited number of wholesalers and specialty distributors in the U.S. (collectively, our "Customers").

Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short-term and we expect to receive payment in less than one year, there is no significant financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, pharmacies and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. There have been no material adjustments to these estimates for the nine months ended September 30, 2020 and 2019.

Product Returns: Consistent with industry practice, we offer our Customers a limited right of return based on the product's expiration date for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We consider several factors in the estimation of potential product returns including expiration dates of the product shipped, the limited product return rights, available information about Customers' inventory, shelf life of the product and other relevant factors.

Chargebacks: Our Customers subsequently resell our product to healthcare providers, pharmacies and others. In addition to distribution agreements with Customers, we enter into arrangements with qualified healthcare providers that provide for chargebacks and discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are determined at the time of resale to the qualified healthcare providers by Customers, and we issue credits for such amounts generally within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to the qualified healthcare providers, and chargebacks for units that our Customers have sold to the qualified healthcare providers, but for which credits have not been issued.

Trade Discounts and Allowances: We provide our Customers with discounts which include early payment incentives that are explicitly stated in our contracts, and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Distribution Fees: Distribution fees include fees paid to certain Customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

Rebates: Under certain contracts, customers may obtain rebates for purchasing minimum volumes of our product. We estimate these rebates based upon the expected purchases and the contractual rebate rate and record this estimate as a reduction in revenue in the period the related revenue is recognized.

Product Revenue, Net – CpG 1018

We also sell our novel adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. We have determined that our collaboration partners meet the definition of customers under ASC 606. Therefore, we accounted for our CpG 1018 sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer. Because the timing between the recognition of revenue for product sales and the receipt of payment is less than one year, there is no significant financing component on the related receivables.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Collaboration and Manufacturing Service Revenue

We have entered into collaborative arrangements and arrangements to provide manufacturing services to other companies. Such arrangements may include promises to customers which, if capable of being distinct, are accounted for as separate performance obligations. For agreements with multiple performance obligations, we allocate estimated revenue to each performance obligation at contract inception based on the estimated transaction price of each performance obligation. Revenue allocated to each performance obligation is then recognized when we satisfy the performance obligation by transferring control of the promised good or service to the customer. Collaboration and manufacturing service revenue are recorded in other revenue in the condensed consolidated statements of operations.

Leases

We determine if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities and long-term portion of lease liabilities in our condensed consolidated balance sheets. Right-of-use assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, we use our incremental borrowing rate which represents an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date.

The operating lease right-of-use assets also include any lease payments made and exclude any lease incentives. Our leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that we will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. We have elected not to apply the recognition requirements of ASC 842 for short-term leases. We have also elected the practical expedient to not separate lease components from non-lease components.

As lessors, we determine if an arrangement includes a lease at inception. We elected the practical expedient to not separate lease components from non-lease components. Rent revenue is recognized on a straight-line basis over the expected lease term and is included in other income (expense) in our condensed consolidated statements of operations.

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the nine months ended September 30, 2020 and 2019, there were no inventory reserves recognized.

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to the required regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory but are expensed as research and development costs. We begin capitalization of these inventory related costs once regulatory approval is obtained.

HEPLISAV-B was approved by the FDA on November 9, 2017, at which time we began to capitalize inventory costs associated with the vial presentation of HEPLISAV-B. In March 2018, we received regulatory approval of the pre-filled syringe (“PFS”) presentation of HEPLISAV-B. Prior to FDA approval of HEPLISAV-B, all costs related to the manufacturing of HEPLISAV-B that could potentially be available to support the commercial launch of our products, were charged to research and development expense in the period incurred as there was no alternative future use. Prior to regulatory approval of PFS, costs associated with resuming operating activities at the Düsseldorf manufacturing facility were also included in research and development expense. Subsequent to regulatory approval of PFS, costs associated with resuming manufacturing activities at the Düsseldorf facility were included in cost of sales – product, until commercial production resumed in mid-2018 at which time these costs were recorded as raw materials inventory.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. We estimate research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. There have been no material adjustments to the prior period accrued estimates for clinical trial activities for the nine months ended September 30, 2020 and 2019.

Recent Accounting Pronouncements

Accounting Standards Update 2016-13

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments. The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. As a smaller

reporting company, this ASU and its subsequent updates, is effective for fiscal years beginning after December 15, 2022. We are currently evaluating the impact this standard will have on our condensed consolidated financial statements.

Accounting Standards Update 2019-12

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes (Topic 740). This ASU simplifies the accounting for income taxes by removing certain exceptions and improving consistent application in certain areas of Topic 740. The ASU is effective for annual periods beginning after December 15, 2020 with early adoption permitted. We are currently evaluating the impact this standard will have on our condensed consolidated financial statements.

Accounting Standards Update 2020-06

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for convertible instruments. This ASU also requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The ASU is effective for annual periods beginning after December 15, 2021 with early adoption permitted. We are currently evaluating the impact this standard will have on our condensed consolidated financial statements.

2. Fair Value Measurements

We measure fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities; therefore, requiring an entity to develop its own valuation techniques and assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. There were no transfers between Level 1, 2 and 3 during the nine months ended September 30, 2020.

The carrying amounts of cash equivalents, accounts and other receivables, accounts payable and accrued liabilities are considered reasonable estimates of their respective fair value because of their short-term nature.

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and liabilities measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
September 30, 2020				
Assets				
Money market funds	$ 25,138	$ -	$ -	$ 25,138
U.S. treasuries	-	30,673	-	30,673
U.S. government agency securities	-	48,417	-	48,417
Corporate debt securities	-	69,935	-	69,935
Total assets	$ 25,138	$ 149,025	$ -	$ 174,163
Liabilities				
Warrant liability	$ -	$ -	$ 10,660	$ 10,660

	Level 1	Level 2	Level 3	Total
December 31, 2019				
Assets				
Money market funds	$ 27,854	$ -	$ -	$ 27,854
U.S. treasuries	-	6,517	-	6,517
U.S. government agency securities	-	51,273	-	51,273
Corporate debt securities	-	61,373	-	61,373
Total assets	$ 27,854	$ 119,163	$ -	$ 147,017
Liabilities				
Warrant liability	$ -	$ -	$ 14,860	$ 14,860
Sublicense liability	-	-	6,948	6,948
Total liabilities	$ -	$ -	$ 21,808	$ 21,808

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. treasuries, U.S. government agency securities and corporate debt securities are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

Warrants were issued in connection with the underwritten public offering in August 2019 and are accounted for as a derivative liability at fair value. See Note 11. The fair value of the warrant liability is estimated using the Black-Scholes model which requires assumptions such as expected term, expected volatility and risk-free interest rate. These assumptions are subjective and require judgement to develop. Expected term is estimated using the full remaining contractual term of the warrants. We determine expected volatility based on our historical common stock price volatility. The warrant liability is classified as a Level 3 instrument as its value is based on unobservable inputs that are supported by little or no market activity.

As of September 30, 2020, we used the following key assumptions to estimate the fair value of warrant liability:

Number of shares	5,841,250
Expected term	1.4 years
Expected volatility	1.0
Risk-free interest rate	0.1%
Dividend yield	0%

The following table provides a summary of changes in the fair value warrant liability for the nine months ended September 30, 2020 (in thousands):

Balance at December 31, 2019	$ 14,860
Decrease in the estimated fair value of warrant liability upon revaluation	(4,200)
Balance at September 30, 2020	$ 10,660

3. Cash, Cash Equivalents, Restricted Cash and Marketable Securities

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 amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30, 2020	December 31, 2019	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 32,688	$ 39,884	$ 37,297	$ 49,348
Restricted cash	226	216	619	619
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 32,914	$ 40,100	$ 37,916	$ 49,967

Restricted cash balances relate to certificates of deposit issued as collateral to certain letters of credit issued as security to our facility leases. See Note 6.

Cash, cash equivalents and marketable securities consist of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2020				
Cash and cash equivalents:				
Cash	$ 2,998	$ -	$ -	$ 2,998
Money market funds	25,138	-	-	25,138
Corporate debt securities	4,552	-	-	4,552
Total cash and cash equivalents	32,688	-	-	32,688
Marketable securities available-for-sale:				
U.S. treasuries	30,622	51	-	30,673
U.S. government agency securities	48,408	11	(2)	48,417
Corporate debt securities	65,362	22	(1)	65,383
Total marketable securities available-for-sale	144,392	84	(3)	144,473
Total cash, cash equivalents and marketable securities	$ 177,080	$ 84	$ (3)	$ 177,161
December 31, 2019				
Cash and cash equivalents:				
Cash	$ 4,038	$ -	$ -	$ 4,038
Money market funds	27,854	-	-	27,854
Corporate debt securities	7,992	-	-	7,992
Total cash and cash equivalents	39,884	-	-	39,884
Marketable securities available-for-sale:				
U.S. treasuries	6,511	6	-	6,517
U.S. government agency securities	51,235	50	(12)	51,273
Corporate debt securities	53,353	28	-	53,381
Total marketable securities available-for-sale	111,099	84	(12)	111,171
Total cash, cash equivalents and marketable securities	$ 150,983	$ 84	$ (12)	$ 151,055

The maturities of our marketable securities available-for-sale are as follows (in thousands):

	September 30, 2020	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 108,016	$ 108,093
Mature after one year through two years	36,376	36,380
	$ 144,392	$ 144,473

We have classified our entire investment portfolio as available-for-sale and available for use in current operations and accordingly have classified all investments as short-term. Available-for-sale securities are carried at fair value based on inputs that are observable, either directly or indirectly, such as quoted market prices for similar securities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the securities, with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

- whether the investment has been in a continuous unrealized loss position for over 12 months;
- the duration to maturity of our investments;
- our intention and ability to hold the investment to maturity and if it is not more likely than not that we will be required to sell the investment before recovery of the amortized cost bases;
- the credit rating, financial condition and near-term prospects of the issuer; and
- the type of investments made.

For both the three and nine months ended September 30, 2020, there were gross realized gains on investments of $0.1 million and no gross realized losses. There were no gross realized gains or losses on investments for the three and nine months ended September 30, 2019. Realized gains are included in interest income in the condensed consolidated statements of operations. All investments with unrealized losses at September 30, 2020 have been in a loss position for less than twelve months. We do not intend to sell the investments that are in an unrealized loss position before recovery of their amortized cost basis. To date, there have been no declines in fair value that have been identified as other than temporary.

4. Inventories, net

The following table presents inventories, net (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 20,920	$ 15,198
Work-in-process	27,109	22,890
Finished goods	11,004	3,244
Total	$ 59,033	$ 41,332

5. Intangible Assets, net

Intangible assets are related to certain capitalized milestone and sublicense payments. The following table presents intangible assets (in thousands):

	September 30, 2020	December 31, 2019
Intangible assets	$ 19,773	$ 19,773
Less accumulated amortization	(19,773)	(17,273)
Total	$ -	$ 2,500

No cost of sales - amortization of intangible assets was recorded for the three months ended September 30, 2020. We recorded cost of sales - amortization of intangible assets of $2.3 million for the three months ended September 30, 2019. We recorded cost of sales - amortization of intangible assets of $2.5 million and $6.9 million for the nine months ended September 30, 2020 and 2019, respectively. See Note 7.

Sale of SD-101 Program

In May 2019, we announced a strategic restructuring to focus on our vaccine business and curtail our investment in our immuno-oncology programs. In July 2020, we sold assets related to our immuno-oncology compound, SD-101, which included intellectual property, clinical and non-clinical data, regulatory filings, clinical supply inventory and certain contracts to Surefire Medical Inc. d/b/a TriSalus Life Sciences ("TriSalus"). Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction. TriSalus also agreed to pay us $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound. In connection with our 2009 agreement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC ("Holdings") in November 2009, we paid $2.5 million to Holdings in August 2020. See Note 6.

In the third quarter of 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, based on the amount of consideration received, net of any transaction costs. As of September 30, 2020, the additional cash payment of $4 million was included in accounts and other receivables, net in our condensed consolidated balance sheets. The $2.5 million payment to Holdings was included in selling, general and administrative expense in our condensed consolidated statement of operations.

6. Commitments and Contingencies

Leases

We lease our facilities in Emeryville, California and Düsseldorf, Germany.

In July 2019, we entered into a sublease for office space located at 2100 Powell Street, Emeryville, California (the "Powell Street Sublease") and the lease for our former corporate headquarters at 2929 Seventh Street, Berkeley, California was terminated effective August 31, 2019. Under the terms of the Powell Street Sublease, we are leasing 23,976 square feet at the rate of $3.90 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and we are responsible for certain operating expenses and taxes throughout the life of the Powell Street Sublease. The Powell Street Sublease will continue until June 30, 2022. There is no option to extend the sublease term.

On September 17, 2018, we entered into a lease ("Horton Street Master Lease") for office and laboratory space located at 5959 Horton Street, Emeryville, California ("Horton Street Premises"). Under the terms of the Horton Street Master Lease, we are leasing 75,662 square feet at the rate of $4.75 per square foot, paid on a monthly basis, starting on April 1, 2019 ("Commencement Date"). Rent is subject to scheduled annual increases, and we are also responsible for certain operating expenses and taxes throughout the life of Horton Street Master Lease. In connection with the Horton Street Master Lease, we are entitled to a tenant improvement allowance of up to $8.3 million, of which $7.9 million has been received through September 30, 2020. The Horton Street Master Lease has an initial term of 12 years, following the Commencement Date with an option to extend the lease for two successive five-year terms. The optional periods were not included in the lease term used in determining the right-of-use asset or the lease liability as we did not consider it reasonably certain that we would exercise the options. The operating lease right-of-use assets and liabilities on our September 30, 2020 condensed consolidated balance sheets primarily relate to the Horton Street Master Lease.

In connection with the organizational restructuring in May 2019, we did not occupy the Horton Street Premises and in July 2019, we entered into an agreement to sublease the Horton Street Premises to a third party ("Horton Street Sublease"). Under the terms of the Horton Street Sublease, we are subleasing the entire 75,662 rentable square feet at the rate of $5.50 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and the subtenant ("Subtenant") is responsible for certain operating expenses and taxes throughout the life of the Horton Street Sublease. The Horton Street Sublease term is until March 31, 2031, unless earlier terminated, concurrent with the term of our Horton Street Master Lease. The Subtenant has no option to extend the sublease term. Sublease income for the three months ended September 30, 2020 and 2019 were $1.9 million and $0.9 million, respectively. Sublease income for the nine months ended September 30, 2020 and 2019 were $5.8 million and $0.9 million, respectively. Sublease income is included in other income (expense) in our condensed consolidated statements of operations.

Under the terms of the Horton Street Master Lease, rent received from the Subtenant in excess of rent paid to the landlord shall be shared by paying the landlord 50% of the excess rent. The excess rent is considered a variable lease payment and the total estimated payments are being recognized as additional rent expense on a straight-line basis.

Our lease expense comprises of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease expense	$ 1,550	$ 1,789	$ 4,703	$ 5,274

Cash paid for amounts included in the measurement of lease liabilities for the nine months ended September 30, 2020 and 2019 was $5.1 million and $3.8 million, respectively, and was included in operating cash flows in our condensed consolidated statement of cash flows.

The balance sheet classification of our operating lease liabilities was as follows (in thousands):

	September 30, 2020	December 31, 2019
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 3,149	$ 3,039
Long-term portion of lease liabilities	35,519	37,845
Total operating lease liabilities	$ 38,668	$ 40,884

At September 30, 2020, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2020 (remaining)	$ 1,286	$ 1,730
2021	5,201	6,925
2022	5,357	6,239
2023	5,518	5,377
2024	5,684	5,521
Thereafter	39,596	36,373
Total	$ 62,642	62,165
Less:		
Present value adjustment		(23,497)
Total		$ 38,668

The weighted average remaining lease term and the weighted average discount rate used to determine the operating lease liability were as follows:

	September 30, 2020	December 31, 2019
Weighted average remaining lease term	9.3 years	9.7 years
Weighted average discount rate	10.1%	10.1%

Commitments

On February 20, 2018, we entered into a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. We borrowed $100.0 million under the Loan Agreement at closing and the remaining $75.0 million in March 2019 (collectively, “Term Loans”). At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through September 30, 2020, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $180.9 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. See Note 8.

As of September 30, 2020, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 and for clinical research, totaled $28.1 million.

During 2004, we established a letter of credit with Deutsche Bank as security for our Düsseldorf lease in the amount of €0.2 million (Euros). The letter of credit remained outstanding through September 30, 2020 and is collateralized by a certificate of deposit for €0.2 million, which has been included in restricted cash in the consolidated balance sheets as of September 30, 2020.

In conjunction with our agreement with Holdings in November 2009, we agreed to make contingent cash payments to Holdings equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. In July 2020, we sold assets related to our SD-101 compound to TriSalus. See Note 5. We are obligated to pay Holdings 50% of the contingent pre-commercialization milestone payments that we may receive under the Asset Purchase Agreement. No liability has been recorded under this agreement as of September 30, 2020.

Contingencies

From time to time, we may be involved in claims, suits, and proceedings arising from the ordinary course of our business, including actions with respect to intellectual property claims, commercial claims, and other matters. Such claims, suits, and proceedings are inherently uncertain and their results cannot be predicted with certainty. Regardless of the outcome, such legal proceedings can have an adverse impact on us because of legal costs, diversion of management resources, and other factors. In addition, it is possible that a resolution of one or more such proceedings could result in substantial damages, fines, penalties or orders

requiring a change in our business practices, which could in the future materially and adversely affect our financial position, results of operations, or cash flows in a particular period.

7. Collaborative Research, Development and License Agreements

Coalition for Epidemic Preparedness Innovations

In September 2020, we entered into a Reservation Agreement for the Provision of Goods (the "Reservation Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") to make available specified quantities of CpG 1018 adjuvant, for purchases at certain prices, to CEPI and its COVID-19 vaccine development partners ("CEPI Partners"). Payments received under the Reservation Agreement are considered an exchange for our CpG 1018 adjuvant which is an output of our ordinary activities. As such, we account for the arrangement under the scope of ASC 606. Payments are recorded as deferred revenue and recognized as revenue in the period when we satisfy our performance obligation to deliver CpG 1018 ordered or when CEPI's right to place an order expires. Pursuant to the Reservation Agreement, CEPI has paid us $6.3 million for production scale-up and a fourth quarter 2020 reservation fee.

The $6.3 million payment is recorded as deferred revenue in our condensed consolidated balance sheets as of September 30, 2020. No revenue was recognized for the three months ended September 30, 2020.

In October 2020, CEPI terminated the Reservation Agreement and its right to place an order expired. Therefore, we will recognize $6.3 million as revenue in the fourth quarter of 2020.

Valneva SE

In April 2020, we entered into a Collaboration Agreement with Valneva Scotland Limited ("Valneva") to provide CpG 1018 adjuvant for use in the development of Valneva's COVID-19 vaccine candidate. The Collaboration Agreement was amended in July 2020, to provide additional quantities of CpG 1018 adjuvant. In September 2020, we entered into a Supply Agreement ("Supply Agreement") with Valneva to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the commercialization of Valneva's COVID-19 vaccine candidate.

We concluded that the Collaboration Agreement and the Supply Agreement were entered into at or near the same time, with the same customer and were negotiated as a package with a single commercial objective, that is the provision of CpG 1018 adjuvant to Valneva. Therefore, the Collaboration Agreement and the Supply Agreement should be combined and accounted for as a single arrangement.

Pursuant to the Supply Agreement, we issued an invoice for $14.2 million, upon acceptance of Valneva's binding purchase order, for advanced payment to purchase specified quantities of CpG 1018 adjuvant in the first and second quarters of 2021. In addition, we issued an invoice for $5.7 million for the first payment to purchase additional specified quantities of CpG 1018 adjuvant in the second quarter of 2021. We recorded the $14.2 million and $5.7 million as deferred revenue and other current liabilities, respectively in our condensed consolidated balance sheets.

Bill & Melinda Gates Foundation Grant Agreement

In July 2020, we entered into a grant agreement (the "Grant Agreement") with Bill & Melinda Gates Foundation ("BMGF"), under which we were awarded a grant of up to $3.4 million to scale up production of our CpG 1018 adjuvant to support the global COVID-19 response (the "Project") and we received $1.2 million of the grant from BMGF which we accounted for as deferred revenue in our condensed consolidated balance sheets at September 30, 2020. Any grant funds, plus any income, that have not been used for, or committed to, the Project must be returned promptly to BMGF upon expiration or termination of the Grant Agreement.

We and BMGF had also planned to execute a Global Access and Strategy/Commitment Agreement ("GASC Agreement") in connection with the Grant Agreement. Upon execution of the GASC Agreement, we would receive the remaining $2.2 million in grant funding. As of November 5, 2020, the GASC Agreement has not been executed and if it is not executed we will not receive the remaining grant funding.

Serum Institute of India Pvt. Ltd.

In June 2017, we entered into an agreement to provide Serum Institute of India Pvt. Ltd. ("SIIPL") with technical support. In consideration, SIIPL agreed to pay us at an agreed-upon hourly rate for services and reimburse certain out-of-pocket expenses. In addition, we have rights to commercialization of certain potential products manufactured at the SIIPL facility. For the three months ended September 30, 2020, we recognized collaboration revenue of $0.1 million. No collaboration revenue was recognized for the

three months ended September 30, 2019. For the nine months ended September 30, 2020 and 2019, we recognized collaboration revenue of $0.8 million and $0.1 million, respectively.

Merck, Sharp & Dohme Corp.

In February 2018, we entered into a Sublicense Agreement (the "Sublicense Agreement") with Merck. The Sublicense Agreement grants us, under certain non-exclusive U.S. patent rights controlled by Merck which relate to recombinant production of hepatitis B surface antigen, the right to manufacture, use, offer for sale, sell and import HEPLISAV-B in the United States and includes the right to grant further sublicenses. Under the terms of the Sublicense Agreement, we were obligated to pay $21.0 million in three installments. The first, second and third installment of $7.0 million each was paid in February 2018, 2019 and 2020, respectively. The Sublicense Agreement expired in April 2020, at which time the license became perpetual, irrevocable, fully paid-up and royalty free. As of September 30, 2020, the intangible asset has been fully amortized. At December 31, 2019, the intangible asset, net balance was $2.5 million. See Note 5.

8. Long-Term Debt

On February 20, 2018, we entered into a $175.0 million Loan Agreement with CRG Servicing LLC. Net proceeds under the Loan Agreement were $173.3 million. The Term Loans under the Loan Agreement bear interest at a rate equal to 9.5% per annum. At September 30, 2020, the effective interest rate was 10.3%. At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through September 30, 2020, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $180.9 million, excluding debt discount of $1.2 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. The Term Loans and paid-in-kind interest will be entirely payable at maturity.

In August 2019, we entered into a second amendment to the Loan Agreement (the "Second Amendment"). The Second Amendment amended the annual net sales threshold for sales of HEPLISAV-B, revising the twelve-month measurement periods from beginning on January 1 of each year to beginning on July 1 of each year (including 2019) and ending on June 30, 2023. The Second Amendment also revised the fee payable upon partial prepayment or at maturity of the Term Loans from 3% to 4% of the aggregate principal amounts.

In November 2020, we entered into a third amendment to the Loan Agreement (the "Third Amendment"). The Third Amendment modified the annual net sales threshold requirement to include sales of CpG 1018 and it removed the annual net sales threshold requirement for the twelve-month period beginning July 1, 2020 and ending on June 30, 2021.

The obligations under the Loan Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the Company and any future subsidiary guarantors, except for certain customary excluded property, and (ii) all of the capital stock owned by the Company and such future subsidiary guarantors (limited, in the case of the stock of certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, to 65% of the capital stock of such subsidiaries, subject to certain exceptions). The obligations under the Loan Agreement will be guaranteed by each of the Company's future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions). The Loan Agreement contains customary covenants and requires us to comply with a $15.0 million daily minimum combined cash and investment balance covenant and a twelve-month period revenue requirement starting on July 1, 2019 for sales of HEPLISAV-B.

We recorded $4.8 million and $4.7 million of interest expense related to the Term Loans during the three months ended September 30, 2020 and 2019, respectively. We recorded $14.2 million and $11.8 million of interest expense related to the Term Loans during the nine months ended September 30, 2020 and 2019, respectively.

9. Revenue Recognition

Our product revenue, net consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
HEPLISAV-B	$ 11,599	$ 10,158	$ 24,518	$ 24,086
CpG 1018	1,677	-	1,677	-
Total	$ 13,276	$ 10,158	$ 26,195	$ 24,086

All of our HEPLISAV-B sales were in the U.S. For the nine months ended September 30, 2020 and 2019, our three largest Customers collectively represented approximately 68% and 63% of our HEPLISAV-B product revenue, respectively. All of our CpG 1018 sales were outside the U.S.

The following table summarizes balances and activity in HEPLISAV-B product revenue allowance and reserve categories for the nine months ended September 30, 2020 (in thousands):

	Balance at Beginning of Period	Provisions related to current period sales	Credit or payments made during the period	Balance at End of Period
Nine months ended September 30, 2020:				
Accounts receivable reserves(1)	$ 2,701	$ 8,806	$ (7,945)	$ 3,562
Revenue reserve accruals(2)	$ 3,893	$ 5,029	$ (3,240)	$ 5,682

(1) Reserves are for chargebacks, discounts and other fees.
(2) Accruals are for returns, rebates and other fees.

10. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and giving effect to all potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, outstanding stock options, stock awards, warrants and Series B Convertible Preferred Stock are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following is a reconciliation of the numerator and the denominator used in the calculation of basic and diluted net loss per share (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator				
Net income (loss), basic	$ 4,401	$ (36,726)	$ (59,773)	$ (119,111)
Removal of change in fair value of warrant liability	(21,245)	-	(4,200)	-
Net loss, diluted	$ (16,844)	$ (36,726)	$ (63,973)	$ (119,111)
Denominator				
Weighted average shares used to compute basic net loss per share	109,816	75,106	97,589	68,032
Effect of dilutive warrants	2,157	-	988	-
Weighted average shares used to compute diluted net loss per share	111,973	75,106	98,577	68,032

The following were excluded from the calculation of diluted net loss per share as the effect of their inclusion would have been anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Outstanding securities not included in diluted net loss per share calculation (in thousands):				
Stock options and stock awards	10,984	10,065	10,984	10,065
Series B Convertible Preferred Stock (as converted to common stock)	4,140	4,840	4,140	4,840
Warrants (as exercisable into common stock)	-	5,841	-	5,841
	15,124	20,746	15,124	20,746

11. Common Stock, Preferred Stock and Warrants

Common Stock

On May 28, 2020, our Amended and Restated Certificate of Incorporation was amended to increase the number of authorized shares of our common stock, par value $0.001, from 139,000,000 shares to 278,000,000 shares. As of September 30, 2020, there were 110,172,859 shares of our common stock outstanding.

In August 2019, we sold (i) 18,525,000 shares of our common stock, par value $0.001 per share, (ii) 4,840 shares of our Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred Stock") and (iii) warrants to purchase up to an aggregate of 5,841,250 shares of our common stock in an underwritten public offering (the "Offering"). Each share of common stock was sold together with a warrant to purchase 0.25 shares of common stock, at a combined price of $3.00 per share of common stock and the accompanying warrant. Each share of Series B Preferred Stock was sold together with a warrant to purchase 250 shares of common stock, at a combined price of $3,000 per share and the accompanying warrant. Proceeds from the Offering were approximately $65.6 million, net of issuance costs of $4.5 million.

Investment funds associated with Bain Capital Life Sciences Investors, LLC ("Bain Capital Life Sciences") purchased approximately $35.0 million of common stock, Series B Preferred Stock and warrants in the Offering at the public offering price. Pursuant to the Offering, (i) Bain Capital Life Sciences Fund, L.P. purchased 6,826,266 shares of common stock, 3,756 shares of Series B Preferred Stock and warrants to purchase 2,645,566 shares of common stock for a total purchase price of approximately $31.7 million and (ii) BCIP Life Sciences Associates, LP purchased 698,734 shares of common stock, 384 shares of Series B Preferred Stock and warrants to purchase 270,684 shares of common stock for a total purchase price of approximately $3.2 million (together, "Bain Life Sciences Funds"). Bain Capital Life Sciences is the general partner of Bain Life Sciences Funds. The participation by these investors was on the same terms as the other investors in the Offering.

Following the Offering, Andrew A. F. Hack, M.D., Ph.D and Managing Director of Bain Capital Life Sciences (a related party), was appointed to our board of directors.

On March 11, 2020, we entered into a warrant exchange agreement with Bain Life Sciences Funds pursuant to which we agreed that we would, upon future notice from Bain Life Sciences Funds, exchange all or a portion of the common stock warrants held by Bain Life Sciences Funds for warrants to purchase a new Series C convertible preferred stock ("Series C Warrants"). Each share of Series C convertible preferred stock would be convertible into 1,000 shares of common stock, with a conversion price of $4.50 and would have substantially identical rights to our Series B Preferred Stock. As of September 30, 2020, Bain Life Sciences Funds have not exercised their rights to exchange common stock warrants with Series C Warrants.

In May 2020, we completed an underwritten public offering of 16,100,000 shares of our common stock, par value $0.001 per share, including 2,100,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriters. All of the shares were offered at a price to the public of $5.00 per share. The net proceeds to us from this offering were approximately $75.4 million, after deducting the underwriting discount and other estimated offering expenses payable by us. Bain Life Sciences Funds purchased 1,000,000 shares of common stock in the underwritten public offering. Bain Capital Life Sciences is the general partner of Bain Life Sciences Funds. The participation by Bain Life Sciences Funds was on the same terms as the other investors in the offering.

For the nine months ended September 30, 2020, we sold 8,005,467 shares of our common stock and received net cash proceeds of $32.3 million pursuant to a 2017 At Market Sales Agreement with Cowen and Company, LLC ("2017 ATM Agreement") that terminated in August 2020.

On August 6, 2020, we entered into an at-the-market Sales Agreement (the "2020 ATM Agreement") with Cowen and Company, LLC ("Cowen"), under which we may offer and sell from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150 million through Cowen as our sales agent. We agreed to pay Cowen a commission of up to 3% of the gross sales proceeds of any common stock sold through Cowen under the 2020 ATM Agreement. For the nine months ended September 30, 2020, we received net cash proceeds of $0.8 million resulting from sales of 109,176 shares of our common stock pursuant to the 2020 ATM Agreement. As of September 30, 2020, we had $149.1 million remaining under the 2020 ATM Agreement.

Preferred Stock

As of September 30, 2020, there were 4,140 shares of Series B Preferred Stock outstanding.

In the second quarter of 2020, 700 shares of our Series B Preferred Stock were converted into 700,000 shares of common stock.

Each share of Series B Preferred Stock is convertible into 1,000 shares of common stock at any time at the holder's option. However, the holder is prohibited from converting the Series B Preferred Stock into shares of common stock if, as a result of such conversion, the holder and its affiliates would own more than 4.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holders' election to a higher or lower percentage (not to exceed 19.99%) upon 61 days' notice to the Company. In the event of liquidation, dissolution, or winding up, the holder of Series B Preferred Stock will receive payment on shares of Series B Preferred Stock (determined on an as-converted to common stock basis) equal to the amount that would be paid on our common stock. Shares of Series B Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock is required to amend the terms of the Series B Preferred Stock. Holders of Series B Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. The Series B Preferred Stock ranks on parity with our common stock as to distributions of assets upon liquidation, dissolution or winding up. The Series B Preferred Stock may rank senior to, on parity with or junior to any class or series of capital stock created in the future depending upon the specific terms of such future stock issuance.

The fair value of the common stock into which the Series B Preferred Stock is convertible exceeded the allocated purchase price of the Series B Preferred Stock by $3.3 million on the date of issuance, for which we recorded a deemed dividend. We recognized a deemed dividend equal to the number of shares of common stock into which the Series B Preferred Stock is convertible multiplied by the difference between the value of the common stock and the Series B Preferred Stock conversion price per share on the date of issuance, which is the date the stock first became convertible. The dividend was reflected as a one-time, non-cash, deemed dividend to the holders of Series B Preferred Stock on the date of issuance.

Warrants

As of September 30, 2020, the following common stock warrants were outstanding:

Warrants Issuance Date	Shares Issuable (in thousands)	Expiration Date	Exercise Price per Share	Outstanding as of September 30, 2020 (in thousands)
August 12, 2019	5,841	February 12, 2022	$ 4.50	5,841

Warrants were exercisable upon issuance. The holder is prohibited from exercising these warrants if, as a result of such exercise, the holder and its affiliates, would own more than 4.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holders' election to a higher or lower percentage (not to exceed 19.99%) upon 61 days' notice to the Company.

The warrants contain provisions that may obligate us to repurchase them for an amount that does not represent fair value in the event of a change of control. Due to this provision, the warrants do not meet the criteria to be considered indexed to our own stock. Accordingly, we recorded the warrants as a derivative liability at fair value of $7.4 million on the issuance date, which was estimated using the Black-Scholes model.

The warrants will be revalued at each reporting period using the Black-Scholes model and the change in the fair value of the warrants will recognized as other income (expense) in the condensed consolidated statements of operations. At September 30, 2020, the estimated fair value of warrant liability was $10.7 million. For the three and nine months ended September 30, 2020, we recognized the decrease in the estimated fair value of warrant liability of $21.2 million and $4.2 million, respectively as income in other income (expense) in our condensed consolidated statements of operations.

12. Equity Plans and Stock-Based Compensation

Our 2018 Equity Incentive Plan (the "2018 EIP") is intended to be the successor to and continuation of the Dynavax Technologies Corporation 2011 Equity Incentive Plan (the "2011 EIP"). The aggregate number of shares of our common stock that may be issued under the 2018 EIP (subject to adjustment for certain changes in capitalization) is comprised of the sum of (i) 5,000,000 newly reserved shares of common stock, (ii) 140,250 unallocated shares of common stock remaining available for grant under the 2011 EIP as of May 31, 2018, and (iii) 7,477,619 shares subject to outstanding stock awards granted under the 2011 EIP and the Dynavax Technologies Corporation 2017 Inducement Award Plan that may become available from time to time as set forth in the 2018 EIP. The 2018 EIP provides for the issuance of up to 12,617,869 shares of our common stock to our employees and directors.

On May 28, 2020 and on May 30, 2019, our stockholders approved an amendment to 2018 Equity Incentive Plan (the "Amended 2018 EIP") to, among other things, increase the aggregate number of shares of common stock authorized for issuance by 7,600,000 and 2,300,000, respectively. Under the Amended 2018 EIP, the aggregate number of shares of our common stock that may be issued to employees and directors (subject to adjustment for certain changes in capitalization) is 22,517,869.

Option activity under our stock-based compensation plans during the nine months ended September 30, 2020 was as follows (in thousands except per share amounts):

	Shares Underlying Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2019	8,006	$ 13.86		
Options granted	1,860	5.83		
Options exercised	(55)	4.32		
Options cancelled:				
Options forfeited (unvested)	(263)	7.63		
Options expired (vested)	(378)	18.61		
Balance at September 30, 2020	9,170	$ 12.27	4.27	$ 490
Vested and expected to vest at September 30, 2020	8,938	$ 12.43	4.20	$ 483
Exercisable at September 30, 2020	5,870	$ 15.23	3.23	$ 412

Restricted stock unit activity under our stock-based compensation plans during the nine months ended September 30, 2020 was as follows (in thousands except per share amounts):

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2019	1,784	$ 9.16
Granted	1,335	5.33
Vested	(1,139)	8.18
Forfeited	(166)	7.72
Non-vested as of September 30, 2020	1,814	$ 7.09

The aggregate intrinsic value of the restricted stock units outstanding as of September 30, 2020, based on our stock price on that date was $7.8 million. Fair value of restricted stock units is determined at the date of grant using our closing stock price.

As of September 30, 2020, approximately 136,500 shares underlying stock options and approximately 169,550 restricted stock unit awards with performance-based vesting criteria were outstanding.

Under our stock-based compensation plans, option awards generally vest over a three or four-year period contingent upon continuous service, and expire seven to ten years from the date of grant (or earlier upon termination of continuous service). The fair value-based measurement of each option is estimated on the date of grant using the Black-Scholes option valuation model.

The fair value-based measurements and weighted-average assumptions used in the calculations of these measurements are as follows:

	Stock Options Three Months Ended September 30,		Stock Options Nine Months Ended September 30,		Employee Stock Purchase Plan Nine Months Ended September 30,	
	2020	2019	2020	2019	2020	2019
Weighted-average fair value per share	$ 5.82	$ 2.74	$ 3.95	$ 4.61	$ 2.17	$ 2.72
Risk-free interest rate	0.3%	1.6%	1.1%	2.2%	1.5%	1.9%
Expected life (in years)	4.5	4.5	4.5	4.5	1.2	1.3
Volatility	1.0	0.9	0.9	0.9	0.6	0.7

The components of stock-based compensation expense were (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 778	$ 1,661	$ (21)	$ 5,817
Selling, general and administrative	2,504	2,278	7,437	7,828
Restructuring	-	-	-	4,122
Cost of sales - product	137	189	452	819
Inventory	683	620	2,100	1,681
Total	$ 4,102	$ 4,748	$ 9,968	$ 20,267

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. Stock-based compensation for the nine months ended September 30, 2020 included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020.

As of September 30, 2020, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to $19.2 million, which is expected to be recognized over the remaining weighted-average vesting period of approximately 2 years. Additionally, as of September 30, 2020, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $0.9 million.

Employee Stock Purchase Plan

The Amended and Restated 2014 Employee Stock Purchase Plan (the “Purchase Plan”) provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. On May 31, 2018, our stockholders approved an amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance by 600,000 shares. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the two-year offer period (generally, the sixteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fifteenth day in February or August). For the nine months ended September 30, 2020, employees have acquired 195,334 shares of our common stock under the Purchase Plan and 255,583 shares of our common stock remained available for future purchases under the Purchase Plan.

13. Restructuring

On May 23, 2019, we implemented a strategic organizational restructuring, principally to align our operations around our vaccine business and significantly curtail further investment in our immuno-oncology business. In connection with the restructuring, we reduced our workforce by approximately 80 positions, or approximately 36%, of U.S.-based personnel. Also, in connection with the restructuring, our Chief Executive Officer, also a member of the Board of Directors (the “Board”), retired from the Company and the Board, effective August 1, 2019.

During the three months ended September 30, 2019, we identified certain long-lived assets installed at the Horton Street Premises that were or would be disposed of by the Subtenant. We recorded accelerated depreciation charges of $3.0 million on these assets. For the nine months ended September 30, 2019, we recognized restructuring charges of $12.7 million, of which $5.6 million was related to severance and other termination benefits $4.1 million was related to stock-based compensation expense as a result of accelerated vesting of stock awards and the extension of exercise period of stock options and $3.0 million was related to accelerated depreciation. At December 31, 2019, we have completed our restructuring activities and all of restructuring costs totaling $13.4 million have been incurred.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Quarterly Report on Form 10-Q and the Consolidated Financial Statements and the related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2019.

Overview

We are a fully-integrated biopharmaceutical company focused on developing and commercializing novel vaccines. Our first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] is approved by the United States Food and Drug Administration ("FDA") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We are also working to develop our novel adjuvant, CpG 1018, as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza.

We commenced commercial shipments of HEPLISAV-B in January 2018. In Phase 3 trials, HEPLISAV-B demonstrated faster and higher rates of protection with two doses in one month compared to another currently approved hepatitis B vaccine which requires three doses over six months, with a similar safety profile. HEPLISAV-B is the only two-dose hepatitis B vaccine for adults approved in the U.S.

We have worldwide commercial rights to HEPLISAV-B. There are three other vaccines approved for the prevention of hepatitis B in the U.S.: Engerix-B and Twinrix® from GlaxoSmithKline plc and Recombivax-HB® from Merck & Co.

All of our HEPLISAV-B sales are to certain wholesalers and specialty distributors in the U.S. whose principal customers include independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Departments of Defense and Veterans Affairs and retail pharmacies. For the three and nine months ended September 30, 2020, HEPLISAV-B product revenue, net was $11.6 million and $24.5 million, respectively.

In the third quarter of 2020, we commenced selling our novel adjuvant, CpG 1018, to certain of our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. For the three months ended September 30, 2020, CpG 1018 product revenue, net was $1.7 million. During the quarter we also announced a commercial supply agreement with Valneva Scotland Limited ("Valneva") to cover the supply of CpG 1018 for up to 190 million doses of their SARS-COV-2 vaccine candidate, subject to the terms of the agreement and contingencies contained therein.

In August 2020, we entered into a new At Market Sales Agreement with Cowen ("2020 ATM Agreement"), which replaced the 2017 At Market Sales Agreement ("2017 ATM Agreement"). Under the 2020 ATM Agreement, we can offer and sell up to $150 million of our common stock from time to time. For the nine months ended September 30, 2020, we received net cash proceeds of $33.1 million from sales of 8,114,643 shares of our common stock under the 2017 ATM Agreement and 2020 ATM Agreement.

In July 2020, we sold assets related to our immuno-oncology compound, SD-101 to Surefire Medical Inc. d/b/a TriSalus Life Sciences ("TriSalus"). Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction. TriSalus also agreed to pay us $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound. In the third quarter of 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, net of transaction costs.

COVID-19 Update

The ongoing COVID-19 global pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 virus, the actions taken to contain it or treat its impact and the economic impact on local,

regional, national and international markets. We continue to assess the potential impact of the COVID-19 pandemic on our business and operations.

To date, we and our distribution partners have been able to continue to supply HEPLISAV-B throughout the United States, and currently do not anticipate any interruptions in supply. Due to the ongoing COVID-19 global pandemic, most medical centers have restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in mid-March. As states began phasing out restrictions in late May/early June, medical centers have been operating under limited capacity and strict social distancing rules. This has resulted in significantly reduced utilization of adult vaccines since the end of the first quarter of 2020, including HEPLISAV-B. This reduced utilization has significantly impacted sales and is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions.

We are continuing to closely monitor the impact of the COVID-19 pandemic on our business and are taking proactive efforts to help protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important new vaccines to patients as rapidly as possible. We have implemented measures to help protect the health and safety of our workforce, including a mandatory work-from-home policy for employees who can perform their jobs offsite. In the conduct of our business activities, we are also taking actions to help protect the safety of patients and healthcare professionals. Our field-based personnel have reduced in-person customer interactions in healthcare settings and are primarily using electronic communication, such as emails, phone calls and video conferences. Many health care and contracting professionals at hospitals and other medical institutions with whom our field-based personnel interact are conducting a greater proportion of their work from their homes and are facing additional demands on their time during the COVID-19 pandemic. We expect that the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, could reduce the effectiveness of our sales personnel, our customers' procurement activities and those of our collaborators, which could negatively affect our product sales.

Currently, our HEPLISAV-B post-marketing observational studies are fully enrolled and continuing uninterrupted. Due to the design and conduct of the studies, we do not anticipate an impact to the integrity of the studies from "shelter in place" mandates. The HEPLISAV-B dialysis study is able to continue, because the dialysis treatment is classified under "essential travel" exemptions. However, if the COVID-19 pandemic persists for an extended period of time, we could experience significant disruptions to our post-marketing studies, which could adversely affect our business and growth prospects.

The extent of the impact of the COVID-19 pandemic on our ability to generate sales and revenues, our regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Because of the above and other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance. For additional information on the various current and future potential risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors, included herein.

We have been actively pursuing opportunities to collaborate with other organizations on the development of a COVID-19 vaccine, by leveraging our novel toll-like receptor 9 ("TLR9") agonist adjuvant, CpG 1018, which is the adjuvant used in our HEPLISAV-B product. In 2020, we announced multiple collaborations focused on COVID-19 and we continue to work to identify other programs where CpG 1018 can be utilized to enhance the immune response to a coronavirus vaccine. We and our contract manufacturer are developing plans to help scale-up activities to support pandemic-level of production of our CpG 1018 adjuvant, as necessary to support these and any future collaborations. There can be no assurance we will be successful in our efforts to help develop or supply an adjuvanted COVID-19 vaccine.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, assumptions and judgments described below that have the greatest potential impact on our condensed consolidated financial statements, including those related to revenue recognition, research and development activities, stock-based compensation, inventories and leases. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from these estimates under different assumptions or conditions.

We believe that there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2020, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Results of Operations

Revenues

Revenues consisted of amounts earned from product sales and collaboration revenue. Product revenue, net, includes sales of our HEPLISAV-B and our CpG 1018 adjuvant.

Revenue from HEPLISAV-B product sales is recorded at the net sales price, which includes estimates of product returns, chargebacks, discounts, rebates and other fees. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract.

We sell our novel adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. Revenue from CpG 1018 product sales is recorded at the net sales price which reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract.

Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following is a summary of our revenues (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
Revenues:	**2020**	**2019**	**$**	**%**	**2020**	**2019**	**$**	**%**
HEPLISAV-B	$ 11,599	$ 10,158	$ 1,441	14%	$ 24,518	$ 24,086	$ 432	2%
CpG 1018	1,677	-	1,677	NM	1,677	-	1,677	NM
Total product revenue, net	$ 13,276	$ 10,158	$ 3,118	31%	$ 26,195	$ 24,086	$ 2,109	9%
Other revenue	138	417	(279)	(67)%	806	563	243	43%
Total revenues	$ 13,414	$ 10,575	$ 2,839	27%	$ 27,001	$ 24,649	$ 2,352	10%

NM=Not Meaningful

HEPLISAV-B revenue, net for the three and nine months ended September 30, 2020 increased, as compared to the same periods in 2019, due to an increase in sales volume. For the nine months ended September 30, 2020, the increase in HEPLISAV-B product revenue, net in the first and third quarters was offset by lower sales volume in the second quarter due to lower adult vaccine utilization caused by the COVID-19 global pandemic. Utilization of adult vaccines improved during the third quarter as health care providers gradually expanded their services under strict social distancing rules and distributors replenished inventory. Sales during the third quarter also include an initial stocking order from a large retail chain and the effect of seasonal Department of Defense purchases.

In the third quarter of 2020, we began selling our novel adjuvant, CpG 1018, to our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines.

Other revenue includes collaboration revenue related to services performed under a collaboration agreement with Serum Institute of India Pvt. Ltd.

Cost of Sales – Product

The following is a summary of our cost of sales - product (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
	2020	**2019**	**$**	**%**	**2020**	**2019**	**$**	**%**
Cost of sales - product	$ 4,031	$ 3,824	$ 207	5%	$ 7,352	$ 7,765	$ (413)	(5)%

Cost of sales - product consists primarily of raw materials, certain fill, finish and overhead costs and any inventory adjustment charges for pre-filled syringes (“PFS”) of HEPLISAV-B. Our HEPLISAV-B PFS finished goods inventory previously included

components for which a portion of the manufacturing costs were expensed to research and development prior to the approval of the PFS presentation by the FDA in March 2018. Substantially all the inventory that was previously expensed to research and development had been sold to customers. For the three months ended September 30, 2020, cost of sales-product included $0.8 million of costs to produce CpG 1018 for our collaboration partners.

We expect our cost of sales - product for HEPLISAV-B, as a percentage of product sales, net, to stabilize for the foreseeable future, excluding potential unknown one-time charges. We expect our cost of sales-product for CpG 1018 to increase substantially in 2021 due to increased production of CpG 1018 for Valneva.

For the three months ended September 30, 2020, cost of sales-product increased, as compared to the same period in 2019, primarily due to higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing offset by a charge in the third quarter of 2019 related to a terminated batch.

For the nine months ended September 30, 2020, cost of sales-product decreased, as compared to the same period in 2019, primarily due to higher overhead costs in the first nine months of 2019 and a charge in the third quarter of 2019 for costs related to a terminated batch offset by higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing.

Cost of Sales - Amortization of Intangible Assets

The following is a summary of our cost of sales – amortization of intangible assets (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
	2020	2019	$	%	2020	2019	$	%
Cost of sales - amortization of intangible assets	$ -	$ 2,324	$ (2,324)	NM	$ 2,500	$ 6,894	$ (4,394)	(64)%

NM=Not Meaningful

Cost of sales - amortization of intangible assets consists of amortization of the intangible asset recorded as a result of sublicense payments to Merck, Sharpe & Dohme Corp. (“Merck”), upon or after FDA approval of HEPLISAV-B in November 2017. The intangible asset has been fully amortized as of April 2020 as the sublicense agreement expired.

Research and Development Expense

Research and development expense consists, primarily, of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services consist of costs associated with clinical development, process development, preclinical discovery and development, regulatory filings and research, including fees and expenses incurred by contract research organizations, clinical study sites, and other service providers.

The following is a summary of our research and development expense (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
Research and Development:	2020	2019	$	%	2020	2019	$	%
Compensation and related personnel costs	$ 2,189	$ 4,026	$ (1,837)	(46)%	$ 6,412	$ 17,980	$ (11,568)	(64)%
Outside services	5,381	5,123	258	5%	12,258	20,019	(7,761)	(39)%
Facility costs	173	1,850	(1,677)	(91)%	409	6,246	(5,837)	(93)%
Non-cash stock-based compensation	778	1,661	(883)	(53)%	(21)	5,817	(5,838)	(100)%
Total research and development	$ 8,521	$ 12,660	$ (4,139)	(33)%	$ 19,058	$ 50,062	$ (31,004)	(62)%

For the three and nine months ended September 30, 2020, compensation and related personnel costs and non-cash stock-based compensation decreased, as compared to the same periods in 2019, due to lower research and development headcount as a result of our restructuring in May 2019. In addition, non-cash stock-based compensation for the nine months ended September 30, 2020 included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020.

For the nine months ended September 30, 2020, the decrease in outside services, as compared to the same period in 2019, was primarily the result of winding down of our immuno-oncology programs. Outside services for the three months ended September 30, 2020 included CpG 1018 development costs at our third-party manufacturing facility to support increased CpG 1018 demand from our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine.

Facility costs, which primarily comprise of occupancy and related expenses, decreased, as compared to the same periods in 2019, due to lower overhead allocation to research and development functions. In addition, facility costs for the three and nine months ended September 30, 2019 included accelerated depreciation in connection with the restructuring in May 2019.

Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of compensation and related costs for our commercial support personnel, medical education professionals and personnel in executive and other administrative functions, including legal, finance and information technology; costs for outside services such as sales and marketing, post-marketing studies of HEPLISAV-B, accounting, commercial development, consulting, business development, investor relations and insurance; legal costs that include corporate and patent-related expenses; allocated facility costs and non-cash stock-based compensation.

The following is a summary of our selling, general and administrative expenses (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
Selling, General and Administrative:	**2020**	**2019**	**$**	**%**	**2020**	**2019**	**$**	**%**
Compensation and related personnel costs	$ 7,817	$ 7,717	$ 100	1%	$ 23,539	$ 21,184	$ 2,355	11%
Outside services	7,700	5,817	1,883	32%	19,909	18,949	960	5%
Legal costs	722	521	201	39%	2,038	1,724	314	18%
Facility costs	2,795	2,126	669	31%	8,495	4,983	3,512	70%
Non-cash stock-based compensation	2,504	2,278	226	10%	7,437	7,828	(391)	(5)%
Total selling, general and administrative	$ 21,538	$ 18,459	$ 3,079	17%	$ 61,418	$ 54,668	$ 6,750	12%

For the nine months ended September 30, 2020, the increase in compensation and related personnel costs, as compared to the same period in 2019, was due to higher headcount resulting from the conversion of the external sales force to our employees effective April 1, 2019, offset by decrease in business travel due to COVID-19 travel restrictions.

Outside services for the three and nine months ended September 30, 2020 increased, as compared to the same periods in 2019 primarily due to the $2.5 million payment to Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”) in connection with the sale of our immuno-oncology compound, SD-101. The payment was required under our agreement with Holdings entered into in November 2009. In addition, for the nine months ended September 30, 2020, the increase in outside services was offset by the decrease in costs resulting from the conversion of the external sales force to our employees effective April 1, 2019 and an increase in costs related to the HEPLISAV-B post-marketing study.

For the three and nine months ended September 30, 2020, facility costs, which primarily comprise of occupancy and related expenses, increased, as compared to the same periods in 2019, due to higher overhead allocation to selling, general and administrative functions.

Non-cash stock-based compensation for the nine months ended September 30, 2020 decreased, as compared to the same period in 2019, due to the retirement of our former CEO in August 2019 and included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020.

Gain on Sale of Assets

In July 2020, we sold assets related to our immuno-oncology compound, SD-101, which included intellectual property, clinical and non-clinical data, regulatory filings, clinical supply inventory and certain contracts to TriSalus. Pursuant to the Asset Purchase Agreement, we received $5 million upon closing of the transaction. TriSalus also agreed to pay us $4 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of product containing SD-101 compound.

In the third quarter of 2020, we recognized a gain on sale of SD-101 assets of $6.9 million, net of transaction costs.

Restructuring

On May 23, 2019, we implemented a strategic organizational restructuring, principally to align our operations around our vaccine business and significantly curtail further investment in our immuno-oncology business. In connection with the restructuring, we reduced our workforce by approximately 80 positions, or approximately 36%, of U.S.-based personnel. Also, in connection with the restructuring, our Chief Executive Officer, also a member of the Board of Directors (the "Board"), retired from the Company and the Board, effective August 1, 2019.

During the three and nine months ended September 30, 2019, we recognized restructuring charges of $3.9 million and $12.7 million, respectively. As of December 31, 2019, we have completed our restructuring activities and all costs have been incurred.

Other Income (Expense)

Interest income is reported net of amortization of premiums and discounts on marketable securities and includes realized gains on investments. Interest expense includes the stated interest and accretion of discount and end of term fee related to our long-term debt agreement. Sublease income is recognized in connection with our sublease of office and laboratory space. Change in fair value of warrant liability reflects the changes in fair value of warrants issued in connection with equity financing in August 2019. Other includes gains and losses on foreign currency transactions and disposal of property and equipment.

The following is a summary of our other income (expense) (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2019 to 2020		Nine Months Ended September 30,		Increase (Decrease) from 2019 to 2020	
	2020	2019	$	%	2020	2019	$	%
Interest income	$ 269	$ 890	$ (621)	(70)%	$ 1,190	$ 2,604	$ (1,414)	(54)%
Interest expense	$ (4,794)	$ (4,779)	$ 15	0%	$ (14,257)	$ (12,111)	$ 2,146	18%
Sublease income	$ 1,926	$ 891	$ 1,035	116%	$ 5,779	$ 891	$ 4,888	549%
Change in fair value of warrant liability	$ 21,245	$ -	$ 21,245	NM	$ 4,200	$ -	$ 4,200	NM
Other	$ (420)	$ 168	$ (588)	(350)%	$ (209)	$ 226	$ (435)	(192)%

NM=Not Meaningful

Interest income for the three and nine months ended September 30, 2020 decreased, as compared to the same periods in 2019, primarily due to lower yields on our marketable securities portfolio. Interest expense for the nine months ended September 30, 2020 increased, as compared to the same period in 2019, due to the borrowing of the remaining $75.0 million in March 2019 under the term loan agreement with CRG Servicing LLC ("Loan Agreement"). For the three and nine months ended September 30, 2020, we recognized sublease income of $1.9 million and $5.8 million, respectively, in connection with our sublease of office and laboratory space located at 5959 Horton Street, Emeryville, California to a third party in July 2019. The change in the fair value of the warrant liability is primarily due to a decrease in our stock price. The change in other is primarily due to foreign currency transactions and related fluctuations in the value of the Euro compared to the U.S. dollar.

Liquidity and Capital Resources

As of September 30, 2020, we had $177.2 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, borrowings, government grants and revenues from product sales and collaboration agreements to fund our operations. Our funds are currently invested in money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We currently anticipate that our cash, cash equivalents and short-term marketable securities as of September 30, 2020, and anticipated revenues from HEPLISAV-B and CpG 1018 will be sufficient to fund our operations for at least the next 12 months from the date of this filing.

In February 2018, we entered into a term loan agreement with CRG Servicing LLC. At September 30, 2020, the principal amount of the term loan was $180.9 million, excluding debt discount of $1.2 million. The loan and the related unpaid interest and fees are due in December 2023.

In May 2020, we completed an underwritten public offering of 16,100,000 shares of our common stock at a public offering price of $5.00 per share. The net proceeds from this offering were approximately $75.4 million, after deducting the underwriting discount and other estimated offering expenses.

For the nine months ended September 30, 2020, we sold 8,005,467 shares of our common stock and received net cash proceeds of $32.3 million pursuant to a 2017 At Market Sales Agreement with Cowen and Company, LLC ("2017 ATM Agreement") that terminated in August 2020.

On August 6, 2020, we entered into an at-the-market Sales Agreement (the "2020 ATM Agreement") with Cowen and Company, LLC ("Cowen"), under which we may offer and sell from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150 million through Cowen as our sales agent. For the nine months ended September 30, 2020, we received net cash proceeds of $0.8 million resulting from sales of 109,176 shares of our common stock pursuant to the 2020 ATM Agreement. As of September 30, 2020, we had $149.1 million remaining under the 2020 ATM Agreement.

During the nine months ended September 30, 2020, we used $76.5 million of cash for our operations primarily due to our net loss of $59.8 million, of which $8.7 million consisted of non-cash items which included change in fair value of warrant liability, gain on sale of assets, stock-based compensation, depreciation and amortization, amortization of intangible assets, non-cash interest expense, amortization of right-of-use assets and accretion and amortization on marketable securities. By comparison, during the nine months ended September 30, 2019, we used $98.2 million of cash for our operations primarily due to our net loss of $115.8 million, of which $40.2 million consisted of non-cash charges such as stock-based compensation, amortization of intangible assets, amortization of right-of-use assets, depreciation and amortization, non-cash interest expense and accretion and amortization on marketable securities. Cash used in our operations during the first nine months of 2020 decreased by $21.7 million. For the nine months ended September 30, 2020, we received tenant improvement reimbursements from the landlord of 5959 Horton Street totaling $0.9 million and invested approximately $17.7 million in HEPLISAV-B inventory. Net cash used in operating activities is also impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the nine months ended September 30, 2020 and 2019, net cash used in investing activities was $40.9 million and $67.6 million, respectively. Cash used in investing activities during the first nine months of 2020 included $33.4 million of net purchases of marketable securities compared to $40.1 million of net purchases of marketable securities during the first nine months of 2019. During each of the first nine months of 2020 and 2019, we paid $7.0 million of sublicense payment to Merck. Cash used in net purchases of property plant and equipment decreased by $17.3 million during the first nine months of 2020 compared to the same period in 2019. The decrease was, primarily, due to the installation of facility improvements in the first nine months of 2019. In addition, for the nine months ended September 30, 2020, we received $2.9 million from sale of SD-101 assets, net of transaction costs.

During the nine months ended September 30, 2020 and 2019, net cash provided by financing activities was $109.4 million and $154.4 million, respectively. Cash provided by financing activities for the first nine months of 2020 included net proceeds of $75.4 million from our underwritten public offering in May 2020, $32.3 million from our, now terminated, 2017 ATM Agreement and $0.8 million from our 2020 ATM Agreement. Cash provided by financing activities in the first nine months of 2019 included net proceeds of $74.3 million from the second tranche of the Loan Agreement, net proceeds of $13.9 million from the issuance of common stock under our 2017 ATM Agreement and net proceeds of $65.6 million from our underwritten public offering in August 2019.

We expect to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B and CpG 1018. If we cannot generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to significantly reduce our operations while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

Contractual Obligations

As of September 30, 2020, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 adjuvant and for clinical research, totaled $28.1 million.

There were no other material changes to the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by rules enacted by the Securities and Exchange Commission, and accordingly, no such arrangements are likely to have a current or future effect on our financial position.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2020, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2019.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”)) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance of achieving the desired control objectives.

Based on their evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report, our management, with participation of our Chief Executive Officer and our Chief Financial Officer, concluded that our disclosure controls and procedures are effective and were operating at the reasonable assurance level to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

(b) Changes in internal controls

There have been no changes in our internal controls over financial reporting as defined in Rule 13a – 15(f) under the Exchange Act during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations. We are not currently aware of any material legal proceedings involving the Company.

ITEM 1A. RISK FACTORS

Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future efforts to obtain regulatory approval, achieve restructuring goals, commercialize approved products, or expectations about our anticipated expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including those in the risk factors that follow. We have marked with an asterisk (*) those risks described below that reflect material changes from, or additions to, the risks described under Part 1, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2019 that was filed with the Securities and Exchange Commission on March 11, 2020.

Risks Related to our Business and Capital Requirements

HEPLISAV-B has been launched in the United States and there is significant competition in the marketplace. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.*

We have established sales, marketing and distribution capabilities and commercialized HEPLISAV-B in the U.S. Successful commercialization of HEPLISAV-B will require significant resources and time and, while Dynavax personnel are experienced with respect to marketing of healthcare products, because HEPLISAV-B is the company's first marketed product, the potential uptake of the product in distribution and the timing for growth in sales, if any, is unpredictable and we may not be successful in commercializing HEPLISAV-B. In particular, successful commercialization of HEPLISAV-B will require that we continue to negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and that we maintain those contractual relationships. There is a risk that we may not complete or maintain all of these important contracts on favorable terms or that in a potentially evolving reimbursement environment our efforts can overcome established competition at favorable pricing.

We converted our contracted field sales team into full-time Dynavax employees in the second quarter of 2019. We have not previously employed an in-house field sales team, and thus have limited experience in overseeing and managing an employed salesforce. In addition, retention of capable sales personnel may be more difficult with a single product offering and we must retain our salesforce in order for HEPLISAV-B to establish a commercial presence.

Moreover, we expect that significant resources will need to be invested in order to successfully market, sell and distribute HEPLISAV-B for use with diabetes patients, one of our targeted patient populations. Although the Centers for Disease Control and Prevention ("CDC") and the CDC's Advisory Committee on Immunization Practices ("ACIP") recommend that patients with diabetes receive hepatitis B vaccinations, we are unable to predict how many of those patients may receive HEPLISAV-B.

In addition to the risks with employing and maintaining our own commercial capabilities and with contracting, other factors that may inhibit our efforts to successfully commercialize HEPLISAV-B include:

- whether we are able to recruit and retain adequate numbers of effective sales and marketing personnel;
- whether we are able to access key health care providers to discuss HEPLISAV-B;
- whether we can compete successfully as a new entrant in established distribution channels for vaccine products; and
- whether we will maintain sufficient funding to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure.

If we are not successful, we may be required to collaborate or partner HEPLISAV-B with a third-party pharmaceutical or biotechnology company with existing products. To the extent we collaborate or partner, the financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish HEPLISAV-B in the market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

We are continuing to closely monitor the impact of the COVID-19 global pandemic on our business and are taking proactive efforts to protect the health and safety of our workforce, patients and healthcare professionals, and to continue our business operations and advance our goal of bringing important new vaccines to patients as rapidly as possible. We have implemented measures to protect the health and safety of our workforce, including a mandatory work-from-home policy for employees who can perform their jobs offsite. In the conduct of our business activities, we are also taking actions to protect the safety of patients and healthcare professionals. Our field-based personnel have paused in-person customer interactions in healthcare settings and are solely using electronic communication, such as emails, phone calls and video conferences. Many health care and contracting professionals at hospitals and other medical institutions with whom our field-based personnel interact are working a greater proportion of their working schedule from home and are facing additional demands on their time during the COVID-19 pandemic. We expect that the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, may reduce the effectiveness of our sales personnel, our customers' procurement activities, as well as those of our collaborators, which could negatively affect our product sales.

In addition, due to the ongoing COVID-19 global pandemic, most medical centers have restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in mid-March. As states began phasing out restrictions in late May/early June, medical centers have been operating under limited capacity and strict social distancing rules. This has resulted in significantly reduced utilization of adult vaccines since the end of the first quarter of 2020, including HEPLISAV-B. This reduced utilization has significantly impacted sales and is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions.

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or in building and maintaining the infrastructure to support commercial operations, we will have difficulty successfully commercializing HEPLISAV-B, which would adversely affect our business and financial condition.

Our business and operations have been and may continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic.*

Our business has been and may continue to be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization ("WHO") as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease. In response to these public health directives and orders, we have implemented work-from-home policies for all employees, except those that need to be at work in order to perform critical responsibilities.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended. In accordance with guidance issued by the Centers for Disease Control and Prevention, WHO and local authorities, beginning in March 2020, most of our global workforce transitioned to working remotely. The principal purchasers of HEPLISAV-B, including independent hospitals and clinics, integrated delivery networks, public health clinics and prisons, the Departments of Defense and Veterans Affairs and retail pharmacies, have all drastically curtailed their day-to-day activities and ceased or significantly reduced allowing access to their facilities for non-COVID-19 related business. Thus, our field sales and medical science employees increased their use of telephone and web-based means to seek to carry out their roles where necessary, which may not be as effective as being in-person.

This has resulted in significantly reduced utilization of adult vaccines since the end of the first quarter of 2020, including HEPLISAV-B, which in turn has significantly and adversely impacted our sales of HEPLISAV-B and our business and operating results since mid-March. This reduced utilization is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions.

We also cannot predict to what extent the COVID-19 pandemic may continue to disrupt demand for HEPLISAV-B, but the overall magnitude of the disruption to our business will depend, in part, on the length and ongoing severity of the restrictions, and other limitations on our ability to conduct our business in the ordinary course, and prolonged disruptions would likely materially and negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders related to COVID-19 have had no material impact on the supply of HEPLISAV-B and we have no current expectation that they will. However, if they continue for a substantial period of time, they could impact personnel at our manufacturing facility in Germany and third-party manufacturing facilities in the United States. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B sufficient to meet demand.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business, our future sales of HEPLISAV-B and revenue will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, social distancing requirements and business closures in the United States, business disruptions and the effectiveness of actions taken in the United States to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, operations or the global economy as a whole. However, these impacts could continue to adversely impact affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this ‘‘Risk Factors’’ section.

We have entered into collaborative relationships to develop vaccines utilizing CpG 1018, including collaborations to develop a vaccine for COVID-19. These collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 are inadequate; we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.*

As part of our business, we are working to develop our novel adjuvant, CpG 1018, as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. There are risks and uncertainties inherent in vaccine research and development, including the timing of completing development, the results of clinical trials, whether the vaccine will be approved for use, the extent of competition, and whether a vaccine can be successfully commercialized. As a result, these collaborative efforts may not be successful.

In addition, our collaborators have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval of potential vaccines, including any potential vaccine for COVID-19 containing CpG 1018. We have limited or no control over our collaborators’ decisions, including the amount and timing of resources that any of these collaborators will dedicate to such activities. If a collaborative partner fails to conduct collaborative activities successfully, the development of a vaccine will be delayed, and may not occur at all. We also rely on a single supplier to produce CpG 1018. If we were unable to maintain our existing supplier for CpG 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing any potential adjuvanted vaccines by our third-party collaborators. We or other third parties may not be able to produce CpG 1018 at a cost, quantity and quality similar to that available from our current third-party supplier, or at all.

CpG 1018 has no composition of matter patent protection. We have filed patent applications claiming compositions and methods of use of CpG 1018 for COVID-19 and other vaccines. In addition, we rely on trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to CpG 1018. If we are unable to adequately obtain or enforce our proprietary rights relating to CpG 1018, we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), including those over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third-party payors, which may make it difficult or impossible to sell our product or product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price, as well as the availability of coverage and adequate reimbursement, from third-party payors, in particular for HEPLISAV-B, where existing products are already marketed. In the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, and we have achieved coverage with most third-party payors. However, there is a risk that some payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include HEPLISAV-B. Thus, there can be no assurance that HEPLISAV-B will achieve and sustain stable pricing and favorable reimbursement. Our ability to successfully obtain and retain market share and achieve and sustain profitability will be significantly dependent on the market’s acceptance of a price for HEPLSIAV-B sufficient to achieve profitability, and future acceptance of such pricing.

Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing, as well as coverage and reimbursement decisions may not allow our future products to compete effectively with existing competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third-party payors to reimburse for our products is uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability, and such unavailability could harm our future prospects and reduce our stock price.

Also, there has been heightened governmental scrutiny recently in the U.S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In some cases, such legislation and regulations have been designed to encourage importation from other countries and bulk purchasing. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business.

We have applied for, and in some cases have received, grants to help fund the scale-up of CpG 1018 production, and such grants, if and when received, may involve pricing or other restrictions.*

In order to help fund potential scale-up of production of CpG 1018 that may be required in the event that CpG 1018 is included in any approved and commercially-available novel vaccine, whether a COVID-19 vaccine or otherwise, we have applied for, and in some cases have received grants from various charitable and philanthropic organizations, including from Bill and Melinda Gates Foundation. These grants, if and when received, may come with certain pricing requirements, global access requirements or reporting or other covenants to ensure that any funded product is made available by us worldwide on a nondiscriminatory basis. Such covenants may limit the price we can charge for any funded product and may involve a license to use technology we own in the funded products if we do not comply. Such price limitations or licenses, if invoked, could serve to limit the prices we charge, or in some cases, our control over the manufacturing and distribution of grant-funded products. Failure to agree with such requirements, may result in the company not receiving some or all of the grant.

We implemented a strategic restructuring to prioritize our vaccine business and explore strategic alternatives for our immuno-oncology portfolio, and we cannot assure you that we will be able to successfully execute on a strategic alternative for our immuno-oncology portfolio.

In the second quarter of 2019, we implemented a strategic restructuring that would focus our efforts on HEPLISAV-B, which included a reduction in our workforce and operations to focus resources on HEPLISAV-B commercialization and sales execution as well as assess additional opportunities to leverage our CpG 1018 adjuvant. We recently announced the sale of assets related to our SD-101 program. Additionally, we are seeking strategic alternatives for other aspects of our immuno-oncology portfolio, including our development stage product DV281. In connection with the restructuring, we made the determination to wind down ongoing immuno-oncology trials. Our ability to successfully execute on a strategic alternative for our immuno-oncology portfolio is dependent on a number of factors and we may not be able to execute upon a transaction or other strategic alternative for our immuno-oncology portfolio upon favorable terms within an advantageous timeframe and recognize significant value for these assets, if at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative involving our immuno-oncology may be costly and time-consuming. Our strategic restructuring may not result in anticipated savings or other economic benefits, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

We are subject to ongoing FDA post-marketing obligations concerning HEPLISAV-B, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with HEPLISAV-B.

Our HEPLISAV-B regulatory approval in the United States is subject to certain post-marketing obligations and commitments to the FDA. For example, we must conduct an observational comparative study of HEPLISAV-B to Energix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018 and is scheduled to continue through November 2020. We must also conduct an observational surveillance study to evaluate the incidence of new onset immune-mediated diseases, herpes zoster and anaphylaxis; and we are required to establish a pregnancy registry to provide information on outcomes following pregnancy exposure to HEPLISAV-B. These studies will require significant effort and resources, and failure to timely conduct these studies or

complete these studies to the satisfaction of FDA could result in withdrawal of our BLA approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. The results of post-marketing studies may also result in additional warnings or precautions for the HEPLISAV-B label or expose additional safety concerns that may result in product liability and withdrawal of the product from the market, any of which would have a material adverse effect on our business, results of operations, financial condition and prospects.

In December 2019, we filed with the FDA a cumulative report on both interim analyses of the ongoing observational comparative AMI study. The interim analyses were based on currently-available data, and the final results, related findings and conclusions of the study will not be known until its completion and the receipt and review of the complete study data. Interim results may not be reproduced in the future, and thus should be considered carefully and not relied upon as indicative of future study results. Material adverse differences in final data, compared to interim data, could significantly adversely affect our business and business prospects, including our future HEPLISAV-B business. Certain assumptions, estimations, calculations and conclusions may have been made in connection with the interim analyses of the study data, and others, including regulatory agencies, may not accept or agree with these assumptions, estimations, calculations or conclusions, or may interpret or weigh the importance of data differently, which could impact the actual or perceived value of the study, HEPLISAV-B or the Company in general.

In addition, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for HEPLISAV-B are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, GCPs, ICH guidelines, and GLPs. If we are not able to meet and maintain regulatory compliance, we may lose marketing approval and be required to withdraw our product. Withdrawal of our product would have a material adverse effect on our business.

If HEPLISAV-B or any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of HEPLISAV-B or any other products we develop, or limits our marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates, such as the FDA approval of HEPLISAV-B in November 2017, and are able to commercialize them as we have with HEPLISAV-B, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of HEPLISAV-B and any of our future approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of sufficient reimbursement by third-party payors.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors as a result of these disadvantages, we may be unable to generate sufficient or any revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing vaccines and adjuvants. For example, HEPLISAV-B competes in the U.S. with established hepatitis B vaccines marketed by Merck and GlaxoSmithKline plc (“GSK”) and if approved outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies. There are also modified schedules of conventional hepatitis B vaccines for limited age ranges that are approved in the European Union and U.S. In addition, HEPLISAV-B competes against Twinrix, a bivalent vaccine marketed by GSK for protection against hepatitis B and hepatitis A. A three dose HBV vaccine is reported to be under development by VBI Vaccines Inc (“VBI”).

We are in competition with many companies developing vaccines and vaccine adjuvants, including GSK, Pfizer, Sanofi, Merck, Seqirus, Agenus, Emergent BioSolutions, Novavax, Medicago and VBI.

Existing and potential competitors may also compete with us for qualified commercial, scientific and management personnel, as well as for technology that would otherwise be advantageous to our business. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel in the near-term, particularly with respect to HEPLISAV-B commercialization. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We have generated limited revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net losses for nine months ended September 30, 2020 and 2019 were $59.8 million and $115.8 million, respectively. As of September 30, 2020, we had an accumulated deficit of $1.3 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S., we expect to continue incurring operating losses for the foreseeable future. Our expenses have increased substantially as we established and maintain our HEPLISAV-B commercial infrastructure, including investments in internal infrastructure to support our field sales force and investments in manufacturing and supply chain commitments to maintain commercial supply of HEPLISAV-B. The timing for uptake of our product in the U.S. has further increased losses related to commercialization, and the advancement of our oncology pipeline has historically increased our costs as we conducted more and larger studies to invest in clinical development. While we anticipate operating expenditures related to external oncology costs will decrease as a result of our strategic restructuring, due to the numerous risks and uncertainties associated with developing and commercializing vaccine and pharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations.

As of September 30, 2020, we had $177.2 million in cash, cash equivalents and marketable securities. We expect to incur operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B. If we cannot generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of development and business risks and uncertainties, our creditworthiness and the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. In addition, our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to significantly reduce our operations while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates we may develop outside the U.S., requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may seek to introduce HEPLISAV-B, or any other product candidates we may develop, in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial costs as well as burdens on our personnel resources in addition to potential diversion of management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities upon favorable terms;

- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

In the event that we determine to pursue commercialization of HEPLISAV-B outside the United States, such as in Europe, our opportunity will depend upon our receiving regulatory approval, which can be costly and time consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and/or take other measures which will take time and require that we incur significant additional expense. In addition, there is the risk that we may not receive approval in one or more jurisdictions. In March, 2019, we submitted, and the European Medical Agency ("EMA") accepted, our Marketing Authorization Application ("MAA") for HEPLISAV-B. We may not be able to provide sufficient data or respond to comments to our MAA sufficient to obtain regulatory approval in Europe in a reasonable time period or at all.

The results of clinical trials conducted to support regulatory approval in one or more jurisdictions, and any failure or delay in obtaining regulatory approval in one or more jurisdictions, may have a negative effect on the regulatory approval process in other jurisdictions, including our regulatory approval in the United States. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

Clinical trials for our commercial product and product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA requirements are expensive and time consuming, may take more time to complete than expected or may not be completed, and may not have favorable outcomes. In addition, results from smaller, earlier stage clinical studies may not be representative of larger, controlled clinical trials that would be required in order to obtain regulatory approval of a product candidate.

Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain Institutional Review Board ("IRB") or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

As a biopharmaceutical company, we engage clinical research organizations ("CROs") to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with Good Clinical Practice ("GCP") standards and other applicable regulatory requirements could result in disqualification of the applicable clinical trial from consideration in support of approval of a potential product.

We are responsible for conducting our clinical trials consistent with GCP standards and for oversight of our vendors to ensure that they comply with such standards. We depend on medical institutions and CROs to conduct our clinical trials in compliance with GCP. To the extent that we or they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of participants.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The

authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including with respect to our product candidates and those of our partners in combination agent studies:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether a product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- a product candidate or combination study may appear to be no more effective than current therapies;
- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- the inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger patient populations, which often occur in later-stage clinical trials, or less favorable clinical outcomes. Moreover, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals.

Third-party organizations such as patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to our drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management’s time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by a Data Safety Monitoring Board (“DSMB”), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

The European Medicines Agency ("EMA") and other Regulatory Authorities may require more clinical trials for our product candidates than we currently expect or are conducting before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates and may impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;
- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

HEPLISAV-B and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue our operations, or reevaluate the viability of strategic alternatives.

Most of our programs, including HEPLISAV-B, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy, or significantly reevaluate strategic alternatives. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture HEPLISAV-B and our product candidates. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. With respect to HEPLISAV-B, we have switched to a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture sufficient supply in this presentation.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing HEPLISAV-B surface antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. The FDA approved our pre-filled presentation of HEPLISAV-B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV-B going forward. We have limited experience in manufacturing and supplying this presentation, and there can be no assurance that we can successfully manufacture sufficient quantities of pre-filled syringes in compliance with GMP in order to meet market demand.

We have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our CpG 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing supplier for CpG 1018, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in manufacturing HEPLISAV-B and developing and commercializing our product candidates. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

In countries outside of the U.S., we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit or disrupt the commercialization of HEPLISAV-B or our other product candidates and could result in significant expense.

As we continue to grow as a commercial organization and enter into supply agreements with customers, those supply agreements will have obligations to deliver product that we are reliant upon third parties to manufacture on our behalf. ***

As our commercial business begins to expand in connection with commercial sales of HEPLISAV-B and CpG 1018, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain

quantities and meeting certain quality thresholds, among other things, all within specified timeframes. If for any reason, whether due to reliance on third-party manufacturers or otherwise, we are unable to deliver timely, compliant products to our customers in quantities that meet our contractual obligation, we could be subject to lost revenue, contractual penalties, suits for damages, harm to our reputation or other problems that could materially and adversely affect our business.

HEPLISAV-B is subject to FDA obligations and continued regulatory review, and if we receive regulatory approval for our other product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review for such products.

With respect to HEPLISAV-B and our other product candidates in development, we and our third-party manufacturers and suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third-party manufacturers and suppliers and any manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of the FDA's inspections, it determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

Further, in March, 2019, we submitted, and the EMA accepted, our MAA for HEPLISAV-B. We may not be able to provide sufficient data or respond to comments to our MAA sufficient to obtain regulatory approval in Europe in a reasonable time period or at all. Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after approval and commercialization.

A key part of our business strategy for products in development is to establish collaborative relationships to help fund development and commercialization of our product candidates and research programs. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to continue to develop and commercialize those products and programs, if at all.

We may need to establish collaborative relationships to obtain domestic and/or international sales, marketing, research, development and distribution capabilities for our product candidates and our discovery research programs. Failure to obtain a collaborative relationship for those product candidates and programs or HEPLISAV-B in markets outside the U.S. requiring extensive sales efforts, may significantly impair the potential for those products and programs and we may be required to raise additional capital to continue them. The process of establishing and maintaining collaborative relationships is difficult and time-consuming, and even if we establish such relationships, they may involve significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;

- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs, and the financial terms upon which collaborators may be willing to enter into such an arrangement cannot be certain.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. Despite our efforts, we may be unable to secure collaborative arrangements. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

The term loan agreement we entered into in February 2018 imposes significant operating and financial restrictions on us that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

In February 2018, we entered into a term loan agreement under which we have borrowed $180.9 million, which includes paid-in-kind interest. The agreement contains covenants that restrict our ability to take various actions, including, among other things, incur additional indebtedness, pay dividends or distributions or make certain investments, create or incur certain liens, transfer, sell, lease or dispose of assets, enter into transactions with affiliates, consummate a merger or sell or other dispose of assets. The agreement also requires us to comply with a daily minimum liquidity covenant and an annual revenue requirement based on the sales of HEPLISAV-B, which are (i) $30 million for the period July 1, 2019 through June 30, 2020, (ii) $50 million for the period July 1, 2020 through June 30, 2021, (iii) $75 million for the period July 1, 2021 through June 30, 2022 and (iv) $100 million for the period July 1, 2022 through June 30, 2023. In November 2020, we entered into an amendment to the term loan agreement that, among other things, (i) changes the annual revenue requirement to include all revenue, including CpG 1018 net sales, rather than net sales of HEPLISAV-B only, and (ii) deletes the $50 million revenue requirement for the period from July 1, 2020 through June 30, 2021 in its entirety. The agreement specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our obligations could result in an event of default and the acceleration of our repayment obligation at a time when we may not have the cash to comply with that obligation, which could result in a seizure of most of our assets. The restrictions contained in the agreement could also limit our ability to meet capital needs or otherwise restrict our activities and adversely affect our ability to finance our operations, enter into acquisitions or to engage in other business activities that would be in our interest.

We rely on CROs and Clinical Sites and Investigators for our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on CROs, Clinical Sites and Investigators for our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our

third-party contractors to ensure that clinical trials are conducted properly and that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

As we focus on commercialization of HEPLISAV-B, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.

As our commercial operations expand, we expect that we will also need to manage additional relationships with various third parties, including sole source suppliers, distributors, wholesalers and hospital customers. Future growth, including managing an in-house field sales team, will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to successfully commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our growth efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

As we plan for broader commercialization of HEPLISAV-B and for expanded capacity to manufacture CpG 1018, our financial commitments to increase supply capacity might outpace actual demand for our products.*

As we plan to scale up production capabilities for HEPLISAV-B as well as production capabilities for our advanced adjuvant, CpG 1018, to support potential vaccine collaborations and response to COVID-19 and other initiatives, we have been, and in the future will be, required to make significant financial commitments to reserve manufacturing capacity at our CMOs. Under ordinary circumstances we would make these commitments close in time and with some level of certainty that we have customers making similar commitments to us. Because of long lead times on manufacturing, uncertainty about who will ultimately buy CpG 1018 from us and in what quantities, if any, as well as the need to book manufacturing capacity in advance, the financial commitments we make to our CMOs to support manufacturing may not be recovered in its entirety, or at all, if our collaborators do not ultimately purchase from us. Capacity reservation fees are generally not recoverable if we do not use the capacity we have reserved as a result of lower than expected demand, or otherwise. As a result, we could end up making financial commitments that we never recover if demand for CpG 1018 does not materialize in the volumes we are expecting, or at all.

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud and abuse, anticorruption, privacy, transparency and other laws of the jurisdictions in which we conduct our business, we may be subject to significant liability.

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. Our interactions with physicians and others in a position to prescribe or purchase our products are subject to a legal regime designed to prevent healthcare fraud and abuse and off-label promotion. We also are subject to laws pertaining to transparency of transfers of value to healthcare providers; privacy and data protection; compliance with industry voluntary compliance guidelines; and prohibiting the payment of bribes. Relevant U.S. laws include:

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- federal false claims laws, including the civil False Claims Act, and civil monetary penalty law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education and Reconciliation Act of 2010 (collectively, “ACA”) which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created, among other things, new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the Foreign Corrupt Practices Act, which prohibits the payment of bribes to foreign government officials and requires that a company's books and records accurately reflect the company's transactions; and
- foreign and state law equivalents of each of the federal laws described above, such as anti-kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information on the pricing of certain drugs; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the federal civil False Claims Act provides the potential for private parties (qui tam relators, or "whistleblowers") to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

In the U.S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information.

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to significant criminal, civil and administrative penalties, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may cause us to incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U.S. or foreign laws.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. For example, the ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. There remain legal and political challenges to certain aspects of ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January l, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and on our business.

Other legislative changes have also been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.

In the future, there will likely continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

In addition, our data security and information technology systems, as well as those of our partners and contractors, are potentially vulnerable to data security breaches, whether by employees or others, that may expose sensitive data or personal information to unauthorized persons. Effective May 25, 2018, the European Union ("EU") implemented the General Data Protection Regulation ("GDPR") a broad data protection framework that expands the scope of current EU data protection law to non-European Union entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data. The GDPR allows for the imposition of fines and/or corrective action on entities that improperly use or disclose the personal information of EU subjects, including through a data security breach.

Also, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 ("CCPA"), which became effective in January 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. It remains unclear how the CCPA will be interpreted, but as currently written, it will likely impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data. As we expand our operations, the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

The loss of key personnel could delay or prevent achieving our objectives. In addition, our continued growth to support commercialization may result in difficulties in managing our growth and expanding our operations successfully.

We depend on our senior executive officers, as well as other key scientific personnel. Our commercial and business efforts could be adversely affected by the loss of one or more key members of our commercial or management staff, including our senior executive officers. We currently have no key person insurance on any of our employees.

As our operations expand, we expect that we will need to manage additional relationships with various vendors, partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to successfully commercialize HEPLISAV-B and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to effectively manage our commercialization efforts, research efforts and clinical trials and hire, train and integrate additional regulatory, manufacturing, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company and achieving profitability.

We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products, including HEPLISAV-B, will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. While we have obtained product liability insurance coverage for HEPLISAV-B, there is a risk that this coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

Our business operations are vulnerable to interruptions by natural disasters, health epidemics and other catastrophic events beyond our control, the occurrence of which could materially harm our manufacturing, distribution, sales, business operations and financial results.

Our business operations are subject to interruption by natural disasters and other catastrophic events beyond our control, including, but not limited to, earthquakes, hurricanes, fires, droughts, tornadoes, electrical blackouts, public health crises and pandemics, war, terrorism, and geo-political unrest and uncertainties. We have not undertaken a systematic analysis of the potential consequences to our business that might result from any such natural disaster or other catastrophic event and have limited recovery plans in place. If any of these events occur, our manufacturing and supply chain, distribution, sales and marketing efforts and other business operations could be subject to business shutdowns or disruptions and financial results could be adversely affected. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions resulting from these events, but if we or any of the third parties with whom we engage, including the suppliers, contract manufacturers, distributors and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely affected in a number of ways, some of which are not predicable.

Our business could be adversely affected by health epidemics in regions where we have manufacturing facilities, sales activities or other business operations. For example, outbreaks of epidemic or pandemic diseases, such as the ongoing COVID-19 pandemic, or the fear of such events, could cause restrictions on supply chains, access to workplaces and affect employee health and availability.

Although we maintain inventories of HEPLISAV-B and its components, our ability and those of our contractors and distributors to produce and distribute HEPLISAV-B could be adversely affected. A pandemic or similar health challenge could severely impact the U.S. healthcare system, which may have an adverse effect on usage and sales of HEPLISAV-B. In addition, any such event could result in widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn that could affect the demand for HEPLISAV-B and future revenue and operating results and our ability to raise additional capital when needed on acceptable terms, if at all.

Additionally, our corporate headquarters in Emeryville, California, is located in a seismically active region that also is subject to possible electrical shutdowns and wildfires. Because we do not carry earthquake insurance for earthquake-related losses and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake or catastrophic event. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us in excess of insured amounts could adversely affect our business and operations.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.*

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support business processes as well as internal and external communications. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal, state and/or international breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, including but not limited to HIPAA, similar state data protection regulations, and the E.U. General Data Protection Regulation, or GDPR (EU) 2016/679, resulting in significant penalties, increased costs or loss of revenue. Recent news reports have also highlighted COVID research-specific hacking and phishing attempts. Because we and our collaborators are working on vaccines, including potential COVID vaccines, we may be at higher-than-average risk for such attempts.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

U.S. and international authorities have been warning businesses of increased cybersecurity threats from actors seeking to exploit the COVID-19 pandemic. We have recently experienced a cybersecurity incident known as a phishing e-mail scam, and although we do not consider its impact on us to be material, if we are unable to prevent this or other such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. Moreover, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory scrutiny. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures that are intended to protect our data security and information technology systems, such measures may not prevent such events.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to our Intellectual Property

We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third-party's patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. From time to time we are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in connection with the commercialization of HEPLISAV-B or any similar product candidate, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third-party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease, and we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.*

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents for a commercially sufficient term or are otherwise effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

For example, CpG 1018 has no composition of matter patent protection in the United States or elsewhere. We must therefore rely primarily on the protection afforded by method of use patents relating to the use of CpG 1018 in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to CpG 1018. We have filed patent applications claiming compositions and methods of use of CpG 1018 for COVID-19 and other vaccines, but we cannot provide any assurances that we will receive an issued patent for any of these patent applications or that, if issued, any of these patents will provide adequate protection for any intended use of CpG 1018 in vaccines. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018, we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018.

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates or our collaborators' vaccines may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection. For example, while many countries such as the United States permit method of use patents relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving and may be unfavorably interpreted to prevent us from successfully prosecuting some or all of our pending patent applications relating to the use of CpG 1018. There are some countries that currently do not allow such method of use patents, or that significantly limit the types of uses that are patentable.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights, we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

Our stock price is subject to volatility, and your investment may suffer a decline in value.*

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future, to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

- impact of COVID-19 on our HEPLISAV-B product revenue;
- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and BLA filing and communications, from the FDA or other regulatory agencies;
- our ability to receive timely regulatory approval for our product candidates;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- the success or failure of clinical trials involving our immuno-oncology product candidates and the product candidates of third-party collaborators in combination studies;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- changes in government regulations, general economic conditions or industry announcements;
- changes in the structure of healthcare payment systems;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- the volume of trading in our common stock.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies, including recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models or prospects of those companies. These broad market fluctuations have adversely affected and may in the future adversely affect the market price of our common stock. In this regard, worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic may negatively affect the market price of our common stock, regardless of our actual operating performance.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action and shareholder derivative litigation has often been brought against a company following a decline in the market price of its securities. We have in the past been, and we may in the future be, the target of such litigation. Securities and shareholder derivative litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 as well as any new rules implemented by the Securities and Exchange Commission and the Nasdaq Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

Under our universal shelf registration statement, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our sales agreement with Cowen, under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million.

The sale or issuance of our securities, including those issuable upon exercise of the outstanding warrants or conversion of the preferred stock, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 5. OTHER INFORMATION

CRG Amendment

In November 2020, we entered into a third amendment to the Loan Agreement (the "Third Amendment"). The Third Amendment modified the annual net sales threshold requirement to include sales of CpG 1018 and it removed the annual net sales threshold requirement for the twelve-month period beginning July 1, 2020 and ending on June 30, 2021.

ITEM 6. EXHIBITS

Exhibit Number	Document	Incorporated by Reference				Filed Herewith
		Exhibit Number	Filing	Filing Date	File No.	
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.5	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.6	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	
3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	May 29, 2020	001-34207	
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	3.1	8-K	August 8, 2019	001-34207	
3.10	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.3	Form of Series B Preferred Stock Certificate	4.3	10-Q	November 7, 2019	001-34207	
4.4	Form of Warrant to Purchase Common Stock	4.1	8-K	August 8, 2019	001-34207	
10.1	Sales Agreement, dated August 6, 2020, between the Company and Cowen and Company, LLC	10.3	10-Q	August 6, 2020	001-34207	
10.2^	Supply Agreement, dated September 11, 2020, by and among the Company, Valneva Scotland Limited and Valneva Austria GmbH					X
10.3+	Amended and Restated Management Continuity and Severance Agreement, dated September 22, 2020, between Michael S. Ostrach and the Company					X
10.4	Amendment No. 3 to Term Loan Agreement and Fee Letter, dated November 2, 2020, by and among Company, CRG Partners III L.P., CRG Partners III-Parallel Fund “A” L.P. and CRG Servicing LLC					X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

\+ Indicates management contract, compensatory plan or arrangement.

^ Portions of this exhibit (indicated by carets) have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.

EX—101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
EX—101.SCH	Inline XBRL Taxonomy Extension Schema Document
EX—101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
EX—101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
EX—101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
EX—101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
EX—104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Emeryville, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

Date: November 5, 2020

By: /s/ RYAN SPENCER
Ryan Spencer
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2020

By: /s/ MICHAEL OSTRACH
Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: November 5, 2020

By: /s/ JUSTIN BURGESS
Justin Burgess
Controller
(Principal Accounting Officer)

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

CONFIDENTIAL

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "**Agreement**"), which shall become effective in accordance with Section 10.1, is entered into by and between **DYNAVAX TECHNOLOGIES CORPORATION**, a Delaware corporation, with a place of business located at 2100 Powell Street, Suite 900, Emeryville, CA 94608, USA ("**Dynavax**"), and **VALNEVA SCOTLAND LIMITED**, a company organized under the laws of Scotland, with its principal place of business at Oakbank Park Rd, Livingston EH53 0TG, United Kingdom ("**Purchaser**"), and **VALNEVA AUSTRIA GMBH**, a company registered in Austria (company number FN 389960 x /HG Wien) whose registered address is at Campus Vienna Biocenter 3, 1030 Vienna, Austria ("**Valneva Austria**"). Dynavax and Purchaser may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

WHEREAS, Dynavax, a biopharmaceutical company, has developed a proprietary toll-like receptor 9 (TLR9) agonist adjuvant known as CpG 1018;

WHEREAS, Purchaser is a specialty vaccine company engaged in the development, manufacture and commercialization of vaccines for the prevention of diseases with major unmet medical needs; and

WHEREAS, Valneva has developed a proprietary vaccine for the prevention of COVID-19, the disease caused by SARS-CoV-2 and Valneva Austria wishes to undertake clinical testing of and commercialize that vaccine initially in the UK under an agreement with the UK Government.

WHEREAS Purchaser wishes to purchase and use Dynavax's proprietary adjuvant for the purposes of commercialisation of Purchaser's vaccine and Dynavax wishes to supply specified quantities of such adjuvant to Purchaser for such use, on the terms and conditions set forth below.

NOW, **THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Affiliate**" means, with respect to any Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party, but for only so long as such control exists. As used in this Section 0, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such

lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

1.2 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et. seq.), as amended (the "**FCPA**"), the Organization for Economic Co-operation and Development (OECD) Convention on combating bribery of foreign public officials in international business transactions, the UK Bribery Act 2010, as amended, and any subordinate legislation made under the FCPA or the UK Bribery Act 2010 from time to time together with any guidance and/or codes of practice issued by the relevant government department concerning the legislation, and any other Applicable Laws of similar effect, and the related regulations and published interpretations thereunder."**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state, and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, or other requirements of any Government Authority having jurisdiction over or related to the subject item or activity or Party.

1.3 "**Batch**" means the specific quantity of CpG Material produced in a single manufacturing production run.

1.4 "**Bioequivalent Version**" means, with respect to the CpG Adjuvant, [***].

1.5 "**Biosimilar Version**" means, with respect to a Product that is being sold in a country or regulatory jurisdiction worldwide (the "**Reference Product**"), a biopharmaceutical product sold by a Third Party (other than a Third Party acting on behalf of or in concert with Purchaser or Dynavax or any Affiliate or sublicensee or assignee of Dynavax or Purchaser) in such country or regulatory jurisdiction worldwide that through reference to the regulatory approval of the Reference Product, is eligible for and has achieved regulatory approval in such country or regulatory jurisdiction pursuant to an abbreviated follow-on biological approval pathway established by the regulatory authority in such country or regulatory jurisdiction pursuant to the applicable law, or otherwise is approved for marketing and sale in such country or regulatory jurisdiction by an abridged procedure in reliance, in whole or in part, on the prior regulatory approval of the Reference Product or on the safety and efficacy data generated for the prior regulatory approval (in such country or regulatory jurisdiction) of the Reference Product, including any such biopharmaceutical product that (i) with respect to such biopharmaceutical product in the United States, has been approved as a biosimilar or interchangeable product by the FDA pursuant to 42 U.S.C. § 262 of the Public Health Service Act, (ii) with respect to such biopharmaceutical product subject to the regulatory jurisdiction of the EMA, has been approved as a similar biological medicine product by EMA as described in CHMP/437/04, issued 30 October 2005, as may be amended, or any subsequent or superseding law, statute or regulation or (iii) with respect to such biopharmaceutical product outside the United States and in a country which is not subject to the regulatory jurisdiction of the EMA, has otherwise obtained Regulatory Approval from a regulatory authority pursuant to similar statutory or regulatory requirement as that described in the foregoing subsections (i) and (ii) in such other country or regulatory jurisdiction.

1.6 "**Business Day**" means each day of the week excluding Saturday, Sunday, and a day on which banking institutions in San Francisco, CA, USA, Edinburgh, Scotland or Vienna, Austria, are closed.

1.7 "**Calendar Quarter**" means each of the three (3) month periods ending March 31 ("**Q1**"), June 30 ("**Q2**"), September 30 ("**Q3**"), and December 31 ("**Q4**"); except that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30, and December 31 thereafter; and (b) the final Calendar Quarter of the Term shall end on the last day of the Term.

1.8 "**Calendar Year**" means each successive period of twelve (12) consecutive calendar months ending on December 31; except that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on December 31 of the calendar year in which the Effective Date falls, and (b) the final Calendar Year of the Term shall end on the last day of the Term.

1.9 "**Certificate of Analysis**" means the written certification specifying that the relevant analytical test results confirm that a specific Batch of CpG Material delivered complies with the applicable Specifications.

1.10 "**Certificate of Conformance**" means the written certification specifying that a specific Batch of CpG Material delivered meets the applicable Specifications and that such Batch has been manufactured in compliance with GMP.

1.11 "**CMO**" means contract manufacturing organization.

1.12 "**Collaboration Agreements**" means (i) the Clinical Collaboration Agreement dated 31 July 2020 between Dynavax and Valneva Austria, and (ii) the Collaboration Agreement dated 15 April 2020 between Dynavax and Valneva Austria, as amended by Amendment No. 1 dated 29 July 2020; in each case, as amended from time to time.

1.13 "**Confidential Information**" means all non-public information owned or controlled by one Party or any of its Affiliates (together, the "**Disclosing Party**") and disclosed or made available to the other Party or any of its Affiliates (together, the "**Receiving Party**") in connection with this Agreement. For clarity, all Dynavax Know-How is the Confidential Information of Dynavax, and the terms of this Agreement shall be deemed the Confidential Information of both Parties.

1.14 "**Cost per Dose**" means the purchase price for one Dose of CpG Material based on the Dose Assumption, as set forth in **Exhibit C**. For clarity, the Cost per Dose is determined based on the actual quantity of CpG Material included within a Dose. In addition to the Cost per Dose based on the Dose Assumption, **Exhibit C** also includes the Cost per Dose based on a Dose containing [***] mg and [***] mg of CpG Material.

1.15 "**COVID-19**" means the disease caused by SARS-CoV-2.

1.16 "**CpG Adjuvant**" means Dynavax's proprietary toll-like receptor 9 (TLR9) agonist adjuvant referred to by Dynavax as CpG 1018, as described in more detail in **Exhibit A**.

1.17 "**CpG Material**" means the CpG Adjuvant [***], as described in more detail in **Exhibit A**.

1.18 "**CTA**" means a clinical trial authorisation filed with the applicable Regulatory Authority in a country or jurisdiction, which application is required to commence human clinical trials in the applicable country or jurisdiction.

1.19 "**Disclosing Party**" has the meaning set forth in Section 1.13.

1.20 "**Dose**" means the quantity (in milligrams) of CpG Material used in a single unit of Product, net of any overage.

1.21 "**Dose Assumption**" means the quantity, in milligrams, of CpG Material that the Parties expect to be included within a single Dose, which as of the Effective Date is [***] mg.

1.22 "**Dynavax Know-How**" means all Know-How owned or controlled by Dynavax as of the Effective Date or during the Term that is necessary for the use, sale, offer for sale, export, or import, of the CpG Material as incorporated into any Product.

1.23 "**Dynavax Patents**" means any and all Patents owned or controlled by Dynavax as of the Effective Date or during the Term that claim any Dynavax Know-How or the CpG Material, including the composition or any formulation thereof and any method of making or using CpG Material.

1.24 "**Dynavax Technology**" means the Dynavax Know-How and Dynavax Patents, including Dynavax Foreground IP.

1.25 "**Export Control Laws**" means (a) all applicable U.S. laws and regulations relating to sanctions and embargoes imposed by U.S. Department of Treasury's Office of Foreign Assets Control (or its successor office or other body having substantially the same function); (b) all applicable U.S. export control laws, including the Arms Export Controls Act (22 U.S.C. Ch. 39), the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including the International Traffic in Arms Regulations (22 C.F.R. §§ 120 et seq.), the Export Administration Regulations (15 C.F.R. §§ 730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury; and (c) all export controls imposed on any goods by any country or organization or nation within the jurisdiction of which either Party operates or does business.

1.26 "**Facility**" means the facility [***], which is located at [***], or, with [***].

1.27 "**FDA**" means the U.S. Food and Drug Administration or its successor.

1.28 "**Field**" means the prevention, treatment, or amelioration of COVID-19 in humans.

1.29 "**GMP**" means the then-current good manufacturing practices applicable to the manufacture of CpG Material under Applicable Laws, including, (a) U.S. 21 C.F.R. Parts 210 and 211 and 21 C.F.R. Parts 600-610, and (b) (i) Directive 2003/94/EC laying down the principles and

guidelines of good manufacturing practice in respect of Medicinal Products for human use and investigational Medicinal Products for human use, (ii) Directive 2001/83/EC laying down the principles and guidelines of good manufacturing practice for Medicinal Products; (iii) further guidance as published by the European Commission in Volume 4 (Good Manufacturing Practice) of "The Rules Governing Medical Products in the European Union" and (iv) ICH Q7 Guideline "Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients".

1.30 "**Government Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization, or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof).

1.31 "**Know-How**" means any and all data, inventions, methods, proprietary information, processes, trade secrets, techniques and technology, whether patentable or not, but which are not known to the public, including discoveries, formulae, materials (including chemicals), biological materials (including expression constructs, nucleic acid sequences, amino acid sequences, and cell lines), practices, test data (including pharmacological, toxicological, pre-clinical and clinical information and test data), analytical and assay information, procedures, designs for experiments and tests, technology, instrumentation, devices, regulatory filings, constructs, compounds, plans, diagrams, drawings, manufacturing practices, methods, models, knowledge, technology, and data (including formulation data), quality control data (including drug stability data), and descriptions, and any other type of information, in any form whatsoever.

1.32 "**Pandemic**" means the COVID-19 pandemic as declared by the World Health Organization.

1.33 "**Patents**" means any and all: (a) patents and patent applications (with the term patent being deemed to include an inventor's certificate and application therefor, and utility model and design model patents and applications), (b) any foreign counterparts thereof, (c) all divisionals, continuations, continuations in part thereof, (d) all patents issuing on any of the foregoing, and any foreign counterparts thereof, and (e) all registrations, reissues, re-examinations (including resulting post-grant amendments to a granted patent), renewals, supplemental protection certificates, substitutions, revalidations, and extensions, supplementary protection certificates, and foreign equivalents of any of the foregoing.

1.34 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or other similar entity or organization, including a government or political subdivision, department, or agency of a government.

1.35 "**Product**" means any pharmaceutical product containing or comprising [***].

1.36 "**Purchase Order**" means each purchase order submitted by Purchaser for Doses of CpG Material.

1.37 "**Quality Agreement**" has the meaning set forth in Section 4.1.

1.38 "[*****] Costs**" mean all reasonable and documented out-of-pocket costs and expenses incurred by or on behalf of [***] and its Affiliates [***], include (a) the costs and expenses of [***], including [***], (b) the costs and expenses [***], (c) the costs and expenses of [***], and (d) any [***] due to [***].

1.39 "**Receiving Party**" has the meaning set forth in Section 1.13.

1.40 "**Regulatory Approval**" means, with respect to a country or other regulatory jurisdiction, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, or sale of a pharmaceutical product in such country or other jurisdiction.

1.41 "**Regulatory Authority**" means any Government Authority that has responsibility over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given jurisdiction, including the FDA in the U.S.

1.42 "**Rolling Forecast**" has the meaning set forth in Section 2.2(a).

1.43 "**Senior Officer**" means, with respect to Dynavax, the Chief Executive Officer or his/her designee, and with respect to Purchaser, the Chief Executive Officer or his/her designee.

1.44 "**Specifications**" means the written specifications for the CpG Material, as set forth in the Quality Agreement.

1.45 "**Term**" has the meaning set forth in Section 10.1.

1.46 "**Third Party**" means any entity other than Dynavax or Purchaser or an Affiliate of Dynavax or Purchaser.

1.47 "**U.S.**" means the United States of America, including its territories and possessions (including Puerto Rico).

1.48 "**Vaccine**" means Purchaser's VLA2001 inactivated, whole-virus SARS-CoV-2 vaccine candidate and, for the avoidance of doubt, does not include the CpG Adjuvant.

1.49 "**Vaccine Formulation**" means the formulation containing the Vaccine and further excipients but not the CpG Adjuvant.

1.50 "**Vaccine Supply Agreement**" has the meaning set forth in Section 3.1.

1.51 "**Valneva**" means the Purchaser, Valenva Austria GmbH and any Affiliate of those parties.

ARTICLE 2
CPG MATERIAL SUPPLY

2.1 Purchase and Sale. Pursuant to the terms and conditions of this Agreement, during the Term, (a) Dynavax (either itself or, in accordance with the provisions of this Agreement, through its Affiliates or Third Party CMOs) shall manufacture and supply the CpG Material to Purchaser in such quantities as are determined in accordance with this Article 2, for use in the manufacture of the Product for commercialization, manufacture and supply in the Field, and (b) subject to Dynavax complying with its obligations under the preceding clause (a) and meeting all of Purchaser's and its Affiliates requirements for CpG Adjuvant, as set out under this Agreement, Purchaser shall purchase from Dynavax all of Purchaser's and its Affiliates' requirements for CpG Adjuvant for such purpose and shall not procure or purchase, or attempt to procure or purchase, the CpG Adjuvant [***] from any Third Party.

2.2 Initial Commitments and Orders.

(a) Committed Volumes. Subject to Section 2.5 below, Purchaser will submit binding Purchase Orders for, purchase, and pay for, and Dynavax will supply, [***] Doses (based on the Dose Assumption plus a [***] overage) of CpG Material for delivery as set out in the table below:

Number of Doses ([***] mg)	**First payment**	**Amount**	**Order deadline**	**Amount paid on order deadline**	**Delivery date**	**Amount paid on delivery date**
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

(b) Indicative Volumes. Purchaser anticipates that it may purchase the amounts set out below (each an "**Indicative Amount**").

	Indicative Amount ([***] mg Doses)	**1st Reserv. Fee Deadline**	**1st Reserv.**	**2nd Reserv. Fee Deadline**	**2nd Reserv.**	**Purchase Order Deadline**	**Purchase Order Payment**	**Delivery Deadline**	**Delivery Payment**
Follow On Amount	**[***]**	[***]	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]
1st Additional Amount	**[***]**	[***]	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]

2nd Additional Amount	**[***]**	[***]	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]
3rd Additional Amount	**[***]**	[***]	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]

(c) If the Purchaser places a Purchase Order, for any Indicative Amounts (which order shall, in the case of any of the 1st, 2nd or 3rd Additional Amounts, specify the precise volume being ordered) by the relevant Purchase Order Deadline, that order shall be a binding Purchase Order and Dynavax shall supply the relevant amount for delivery by the relevant date.

(d) **Reservation Fees**. In respect of any Indicative Amount:

(i) if the Purchaser on or before the 1st Reservation Fee Deadline places a Purchase Order for that Indicative Amount, no Reservation Fee will be payable, but Purchaser shall pay for that Indicative Amount, or if the Purchaser on or before the 1st Reservation Fee Deadline notifies Dynavax in writing that it will not place a Purchase Order ("**Confirmation of No Purchase Notice**"), no Reservation Fee will be payable;

(ii) otherwise:

(1) the Purchaser shall pay the 1st Reservation Fee on the first Business Day after the 1st Reservation Fee Deadline and if the Purchaser places a Purchase Order for that Indicative Amount or serves a Confirmation of No Purchase Notice on or before the 2nd Reservation Fee Deadline, no Second Reservation Fee will be payable; and

(2) if the Purchaser neither places a Purchase Order for that Indicative Amount nor serves a Confirmation of No Purchase Notice on or before the 2nd Reservation Fee Deadline, the Purchaser shall pay the 2nd Reservation Fee on the first Business Day after the 2nd Reservation Fee Deadline;

(e) **Status of Reservation Fees**. If the Purchaser becomes liable to pay, and does pay, a Reservation Fee, Purchaser must place a Purchase Order in respect of the relevant amount on or before the relevant Order Deadline in order to retain the right to purchase such amount, and if the Purchaser does not submit a Purchase Order in respect of such amount on or before such Order Deadline, the Purchaser shall forfeit the Reservation Fee paid and the right to purchase such amount. If the Purchaser becomes liable to pay, and does pay, a Reservation Fee, and subsequently places a Purchase Order in respect of the relevant amount on or before the relevant Order Deadline, the amount of the Reservation Fee paid shall be deemed to be a pre-payment of the aggregate Cost per Dose of the relevant amount and shall be deducted from any subsequent payments of that aggregate Cost per Dose.

All Purchase Orders are subject to Purchaser's cancellation rights set forth in Section 2.5 below.

2.3 Further Forecasts and Orders

(a) Rolling Forecast. On or before the first (1st) Business Day of each Calendar Quarter during the Term, Purchaser may provide to Dynavax a rolling forecast of any quantity of Doses of CpG Material beyond those referred to in Section 2.2 that Purchaser plans to order for delivery during the following [***] Calendar Quarters (each, a "**Rolling Forecast**"). Each Rolling Forecast shall be [***].

(b) Further Purchase Orders. Within [***] days of receiving each Rolling Forecast, Dynavax shall indicate whether it has the capacity to meet, and is willing to supply, any or all of the requirements set out in that forecast and, if so, the amount of the requirements in such forecast that it is willing to supply; *provided*, *however*, that even if Dynavax has available capacity, it shall have no obligation to make such capacity or any portion thereof available to Purchaser. To the extent Dynavax indicates that it has the capacity, and is willing, to supply, any or all of the requirements set out in that forecast, the Purchaser may within a further period of [***] days place a Purchase Order for the indicated amount, and Dynavax shall accept or reject such Purchase Order in writing within [***]Business Days after its receipt of such Purchase Order. Upon Dynavax's acceptance of such Purchase Order, such Purchase Order, subject to Purchaser's cancellation rights set forth in Section 2.5, shall be a binding commitment of the Purchaser to purchase and Dynavax to supply such amount in accordance with such Purchase Order.

2.4 Delivery Terms.

(a) Delivery and Shipping Terms. Each Purchase Order will specify the delivery date(s) for the Doses ordered, provided that the specified delivery date shall be a date no sooner than, in the case of [***] Doses of the first [***] Doses of the Committed Volumes under Section 2.2(a), [***] months from the date of such Purchase Order, and in the case of all other Purchase Orders, [***] months from the date of such Purchase Order ("**Delivery Timeline**"). Dynavax shall package and label all CpG Material in accordance with Applicable Laws and deliver all CpG Material FCA (INCOTERMS 2020) the Facility, and title and risk of loss shall pass from Dynavax to Purchaser upon the CpG Material being loaded onto the carrier's collecting vehicle at the Facility, cleared for export. Purchaser shall be responsible for obtaining all licenses or other authorizations for the import of such shipments, for all freight, handling, insurance, and shipping expenses for such shipments, and shall be the importer of record and responsible for all duties and taxes for import of such shipments. Dynavax shall be responsible for obtaining all licenses or other authorizations for the export of such shipments, and Purchaser shall pay or reimburse Dynavax for all duties and taxes for the export of such shipments. At Purchaser's request, Dynavax shall provide to Purchaser such information as Purchaser may reasonably request to assist Purchaser in obtaining any licenses or other authorizations necessary for the import of such shipments.

(b) [***]. Ahead of Regulatory Approval of the Product, Dynavax will use commercially reasonable efforts to ensure that the CpG Materials shall, at the time of delivery in accordance with Section 2.4(a), [***].

(c) Separate Contracts. Each Purchase Order will constitute a separate contract for the supply of CpG Material under the terms of this Agreement (and excluding all other terms and conditions, including any set out or referred to in any Purchase Order or acceptance

thereof). In the event of a conflict between a Purchase Order (including any acceptance thereof) and the terms of this Agreement, the terms of this Agreement will govern.

2.5 Cancellation of Accepted Purchase Orders. Each Purchase Order accepted by Dynavax hereunder shall be non-cancellable except to the extent expressly set forth below:

(a) The Parties agree that if (i) the export or provision of CpG Material to Purchaser outside of the United States becomes prohibited under Applicable Law, including, U.S. export control or trade sanctions laws and regulations, and regulations issued by the U.S. Department of Homeland Security's Federal Emergency Management Agency, (ii) such prohibition lasts for at least sixty (60) days, and (iii) Dynavax is unable to export or provide CpG Material under a license or other authorization from the relevant Government Authority within such sixty (60) day period, then (x) Purchaser shall have the right to cancel any accepted Purchase Orders for CpG Material that has not been delivered or authorized for delivery by the relevant Government Authority prior to the end of the sixty (60) day period, (y) Purchaser shall have no obligation to make payment to Dynavax for CpG Material under any such cancelled Purchase Order that has not been delivered or authorized for delivery by the relevant Government Authority prior to the end of the sixty (60) day period, and (z) Dynavax shall promptly repay to Purchaser any Advance Payment received from Purchaser for CpG Material under any such cancelled Purchase Order that has not been delivered or authorized for delivery by the relevant Government Authority prior to the end of the sixty (60) day period.

(b) The Parties agree that if the UK Government terminates the Vaccine Supply Agreement for Product, or reduces or terminates any order which has been placed, after a Purchase Order for CpG Material placed under this Agreement has become binding but before payment by Purchaser of the Final Payment for such CpG Material in accordance with Section 3.2, (i) Purchaser shall have the right to cancel such Purchase Order (or, in the case of the UK Government's reduction of an order which has been placed, to reduce such Purchase Order to the extent of such reduction), and (ii) Purchaser shall not be required to pay the Final Payment for such CpG Material for such cancelled or reduced amounts of CpG Material. For clarity, in such event, Dynavax shall have the right to retain the Advance Payment for such CpG Material.

2.6 Supply.

(a) **Documentation**. Dynavax shall establish and maintain any necessary drug master files, standard operating procedures, protocols, and master Batch records for the manufacture of the CpG Material. Dynavax shall, in connection with each shipment of CpG Material to Purchaser, provide to Purchaser the relevant Certificate of Conformance, Certificate of Analysis, and any other documentation as may be required in the Quality Agreement with respect to such shipment verifying that each such shipment meets the warranties set forth in Sections 8.1 and 8.2. Without limiting Dynavax's obligations under the Quality Agreement, Dynavax shall promptly notify Purchaser after the discovery that any lot of shipped CpG Material, which had previously been approved for release in accordance with the Quality Agreement, fails to comply with its applicable Specifications or is otherwise not in compliance with Applicable Laws, including providing Purchaser with all details concerning the nature of any such failure to meet Specifications.

(b) **Release**. The Parties will agree to a mechanism in the Quality Agreement for the shipment of test samples of each Batch of the CpG Material provided to Purchaser for local release testing purposes.

2.7 **Inspection and Acceptance**.

(a) **Shortages**. Purchaser shall notify Dynavax in writing of any shortage in any shipment of CpG Material within [***] days after receipt. In the event of any verified shortage, Dynavax shall make up the shortage at no cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for such shortage amount following receipt thereof), within [***] Business Days if replacement CpG Material stock is available, or, if it is necessary to produce replacement CpG Material, Dynavax shall promptly start another manufacturing run and shall deliver the replacement CpG Material to Purchaser within [***] months after the notice of the shortage at no cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for such shortage amount following receipt thereof).

(b) **Non-Conforming CpG Material**.

(i) Purchaser shall inspect all shipments of CpG Material promptly upon receipt, and shall notify Dynavax in writing in reasonable detail if Purchaser is rejecting any CpG Material because it fails to conform to Dynavax's warranties set forth in Sections 8.2(a) or 8.2(b) upon delivery, with such notice provided within (A) [***] days after receipt of such shipment in the case of any nonconformity that is readily observable by visual inspection, or (B) [***] days of learning of such nonconformity where such non-conforming it not readily observable by visual inspection. All CpG Material not rejected within the applicable [***] period specified in the preceding clause (A) or clause (B), as applicable, will be deemed accepted.

(ii) If Purchaser notifies Dynavax of any nonconformity of any CpG Material in accordance with Section 2.5(b)(i), Dynavax shall have the right to inspect the CpG Material in question and Purchaser shall cooperate with Dynavax's inspection, including providing Dynavax with samples of the CpG Material in question for testing upon request at Dynavax's expense in accordance with the process set forth in the Quality Agreement. If Dynavax agrees with such notice of nonconformity, Dynavax shall, at Purchaser's discretion and Dynavax's expense, either: (A) replace such CpG Material, at no cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for such replacement CpG Material following receipt thereof), as soon as reasonably practicable after receipt of notification of such nonconformity or (B) refund any portion of the aggregate Cost per Dose paid to Dynavax for such CpG Material. If it is necessary to produce replacement CpG Material, Dynavax shall promptly start another manufacturing run and shall deliver the replacement CpG Material to Purchaser within [***] months after the notice of the nonconformity at no cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for such replacement CpG Material following receipt thereof).

(iii) If Dynavax disagrees with Purchaser that the relevant CpG Material did not conform to Dynavax's warranties set forth in Section 8.2(a) or 8.2(b), it may require a sample of the allegedly nonconforming CpG Material to be delivered to a mutually acceptable independent testing laboratory for testing. Except in the case of manifest error, the determination

of the laboratory as to whether the CpG Material is nonconforming will be final and binding on the Parties with respect to Purchaser's obligation to accept and pay for the CpG Materials (or, as applicable, Dynavax's obligation to provide the applicable remedy specified below). The fees and expenses of such laboratory testing shall be borne entirely by the Party against whom such laboratory's determination is made. If such determination is against Purchaser, then such CpG Material shall be deemed accepted by Purchaser for purposes of this Section 2.7(b), and Dynavax shall have no obligation to provide replacement CpG Material. If such determination is against Dynavax, then Dynavax shall, at Purchaser's election, either refund the portion of the aggregate Cost per Dose paid by Purchaser for such CpG Material or replace such CpG Material, at no cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for such replacement CpG Material following receipt thereof), as soon as reasonably practicable after replacement CpG Material becomes available. If it is necessary to produce replacement CpG Material, Dynavax shall promptly start another manufacturing run after the determination against Dynavax and shall deliver the replacement CpG Material to Purchaser within [***] months after such determination at no additional cost or expense to Purchaser (beyond the Purchaser's obligation to make the Final Payment for the replacement CpG Material following receipt thereof).

(c) **Sole Remedy**. [***], the remedies set forth in this Section 2.7 will be Purchaser's sole and exclusive remedy with respect to nonconforming CpG Material delivered to Purchaser by Dynavax hereunder. This Section 2.7 shall apply to any replacement CpG Material supplied by Dynavax.

(d) **Damage after Delivery**. Purchaser shall bear the risk of damage to the CpG Material after delivery to Purchaser pursuant to Section 2.4(a). If the CpG Material is damaged after delivery, and Purchaser intends to order replacement CpG Material, Purchaser shall promptly notify Dynavax of the damage and any orders for replacement CpG Material, and Dynavax shall use commercially reasonable efforts to deliver the requested replacement CpG Material. To the extent such order is accepted by Dynavax, Dynavax shall deliver the accepted quantity of such replacement CpG Material, as soon as reasonably practicable after replacement CpG Material becomes available.

2.8 **Allocation in the Event of Product Shortages**.

The following provisions of this Section 2.8 shall not limit Dynavax's obligations under this Agreement and in particular its obligations under Sections 2.2, 2.3 and 2.4 and its obligations to indemnify the Purchaser set out in Section 9.1:

(a) If at any time, Dynavax determines that it will not be able to deliver the quantities of CpG Material specified in any Purchase Order placed in accordance with this Agreement on the applicable delivery date, or Dynavax is made aware of any future anticipated shortages, then Dynavax shall immediately notify Purchaser of such determination. Such notification shall include the reasons for and the expected duration of Dynavax's anticipated inability to deliver such quantities of CpG Material and steps being taken to immediately commence providing the required quantities of CpG Material. Promptly thereafter, the Parties shall discuss in good faith the matters set forth in such notification and begin good faith negotiations with respect to an alternative delivery schedule or alternative sourcing for the CpG Material.

(b) Subject to paragraph (c) below, if Dynavax is unable to supply, with respect to a Calendar Quarter, the total quantity of CpG Material ordered by Purchaser pursuant to Section 2.2 or 2.3 for delivery in such Calendar Quarter, plus the total quantity of CpG Material required by Dynavax or its Affiliates or other purchasers for their respective use in such Calendar Quarter (such event, a "**Shortfall**"), the following shall apply:

(i) In the event of a Shortfall, the available CpG Material in each Calendar Quarter in which a Shortfall occurs shall be allocated [***] on the basis of [***] for such Calendar Quarter.

(ii) The allocation rules set forth in this Section 2.8(b) shall restart for each Calendar Quarter, without any carryover of a Shortfall realized by either Purchaser or Dynavax in the prior Calendar Quarter.

(c) The provisions of paragraph (b) above shall be subject to the following in respect of Purchase Orders submitted to Dynavax in accordance with Section 2.2:

(i) Dynavax shall in all circumstances take commercially reasonable endeavours to ensure continuity and timeliness of supply of Purchaser's requirements as set forth in such Purchase Orders;

(ii) Dynavax shall notify the Purchaser immediately if it fails, or expects to fail to deliver any amount of CpG Material in full and on time to the Purchaser;

(iii) if Dynavax fails to deliver CpG Material to the Purchaser on time and in full and this results in [***], or [***], [***] the relevant order (but not of any other order) shall [***];

(iv) during any period in which any such CpG Material is awaiting delivery Dynavax shall [***], and Dynavax shall provide weekly update reports on such delay, the causes of such delay and remedial action being taken.

2.9 Supply Contacts. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of CpG Material pursuant to this Agreement ("**Supply Contacts**"). Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of CpG Material under this Agreement. Each Party shall bear its own costs of its Supply Contact.

2.10 Use of CMOs. Dynavax will have the right to use CMOs to supply the CpG Material ordered by Purchaser, [***], provided that: (a) Dynavax shall be responsible for the compliance of any CMOs with this Agreement; (b) Dynavax remains fully and primarily responsible to Purchaser for the performance of, and acts and omissions of, such CMOs, as if committed by Dynavax; and (c) in no event shall Purchaser have any liability to any such CMO for any failure of Dynavax to perform under its agreement with such CMO, including any failure to pay any amounts due to such CMO (it being understood, however, that Purchaser may have

liability to Dynavax for any failure to pay any undisputed amounts due to Dynavax hereunder that results in Dynavax's inability to pay such CMO). [***].

ARTICLE 3
FINANCIALS

3.1 Price. Subject to the remainder of this Article 3, all CpG Material supplied by Dynavax to Purchaser under this Agreement that is manufactured in 2020 and 2021 shall be at a price equal to the Cost per Dose of such CpG Material as set forth in **Exhibit C**. Thereafter the Cost per Dose shall be subject to adjustment, [***], and the Parties shall update **Exhibit C** accordingly. The Cost per Dose is exclusive of (a) any customs duties or taxes imposed with respect to the export of the product and (b) all shipping and associated costs and all taxes, duties, or other fees of whatever nature imposed with respect to CpG Material supplied hereunder by or under the authority of any Government Authority (including any import duty to the UK), all of which Purchaser agrees to pay in addition to the Cost per Dose. For clarity, Dynavax will be solely responsible for payment of taxes on Dynavax's income. The Parties hereby agree that the Cost per Dose set forth in **Exhibit C** as of the Effective Date is valid only for CpG Material that is intended for use in, and is used in, the manufacture of Products for use in the Field during the Pandemic. If Purchaser desires to use any of the CpG Material supplied under this Agreement in any Product for use after the Pandemic, any such use shall be subject to [***] Valneva Austria's SARS-COV2 Vaccine Supply Agreement with the Secretary of State for Business, Energy and Industrial Strategy, on behalf of the UK Crown (the "**Vaccine Supply Agreement**"), and where Purchaser has already paid the Final Payment for such shipment of CpG Material, Purchaser would be obligated to pay Dynavax [***].

3.2 Invoice and Payment. Without prejudice to the obligations to pay Reservation Fees as applicable. in respect of the CpG Material ordered in any accepted Purchase Order, Dynavax will invoice Purchaser for [***] of the aggregate Cost per Dose of such CpG Material (the "**Advance Payment**") upon Dynavax's acceptance of such Purchase Order (provided always that the amount of any Reservation Fee paid in respect of such amount of CpG Material shall be deemed a prepayment against and deducted from such amount of the aggregate Cost per Dose of such CpG Material) and for [***] of the aggregate Cost per Dose of such CpG Material (the "**Final Payment**") upon delivery of such CpG Material in accordance with Section 2.4(a). Purchaser shall pay each invoice, in U.S. Dollars, within [***] days after receipt of such invoice by wire transfer of immediately available funds into an account designated by Dynavax. If Purchaser disputes any invoiced amount hereunder (or a portion thereof), Purchaser shall timely pay any undisputed portion of the invoiced amount in accordance with the preceding sentence and shall notify Dynavax in writing of the disputed amount, including the basis on which Purchaser disputes such amount, within [***] days after receipt of the invoice.

3.3 Late Payment. If any undisputed payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, such payment shall accrue interest from the date due at the annual interest rate of [***] *provided, however,* that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Dynavax from exercising any other rights it may have as a consequence of the lateness of any payment.

3.4 **Tax**. Purchaser shall pay any and all taxes (other than taxes based on Dynavax's income), duties, assessments, and other charges and expenses imposed by any Government Authority on the sale, supply, transfer, export or import of CpG Material hereunder. If a withholding or deduction obligation occurs, then the sum payable by Purchaser in respect of which such deduction or withholding is required to be made shall be increased to the extent necessary to ensure that Dynavax receives a sum equal to the sum which it would have received had no such withholding or deduction occurred.

ARTICLE 4
REGULATORY; QUALITY

4.1 **Quality Agreement**. As soon as reasonably practicable after the Effective Date, but no later than ninety (90) days thereafter, the Parties shall negotiate in good faith and agree to the terms and conditions of a quality agreement (the "**Quality Agreement**"), which shall be consistent in all material respects with Dynavax's quality agreement with its CMO, setting forth the respective responsibilities of Parties in relation to quality as required for compliance with Applicable Laws, including GMP, and including provisions (a) [***] and (b) [***]. The Quality Agreement is hereby incorporated herein by reference. To the extent that the terms of this Agreement and those of the Quality Agreement are in conflict, the terms of this Agreement shall control except with respect to quality issues, which shall be governed by the Quality Agreement. Each Party agrees to comply, and to cause its Affiliates and, in the case of Dynavax, its CMOs, to comply, with such Party's obligations under the Quality Agreement.

4.2 **GMP, Quality Assurance, and Other Audits**. During normal business hours and with reasonable advance notice, Purchaser shall have the right to conduct GMP, quality assurance, and other audits of any location relating to the supply of CpG Material hereunder, including at Dynavax's CMO, as further set forth in the Quality Agreement, and Dynavax shall and shall cause its Affiliates and any such Third Party, including Dynavax's CMO, to cooperate with Purchaser, its Affiliates, and their representatives in any such audit or inspection as further set forth in the Quality Agreement. Purchaser shall be responsible for the reasonable and documented cost of any audit it conducts, including any reasonable and documented amounts charged by Dynavax's CMO in connection therewith.

4.3 **Regulatory Inspections**. Dynavax shall cooperate and cause its Affiliates and CMO to cooperate with any inspection of the Facility by any Government Authority or Regulatory Authority, including in connection with the Regulatory Approval process for the Product. Dynavax shall promptly notify Purchaser in writing if any Regulatory Authority notifies Dynavax that it intends to or (if no notice was provided, that does) visit the Facility for the purpose of reviewing the manufacture of CpG Material. To the extent practicable under the circumstances and not prohibited by such Regulatory Authority, Dynavax shall permit a reasonable number of Purchaser's representatives to be present on site for such visit. Dynavax shall promptly provide Purchaser with a copy of (i) any reports or other correspondence issued by such Regulatory Authority following such visit, and (ii) any material reports, comments, responses or other correspondence prepared by or on behalf of Dynavax, including its CMO, from or to (as applicable) any Regulatory Authority which relates specifically to or would reasonably be expected to affect the Products, including any comments, responses or notices received from the Regulatory Authority with respect thereto, in each of (i) and (ii), redacted as appropriate to protect any

confidential information of Dynavax's other customers. Purchaser acknowledges that it may not direct the manner in which Dynavax fulfills its obligations to permit such inspection by and to communicate with Regulatory Authorities; provided that Dynavax does so in accordance with Applicable Laws.

4.4 Pharmacovigilance Agreement. As soon as reasonably practicable after the Effective Date, and in any event, prior to the use of the Product in any human clinical trial, the Parties shall enter into a pharmacovigilance agreement setting forth the pharmacovigilance responsibilities of the Parties with respect to the CpG Material (the "**Pharmacovigilance Agreement**"). Each Party agrees to comply, and to cause its Affiliates and, in the case of Purchaser, Purchaser's licensees of the Product, to comply, with such Party's obligations under the Pharmacovigilance Agreement.

4.5 Required Licenses.

(a) For CpG Material. Dynavax shall, at all times during the Term, have and maintain all of the licences, permissions, authorizations, consents, and permits that it needs to carry out its obligations under this Agreement in compliance with Applicable Laws, including, if necessary, a drug master file in respect of the CpG Material (the "**DMF**"). Upon request, Dynavax shall provide, or cause its CMO to provide, to relevant Regulatory Authorities letters of authorization or other written statements permitting such Regulatory Authorities to refer to information in the DMF in support of Purchaser's CTAs or Regulatory Approvals for Products, without direct disclosure to Purchaser of such information. Unless required by Applicable Laws, in no event shall Dynavax or its CMO be obligated to provide the DMF or any information contained therein directly to Purchaser or its Affiliates. Upon Purchaser's request, Dynavax will provide directly to relevant Regulatory Authorities such other data and documentation regarding the CpG Materials or the manufacture thereof as are reasonably required for Purchaser to apply for and maintain CTAs and Regulatory Approvals for use of the CpG Materials in the Products, provided that, unless required by Applicable Laws, Dynavax nor its CMO shall have any obligation to provide or disclose any such data or documentation to Purchaser. Subject to the foregoing limitations on Dynavax's obligations, Dynavax shall also, upon Purchaser's request, reasonably assist Purchaser and its designees in preparing and updating any submissions or other documents required by any Regulatory Authority for approval of the Products, and Purchaser shall compensate Dynavax for providing such assistance at a reasonable hourly rate to be mutually agreed by the Parties.

(b) For Products. For the avoidance of doubt, Purchaser shall be solely responsible for obtaining and maintaining all licenses, permissions, authorizations, consents, and permits necessary for the research, development, manufacture (excluding manufacture of the CpG Material), use, marketing, promotion, distribution, handling, storage, sale, or other disposition of the Vaccine and Products, and for complying with all Applicable Laws in connection with carrying out the foregoing activities.

ARTICLE 5
USE OF CPG MATERIAL

5.1 License Grant. Subject to the terms of this Agreement, including Section 5.2, Dynavax hereby grants to Purchaser a worldwide, fully-paid up, royalty-free, non-exclusive, non-transferable (except in connection with a permitted assignment of this Agreement in accordance with Section 11.6), limited license, with the right to grant sublicenses, under the Dynavax Technology solely to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise commercially exploit Products in the Field; *provided, however,* that the foregoing license to make and have made Products is limited to the right to make or have made Products using the CpG Material supplied by Dynavax pursuant to this Agreement, and specifically excludes any license or other right to make or have made the CpG Adjuvant or CpG Material. The license granted to Purchaser in this Section 5.1 includes the right to sublicense (through multiple tiers) to Purchaser's Affiliates and to Purchaser's or Purchaser's Affiliates' licensees or distributors of Products and any other companies that work with Purchaser or Affiliate in connection with the manufacture, supply, and other commercialization of the Products and Purchaser shall be responsible for the compliance of any sublicensees with this Agreement. Purchaser shall not have any other right to grant sublicenses under the license granted to Purchaser in this Section 5.1; *provided, however,* that Purchaser may contract with Third Party CMOs for the manufacture, on Purchaser's behalf, of Products using the CpG Material supplied under this Agreement, and such contracting shall not be considered a sublicense. The foregoing license shall not be construed to obligate Dynavax to disclose or transfer to Purchaser any Dynavax Technology.

5.2 [***].

5.3 No Implied License. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents or Know-How owned or controlled by the other Party.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1 Ownership of CpG Adjuvant, Vaccine and Vaccine Formulation. Purchaser and Valneva Austria acknowledge that the CpG Adjuvant is proprietary to Dynavax, that Dynavax is and shall at all times remain the sole and exclusive owner of, and shall not be restricted in any way from taking any steps to protect, any and all intellectual property rights of any nature whatsoever and whenever and however arising in and to the CpG Adjuvant, and that neither Purchaser nor Valneva Austria shall not obtain any right, ownership interest, or, except as expressly set forth in Section 5.1, license in or to the CpG Material as a result of its purchase, receipt, or use of the CpG Material under this Agreement. Dynavax acknowledges that the Vaccine and Vaccine Formulation are proprietary to Purchaser or its Affiliate, that Purchaser or its Affiliate is and shall at all times remain the sole and exclusive owner of, and shall not be restricted in any way from taking any steps to protect, any and all intellectual property rights of any nature whatsoever and whenever and however arising in and to the Vaccine and Vaccine Formulation, and that Dynavax shall not obtain any right, ownership interest, or license in or to the Vaccine and Vaccine Formulation as a result of the inclusion by Purchaser or Valneva Austria of the CPG Material in the Product or otherwise.

6.2 Ownership of Foreground IP related to CpG Adjuvant, Vaccine, Vaccine Formulation. Dynavax shall own any invention, discovery and know how, as well as any patent or other intellectual property rights thereunder that solely relate to, is an improvement or modification of, or is a new method of use of solely the CpG Adjuvant arising under the Collaboration Agreements ("**Dynavax Foreground IP**"). Purchaser shall own any invention, discovery and know how, as well as any patent or other intellectual property rights thereunder that solely relate to, is an improvement or modification of, or is a new method of use of solely Vaccine or Vaccine Formulation arising under the Collaboration Agreements ("**Valneva Foreground IP**").

6.3 Ownership of Foreground Patents related to Product. Dynavax and Valneva Austria shall jointly own all Patents arising under the Collaboration Agreements, solely where such Patents relate [***] ("**Joint Patents**"). All other intellectual property arising under the Collaboration Agreements other than the Dynavax Foreground IP, the Valneva Foreground IP, and Joint Patents, shall [***].

6.4 License to Dynavax. Valneva Austria hereby grants Dynavax (a) [***] license under the Joint Patents to make, use, develop, sell, and commercialize, any vaccine other than the Product or a Biosimilar Version of the Product, and (b) [***] license under the Joint Patents to make, use, develop, sell, and otherwise commercialize the CpG Adjuvant [***].

6.5 License to Purchaser. In addition to the licenses granted under Section 5.1, Dynavax hereby grants Purchaser (a) [***] license under the Joint Patents to make, use, develop, sell, and otherwise commercialize, any vaccine, and (b) [***] license under the Joint Patents to make, use, develop, sell, and otherwise commercialize the Product or Biosimilar Versions thereof.

6.6 Prosecution, Maintenance of Joint Patents: Dynavax, Valneva Austria and Purchaser agree that the inventorship shall be determined in accordance with U.S. patents laws. Valneva Austria shall have the sole right to file, prosecute and maintain any patent rights with regard to Joint Patents, at Valneva Austria's sole cost. At Valneva Austria's request and cost, Dynavax shall cooperate and assist Purchaser in the preparation, prosecution and maintenance of such Joint Patents. Valneva Austria shall keep Dynavax informed on the status of the preparation, filing, prosecution and maintenance of all Joint Patents. Further, Valneva Austria will (i) allow Dynavax a reasonable opportunity and reasonable time to review and provide comment to Valneva Austria's counsel regarding relevant substantive communications to Valneva Austria's drafts of any responses or other proposed substantive filings by Valneva Austria before any applicable filings are submitted to any relevant patent office (or governmental authority) in a major market and (ii) reflect any reasonable and timely comments offered by Dynavax in any final filings submitted by Valneva Austria to any relevant patent office (or governmental authority) in a major markets unless Valneva Austria believes doing so may delay filing issuance, maintenance or otherwise compromise or adversely affect patent coverage for the Product.

6.7 Enforcement and Defense of Joint Patents: Valneva Austria and its Affiliates and sublicensees shall have the exclusive right to enforce and defend those Joint Patents against Third Parties which infringe the subject matter of any of the Joint Patents solely related to the Product or a Biosimilar Version of the Product (but not any other vaccine). Dynavax shall have the exclusive right to enforce and defend those Joint Patents against Third Parties which infringe the subject matter of any Joint Patents solely related to the CpG Adjuvant [***]. For the avoidance of doubt,

neither Party shall concede the invalidity of the Joint Patents in any settlement discussions with Third Parties. Valneva Austria and Dynavax shall cooperate, at the cost of the requestor, in any enforcement or defense actions of the Joint Patents, including being joined as a party, if required under the relevant Applicable Law. In the event that a Party wishes to enforce and/or defend against any Third Party any Joint Patents that do not (i) solely relate to the Product or a Biosimilar Version of the Product, or (ii) solely relate to the CpG Adjuvant [***], the Parties shall in good faith discuss and agree the basis upon which such enforcement may proceed.

6.8 Collaboration Agreements. This Article 6 supersedes the entirety of Sections 6.2 and 6.4 in that certain Clinical Collaboration Agreement dated July 31, 2020 between Dynavax and Valneva Austria, and the entirety of Section 3 of that certain Collaboration Agreement dated April 15, 2020, between Dynavax and Valneva Austria, as amended by Amendment No. 1 dated July 29, 2020.

ARTICLE 7
CONFIDENTIALITY

7.1 Confidentiality. At all times during the Term and for a period of [***] years thereafter, each Party shall, and shall cause its Affiliates and its and their respective officers, directors, employees, consultants, contractors, and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 7.1 shall not include any information that:

(a) has been published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no wrongful act, fault, or negligence on the part of the Receiving Party;

(b) was in the Receiving Party’s possession (or that of any of its Affiliates) prior to disclosure by the Disclosing Party without any obligation of confidentiality with respect to such information, as evidenced by the Receiving Party's records or other competent proof;

(c) is subsequently received by the Receiving Party (or that of any of its Affiliates) from a Third Party without restriction and without the Receiving Party's knowledge of breach of any agreement between such Third Party and the Disclosing Party;

(d) is made available to Third Parties by the Disclosing Party without restriction on disclosure to the Receiving Party’s knowledge; or

(e) has been independently developed by the Receiving Party (or that of any of its Affiliates) without use of, or access to, the Disclosing Party’s Confidential Information as evidenced by the Receiving Party's records or other competent proof.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential

Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

7.2 Permitted Disclosures. The Receiving Party may disclose the existence or terms of this Agreement or Confidential Information of the Disclosing Party as expressly permitted by this Agreement or to the extent such disclosure is reasonably necessary in the following instances:

(a) obtaining and maintaining CTAs and Regulatory Approvals of CpG Adjuvant (in the case of Dynavax as the Receiving Party) and Products (in the case of Purchaser as the Receiving Party);

(b) complying with valid court orders or Applicable Laws, or the rules of any securities exchange on which a Party's securities are listed or the requirements of any Regulatory Authority or Government Authority;

(c) in the case of the Purchaser, in responding to requests for information from the UK Government requiring such disclosure;

(d) disclosure to its and its Affiliates' employees, consultants, contractors, and agents, in each case on a need-to-know basis in connection with development or manufacture of the CpG Material (in the case of Dynavax) or the development, manufacture, or commercialization of any Product (in the case of Purchaser), in each case in accordance with the terms of this Agreement and under written obligations of confidentiality and non-use at least substantially similar to those herein; and

(e) disclosure to actual and bona fide potential investors, acquirors, and other financial partners for the purpose of evaluating or carrying out an actual or potential investment or acquisition, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; provided that the disclosing Party limits such disclosure to the maximum extent possible and redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment or acquisition.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 7.2(b) or Section 7.2(c), it will, except where impermissible, give reasonable advance notice to the other Party of such required disclosure and comply with all reasonable requests of the Disclosing Party with respect to maintaining confidence of such Confidential Information and in any event shall use at least the same diligent efforts to secure confidential treatment of such Confidential Information as such Party would use to protect its own confidential information of a similar nature, but in no event less than reasonable efforts.

7.3 Use of Name. Except as expressly provided herein, neither Party shall use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or

adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance, which approval shall not be unreasonably withheld or delayed. The restrictions imposed by this Section 7.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the Disclosing Party's counsel, is required by Applicable Law.

7.4 Return of Confidential Information. Upon the earlier of expiration or termination of this Agreement for any reason, each Party shall promptly return to the other Party, or delete or destroy, in each such Party's discretion, all records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations under this Agreement, as required by Applicable Law, or for legal archival purposes, which copy shall remain subject to the non-use and non-disclosure provisions contained herein.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations, Warranties, and Covenants.

(a) Authorizations. Each Party represents and warrants to the other Party that, as of the Effective Date: (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (ii) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, and (iii) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

(b) Debarment. Dynavax represents, warrants, and covenants to Purchaser that none of it, its Affiliates, or, to its knowledge based on representations, warranties and covenants made by its CMOs, its CMOs, is debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, or comparable laws in any country or jurisdiction other than the U.S., (nor is aware of any pending or potential actions that would give rise to such ineligibility) and it and its Affiliates does not, and will not during the Term, employ or use the services of any Person who is debarred or disqualified, in connection with activities relating to the CpG Material or any Product. In the event that Dynavax becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to Dynavax, including Dynavax itself or its Affiliates, that directly or indirectly relate to activities contemplated by this Agreement, Dynavax shall immediately notify Purchaser in writing and shall cease employing, contracting with, or retaining any such Person to perform any such services.

(c) CMOs. Dynavax represents and warrants to Purchaser that (i) each Facility at which CpG Material is manufactured, tested, stored, packaged, labeled or supplied, is operated

in compliance with Applicable Laws, including GMP and is registered with the applicable Regulatory Authority; and (ii) its agreements with its CMOs, including any quality or pharmacovigilance agreements, contain terms that are customary in biopharmaceutical industry and required to ensure that the CpG Material is manufactured, tested, stored, packaged, labeled, and supplied in compliance with Applicable Laws, including GMP.

8.2 **Product Warranties**. Dynavax represents and warrants to Purchaser that:

(a) all CpG Material supplied to Purchaser pursuant to this Agreement will be manufactured in compliance with Applicable Laws relevant to the manufacture of the CpG Material at the Facility, including GMP;

(b) all CpG Material supplied to Purchaser pursuant to this Agreement, at the time of delivery of such CpG Material to Purchaser pursuant to Section 2.4(a), will comply with the Specifications; and

(c) all CpG Material supplied to Purchaser pursuant to this Agreement will, at the time of delivery of such CpG Material to Purchaser pursuant to Section 2.4(a), be free and clear of any liens, security interests, or other encumbrances.

8.3 **Mutual Covenants**. Each Party hereby covenants to the other Party that, in connection with the performance of its activities under this Agreement:

(a) neither such Party nor any of its Affiliates will, (or any of their respective employees and consultants (including CMOs) directly or indirectly through Affiliates or Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including such Party and its Affiliates, nor will such Party or any of its Affiliates (or any of their respective employees and consultants (including CMOs) directly or indirectly promise, offer, or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a public official or entity or any other Person;

(b) neither such Party nor any of its Affiliates (or any of their respective employees and consultants or CMOs), in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement, shall cause the other Party to be in violation of Anti-Corruption Laws or Export Control Laws;

(c) such Party shall immediately notify the other Party if such Party has any information that there is or is likely to be a violation of Anti-Corruption Laws or Export Control Laws in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement; and

(d) each Party shall undertake due diligence activities appropriate to its activities under this Agreement in accordance with applicable Anti-Corruption Laws and related guidance, including guidance issued by the U.S. Department of Justice Criminal Division (entitled "Evaluation of Corporate Compliance Programs") concerning the FCPA, and issued by the U.K.

Ministry of Justice concerning the UK Bribery Act 2010, such activities to include the conduct of appropriate due diligence in relation to Third Party contractors, and shall to the extent permitted by Applicable Law, reasonably collaborate with the other Party to ensure such compliance.

8.4 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Dynavax. Dynavax shall defend, indemnify, and hold harmless Purchaser and its Affiliates and their respective directors, officers, employees, and agents (each, a "**Purchaser Indemnitee**") from and against any and all losses, damages, liabilities, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") incurred by the Purchaser Indemnitees as a result of any claim, demand, action, or other proceeding by a Third Party (collectively, "**Claims**") to the extent caused by: (a) the breach by any Dynavax Indemnitee (including of its CMOs) of any warranty, representation, covenant, or agreement made by Dynavax in this Agreement; or (b) the negligence, gross negligence or willful misconduct of any Dynavax Indemnitee or its CMOs; or (c) the CpG Material provided under this Agreement, including claims that the manufacture, use, supply, import or export of the CpG Materials infringes or misappropriates a Third Party's intellectual property rights; except, in each case ((a) through (c)), to the extent such Losses or Claims result from an event for which Purchaser has an obligation to indemnify Dynavax under Section 9.2.

9.2 Indemnification by Purchaser. Purchaser shall defend, indemnify, and hold harmless Dynavax and its Affiliates and their respective directors, officers, employees, and agents (each, a "**Dynavax Indemnitee**") from and against any and all Losses incurred by the Dynavax Indemnitees as a result of any Claim to the extent caused by: (a) the breach by any Purchaser Indemnitee of any warranty, representation, covenant, or agreement made by Purchaser in this Agreement, (b) the negligence, gross negligence or willful misconduct of any Purchaser Indemnitee, or (c) the disposition by or on behalf of Purchaser of any Product manufactured with CpG Materials under this Agreement, including claims that the manufacture, use, supply, import or export of Product (excluding the CpG Materials), infringes or misappropriates a Third Party's intellectual property rights; except, in each case ((a)-(c)), to the extent such Losses or Claims result from an event for which Dynavax has an obligation to indemnify Purchaser under Section 9.1.

9.3 Indemnification Procedures. A Party that intends to claim indemnification under this Article 9 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of the Claim in respect of which the Indemnitee intends to claim such indemnification, and subject to the remainder of this Section 9.3, the Indemnitor shall have sole control of the defense or settlement thereof at its own expense. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Claim

shall only relieve the Indemnitor of its indemnification obligations under this Article 9 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee may participate in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own choice (but in that case at the Indemnitee's cost and expense). The Indemnitee shall not settle any Claim for which it seeks indemnification hereunder without the consent of the Indemnitor, which consent shall not be unreasonably withheld, conditioned, or delayed. The Indemnitor shall not settle any Claim which imposes any liability or obligation on the Indemnitee (unless the settlement involves only the payment of money), involves any admission of wrongdoing on the part of the Indemnitee, or does not include a release of all claims against the Indemnitee, without the prior written consent of the Indemnitee, which consent shall not to be unreasonably withheld, conditioned, or delayed. The Indemnitee shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification at the Indemnitor's expense.

9.4 Insurance. Each Party shall maintain commercial general liability insurance and product liability and other appropriate insurance, at its own expense, in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall maintain such insurance for the period commencing promptly after the Effective Date until [***] years after the Term. Each Party shall provide evidence of such coverage to the other Party upon request, including a certificate of insurance (if applicable). It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations under this Agreement.

9.5 Limitation of Liability.

(a) EXCEPT AS PROVIDED UNDER SECTION 9.5(b), (I) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES, OR LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, THE CPG MATERIALS, OR THE PRODUCT, INCLUDING ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND (II) EACH PARTY'S MAXIMUM LIABILITY FOR DAMAGES RELATED TO THIS AGREEMENT, THE CPG MATERIALS OR PRODUCT, REGARDLESS OF THE CAUSE OF ACTION, WILL NOT EXCEED [***].

(b) NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT IS INTENDED TO OR SHALL LIMIT OR RESTRICT AND THE LIMITATIONS UNDER SECTION 9.5(a) SHALL NOT APPLY WITH RESPECT TO (I) ANY LOSSES OR CLAIMS SUBJECT TO EITHER PARTY'S INDEMNIFICATION RIGHTS OR OBLIGATIONS UNDER SECTIONS 9.1 OR 9.2, (II) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 7, OR (III) A PARTY'S RIGHT TO RECOVER DAMAGES FOR FRAUD BY THE OTHER PARTY.

ARTICLE 10
TERM AND TERMINATION

10.1 Term.

(a) The provisions of this Section 10.1 and of Section 11.2 shall be legally binding immediately as this Agreement has been signed by both Parties. All other provisions of this Agreement shall be effective and legally binding upon the Parties upon the later of:

(i) the execution of the Vaccine Supply Agreement by both the Valneva Austria and the UK Crown (prompt notice of which will be provided by Purchaser to Dynavax); and

(ii) one minute after the end of trading on NASDAQ on Friday 11 September 2020 (the "**Effective Date**"). If the Vaccine Supply Agreement is not executed by the Valneva Austria and the UK Crown by 11.59 pm UK time on Sunday 13 September 2020, this Agreement will be null and void *ab initio* and will have no effect whatsoever.

(b) This Agreement will commence on the Effective Date and will continue through December 31, 2025 or until earlier terminated by the Parties pursuant to Section 10.2 (the "**Initial Term**"). After the Initial Term, this Agreement shall automatically renew each year thereafter for a period of one (1) year (each, a "**Renewal Term**" and all Renewal Terms together with the Initial Term, the "**Term**"), unless either Party notifies the other Party in writing twelve (12) months prior to the renewal date that the notifying Party does not wish to renew the Agreement.

10.2 Termination.

(a) **Material Breach**. Each Party shall have the right to terminate this Agreement immediately upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the non-breaching Party within [***] days after receipt from the non-breaching Party of written notice specifying the breach and requesting its cure.

10.3 Termination for Insolvency. In the event that a Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

10.4 Purchaser Suspension Rights. Purchaser shall have the right to suspend delivery by Dynavax of any quantities of CpG Material, without liability, in the event of any of the

following occurring, with respect to the clinical trials undertaken with respect to the Product and, where applicable, with respect to the commercialization of the Product:

(a) based on the decision of a Regulatory Authority or independent trial safety monitoring board those trials are cancelled or suspended for more than one hundred eighty (180) days for reasons directly attributable to the CpG Material;

(b) as a result of those trials the CpG Material, or its use in connection with the Vaccine, is deemed unsafe by a Regulatory Authority; or

(c) following the decision of a Regulatory Authority or independent trial safety monitoring board, the commercialization of the Product is suspended or a recall of the Product is demanded.

10.5 Effects of Termination; Survival. Termination or expiration of this Agreement shall not affect the rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Upon termination of this Agreement (a) for any reason, Purchaser shall pay all undisputed outstanding invoices; and (b) by Purchaser pursuant to Section 10.2(a), Purchaser shall have the right to request that Dynavax manufacture and deliver to Purchaser, in which case Dynavax shall manufacture and deliver to Purchaser, the CpG Material under all outstanding accepted Purchase Orders on the relevant scheduled delivery dates and Purchaser shall pay Dynavax the Final Payment for such Purchase Orders not later than [***] days after Purchaser's acceptance date therefor. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Article 1 (Definitions), Section 5.2 (Restrictions on Use of CpG Material), Article 6 (Intellectual Property), Article 7 (Confidentiality), Article 9 (Indemnification), Section 10.5 (Effects of Termination; Survival), and Article 11 (General Provisions).

ARTICLE 11
GENERAL PROVISIONS

11.1 Force Majeure. Neither Party shall be liable to the other for any failure to fulfil its obligations under the Agreement to the extent that such failure is caused by force majeure event. As used in this Section 11.1, a "force majeure event" means any events which a Party could not reasonably have foreseen, prevented, mitigated risks from, or controlled by reason of the unavoidable, unforeseeable, or uncontrollable nature of such events, including (in each case provided they, or events resulting from them, have the preceding characteristics) fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, riots, insurrections, civil or foreign wars, or strikes, as well as any other circumstances beyond the reasonable control of the affected Party. The Party affected by the occurrence of a force majeure event shall (a) promptly inform the other Party thereof and (b) use reasonable efforts to mitigate the consequences of such force majeure event and to remedy the situation and recommence performance as soon as reasonably practicable. Any timelines affected by a force majeure event shall be extended for a period equal to that of the delay. The affected Party shall provide notice of the start and stop of any force majeure event to the other Party.

11.2 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded.

11.3 Dispute Resolution.

(a) General. Any dispute between the Parties arising out of, in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**") shall be resolved pursuant to this Section 11.3.

(b) Senior Officers. Any Dispute shall first be referred to the Senior Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers in writing and signed by authorized representatives of the Parties shall be conclusive and binding on the Parties.

(c) Exclusive Jurisdiction and Venue. If the Senior Officers are not able to agree on the resolution of a Dispute within thirty (30) days (or such other period of time as mutually agreed by the Senior Officers) after such Dispute was first referred to them, then, if a Party wishes to pursue further resolution of such Dispute, subject to Section 11.3(d) below, such Dispute shall be subject to the exclusive jurisdiction of the United States District Court for the Southern District of New York (the "**Court**"). Each Party hereby irrevocably consents to the personal jurisdiction of the Court for any action, suit or proceeding (other than appeals therefrom) arising out of, in connection with or relating to this Agreement or any document or instrument delivered in connection herewith, agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in such Court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum, and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight or express courier service to its address set forth in Section 11.5 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such Court.

Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight or express courier service to its address set forth in Section 11.5 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any Court.

(d) Interim Relief. Notwithstanding anything herein to the contrary, including Section 11.3(b), nothing in this Section 11.3 shall preclude either Party from (i) seeking interim or provisional relief, including a temporary restraining order, preliminary injunction, or other interim equitable relief concerning a Dispute in any court of competent jurisdiction before or after the initiation of a proceeding as set forth in Section 11.3(c), and (ii) the Parties may submit any dispute, controversy, or claim relating to the scope, validity, enforceability or infringement of any intellectual property before any relevant administrative body, in the country in which such

intellectual property was granted or arose without first having complied with the procedures set forth in Section 11.3(c). This Section 11.3(d) shall be specifically enforceable.

11.4 Entire Agreement; Amendment. This Agreement, including the Exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein (including the Confidentiality Agreement between the Parties dated 6 April 2020; provided that all "Confidential Information" disclosed or received under such Confidentiality Agreement shall be deemed "Confidential Information" under this Agreement and subject to the terms and conditions of this Agreement); *provided however*, that except as set forth in Section 6.8, the Collaboration Agreements shall continue in full force and effect in accordance with their respective terms. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the authorized representatives of the Parties to this Agreement. No modification to this Agreement will be effected by the acknowledgment or acceptance of any Purchase Order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

11.5 Notices. Except for any Purchase Orders or any acknowledgement of any Purchase Orders, which will be transmitted electronically, any notice required or permitted to be given under this Agreement must be in writing in English and delivered either in person, by air mail (postage prepaid) requiring return receipt, or by overnight courier to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 11.5. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) if delivered in person, the date of actual receipt, (b) if air mailed, on the date of receipt as evidenced by the date on the return receipt, and (c) if delivered by overnight or express courier, the date of receipt as evidenced by the date on the courier's receipt. Any such notice shall be deemed to have been given on the Business Day delivered, or if delivered or sent on a non-Business Day, then on the next Business Day. Each Party may also provide a courtesy copy of any such notice by e-mail (which copy shall not constitute notice).

If to Purchaser, notices must be addressed to:

Valneva Scotland Limited
Oakbank Park Rd
Livingston EH53 0TG
United Kingdom
Attention: Finance Director

with a copy, which shall not constitute notice, to:

Valneva SE
6 rue Alain Bombard 44800
Saint Herblain
France
Attn: General Counsel
e-mail: [***]

If to Valneva Austria, notices must be addressed to:

Valneva Austria GmbH
Campus Vienna Biocenter 3
1030 Vienna
Austria
Attention: The COVID Programme Director

with a copy, which shall not constitute notice, to:

Valneva SE
6 rue Alain Bombard 44800
Saint Herblain
France
Attn: General Counsel
e-mail: [***]

If to Dynavax, notices must be addressed to:

Dynavax Technologies Corporation
2100 Powell Street, Suite 900
Emeryville, CA 94608
USA
Attn: President and Chief Operating Officer

with a copy, which shall not constitute notice, to:

Dynavax Technologies Corporation
2100 Powell Street, Suite 900
Emeryville, CA 94608
USA
Attn: General Counsel

11.6 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld or conditioned); *provided*, *however*, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to this Agreement to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise; or

(b) to an Affiliate, provided that no such assignment shall relieve the assigning Party of its obligations hereunder; or

(c) in the case of Purchaser, to the UK Crown or any entity of, or on behalf of, the UK Crown.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 11.6. Any assignment not in accordance with this Section 11.6 shall be null and void.

11.7 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

11.9 Severability. In the event that any term of this Agreement is held to be invalid, illegal, or unenforceable, such invalidity, illegality, or unenforceability shall not affect any other portion of this Agreement, and in such case the Parties shall promptly negotiate in good faith to amend such illegal, invalid, or unenforceable term with a valid, legal, and enforceable term that most closely effectuates the original intent of the Parties.

11.10 No Waiver. The failure on the part of a Party to enforce, or any delay in enforcing, any right, power, or remedy that such Party may have under this Agreement shall not constitute a waiver of any such right, power, or remedy, or release the other Party from any obligations under this Agreement, except by a written document signed by the Party against whom such waiver or release is sought to be enforced. Such written document shall specify the particular matter waived and, if applicable, the relevant period of time.

11.11 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

11.12 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context

dictates otherwise because the subjects of the conjunction are, or are intended to be, mutually exclusive. The words “herein”, “hereof”, and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. References to any agreement, contract, statute, act, or regulation are to that agreement, contract, statute, act, or regulation as amended, modified, or supplemented from time to time in accordance with the terms hereof and thereto. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement, shall be in the English language.

11.13 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically, including by DocuSign, or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

{SIGNATURE PAGE FOLLOWS}

IN WITNESS WHEREOF, the Parties hereto have caused this **SUPPLY AGREEMENT** to be executed and entered into by their duly authorized representatives as of the Effective Date.

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ David Novack
Name: David Novack
Title: President and COO

Date: 11 September 2020

VALNEVA SCOTLAND LTD.

By: /s/ David Lawrence
Name: David Lawrence
Title: Director

Date: 11 September 2020

By: /s/ Thomas Lingelbach
Name: Thomas Lingelbach
Title: Director

Date: 11 September 2020

VALNEVA AUSTRIA GMBH
By: /s/ David Lawrence
Name: David Lawrence
Title: Managing Director
Date: 11 September 2020

By: /s/ Frédéric Jacotot
Name: Frédéric Jacotot
Title: Managing Director

Date: 11 September 2020

Exhibit A

CpG Adjuvant and CpG Material

Dynavax's proprietary toll-like receptor 9 (TLR9) agonist adjuvant referred to as CpG 1018

- [***]
- [***]
- [***]
- [***]
- [***]
- [***]

Exhibit B

Initial Forecast in Doses

Delivery schedule in million Doses based on the Dose Assumption (i.e., [***] mg per Dose)
Delivery lead time = [***] months ([***] months for first [***] million Doses)

	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022
UK Order	**[***]**	**[***]**						
UK Delivery		**[***]**	**[***]**	**[***]**				

Exhibit C

Cost per Dose

[***]

[***]

[***]

DYNAVAX TECHNOLOGIES CORPORATION

AMENDED AND RESTATED MANAGEMENT CONTINUITY AND SEVERANCE AGREEMENT

This Amended and Restated Management Continuity and Severance Agreement (the "***Agreement***") is dated as of September 22, 2020, by and between Michael S. Ostrach ("***Employee***") and Dynavax Technologies Corporation, a Delaware corporation (the "***Company***").

RECITALS

A. It is expected that another company may from time to time consider the possibility of acquiring the Company or that a Change of Control (as defined below) may otherwise occur, with or without the approval of the Company's Board of Directors (the "***Board***"). The Board recognizes that such consideration can be a distraction to Employee and can cause Employee to consider alternative employment opportunities. The Board has determined that it is in the best interests of the Company to assure that the Company will have the continued dedication and objectivity of Employee, notwithstanding the possibility, threat, or occurrence of a Change of Control.

B. The Board believes it is in the best interests of the Company to retain Employee and provide incentives to Employee to continue in the service of the Company.

C. The Board further believes that it is imperative to provide Employee with certain benefits upon a qualifying termination of Employee's employment with the Company, which benefits are intended to provide Employee with encouragement to remain with the Company, notwithstanding the possibility of a Change of Control or an employment termination.

D. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Employee, to agree to the terms provided in this Agreement.

E. Employee and the Company previously entered into an Amended and Restated Management Continuity and Severance Agreement dated as of April 19, 2016, by and between Employee and the Company (the "***Prior Agreement***"). Employee and the Company acknowledge and agree that this Agreement amends and supersedes the Prior Agreement, which will be of no further force and effect.

Now therefore, in consideration of the mutual promises, covenants, and agreements contained herein, and in consideration of the continuing employment of Employee by the Company, the parties hereto agree as follows:

1. **At-Will Employment**. The Company and Employee acknowledge that Employee's employment with the Company is and shall continue to be at-will, as defined under applicable law, and that Employee's employment with the Company may be terminated by either party at any time for any or no reason. If Employee's employment with the Company terminates for any reason, Employee shall not be entitled to any payments, benefits, damages, award, or compensation other than as provided in this Agreement, and as may otherwise be available in accordance with the terms of the Company's established employee plans and written policies at

the time of such termination. The terms of this Agreement shall terminate upon the date that all obligations of the parties hereunder have been satisfied.

2. Involuntary Termination and Retirement. Subject to Section 5, if Employee's employment with the Company terminates due to an Involuntary Termination or a Retirement and, in each case, Employee has satisfied the Release requirement set forth in Section 4, then Employee shall be entitled to receive the benefits set forth in Sections 2(a), 2(b), 2(c) and 2(d) below, as applicable, subject to any required payroll deductions and tax withholdings.

(a) Cash Severance Benefit. Employee will be entitled to receive a cash payment equal to the following amount, as applicable (the "***Cash Severance Benefit***"), in a lump sum within sixty (60) days following such Involuntary Termination or Retirement, as applicable:

(i) if such Involuntary Termination is a Non-Change of Control Termination, the Cash Severance Benefit will be equal to twelve (12) months of Employee's annual base salary (as in effect on the date of such termination or, if such termination is due to Good Reason, as defined herein, then as in effect on the date immediately prior to the initial existence of such Good Reason); *provided*, *however*, that if such Involuntary Termination occurs prior to March 31, 2021 and Employee has not received the 2020 Actual Bonus (as defined below) on or prior to the date of such Involuntary Termination, the Cash Severance Benefit will also include an amount equal to (x) 100% of Employee's annual target bonus for the year 2020 (the "***2020 Target Bonus***") under the Company's management incentive program or other similar bonus program (the "***Bonus Program***") if such Involuntary Termination occurs prior to the date that Employee's actual bonus for such year (the "***2020 Actual Bonus***") is determined by the Company under the Bonus Program or (y) the greater of the 2020 Target Bonus or the 2020 Actual Bonus if such Involuntary Termination occurs on or after the date that the 2020 Actual Bonus is determined by the Company under the Bonus Program;

(ii) if such Involuntary Termination is a Change of Control Termination, the Cash Severance Benefit will be equal to the sum of (x) fifteen (15) months of Employee's annual base salary (as in effect on the date of such termination or, if such termination is due to Good Reason, as defined herein, then as in effect on the date immediately prior to the initial existence of such Good Reason) and (y) 125% of Employee's annual target bonus for the year of such termination under the Bonus Program; and

(iii) in the event of a Retirement, the Cash Severance Benefit will be equal to the sum of (x) twelve (12) months of Employee's annual base salary (as in effect on the date of such termination) and (y) if Employee has not received the 2020 Actual Bonus on or prior to the date of such Retirement, then an amount equal to (1) the 2020 Target Bonus if such Retirement occurs prior to the date that the 2020 Actual Bonus is determined by the Company under the Bonus Program or (2) the greater of the 2020 Target Bonus or the 2020 Actual Bonus if such Retirement occurs on or after the date that the 2020 Actual Bonus is determined by the Company under the Bonus Program.

(b) COBRA Severance Benefit and Special Severance Benefit. The Company, in its sole discretion, will either: (x) pay, on Employee's behalf, on a monthly basis, the total amount of monthly premiums required to continue Employee's coverage (including coverage

for Employee's eligible dependents, if any) under the Company's health, dental and vision insurance plans (as in effect on the date of such termination) pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***") ("***COBRA Premiums***") for the following number of months, as applicable (the "***COBRA Severance Benefit***"); or (y) pay directly to Employee an amount equal to the COBRA Premiums for the following number of months, as applicable (the "***Special Severance Benefit***"):

(i) if such Involuntary Termination is a Non-Change of Control Termination, the COBRA Severance Benefit (if any) will be provided for a period of up to twelve (12) months following such termination and the Special Severance Benefit (if any) will be payable for up to twelve (12) months following such termination, provided that the total combined number of months covered by the COBRA Severance Benefit and the Special Severance Benefit will be equal to (and may not exceed) twelve (12) months; *provided, however*, that if such Involuntary Termination occurs prior to March 31, 2021, each reference to "twelve (12) months" in this Section 2(b)(i) will be replaced with "eighteen (18) months";

(ii) if such Involuntary Termination is a Change of Control Termination, the COBRA Severance Benefit (if any) will be provided for a period of up to fifteen (15) months following such termination and the Special Severance Benefit (if any) will be payable for up to fifteen (15) months following such termination, provided that the total combined number of months covered by the COBRA Severance Benefit and the Special Severance Benefit will be equal to (and may not exceed) fifteen (15) months; *provided, however*, that if such Involuntary Termination occurs prior to March 31, 2021, each reference to "fifteen (15) months" in this Section 2(b)(ii) will be replaced with "eighteen (18) months"; and

(iii) in the event of a Retirement, the COBRA Severance Benefit (if any) will be provided for a period of up to eighteen (18) months following such termination and the Special Severance Benefit (if any) will be payable for up to eighteen (18) months following such termination, provided that the total combined number of months covered by the COBRA Severance Benefit and the Special Severance Benefit will be equal to (and may not exceed) eighteen (18) months.

Payment of the Special Severance Benefit (if any) will be made to Employee in a lump sum within sixty (60) days following such Involuntary Termination or Retirement, as applicable.

Notwithstanding the foregoing, the Company will provide Employee with the Special Severance Benefit in lieu of the COBRA Severance Benefit if either (i) Employee is not eligible to continue his or her coverage under the Company's health, dental and vision insurance plans pursuant to COBRA or Employee fails to make an election to continue such coverage pursuant to COBRA within the time period prescribed under COBRA or (ii) the Company determines, at any time and in its sole discretion, that its payment of COBRA Premiums pursuant to the COBRA Severance Benefit would result in a violation of applicable law (including, without limitation, Section 2716 of the Public Health Service Act).

(c) **Equity Vesting Benefit**.

(i) Unless specifically provided otherwise in the applicable equity award agreement, in the event of an Involuntary Termination that is a Change of Control Termination, all equity awards granted by the Company to Employee will become fully vested, effective as of the date of such termination, to the extent that such awards are outstanding and unvested as of the date of such termination (the "***Equity Vesting Benefit***").

(ii) No Equity Vesting Benefit will be provided in the event of an Involuntary Termination that is a Non-Change of Control Termination; *provided*, *however*, that if such Involuntary Termination occurs prior to March 31, 2021, then all stock options granted by the Company to Employee, in each case for which vesting is based solely on the passage of time (the "***Time-Based Options***"), will be credited with an additional six (6) months of vesting, effective as of the date of such termination, to the extent that such Time-Based Options are outstanding and unvested as of the date of such termination.

(iii) In the event of a Retirement, all Time-Based Options will be credited with an additional six (6) months of vesting, effective as of the date of such termination, to the extent that such Time-Based Options are outstanding and unvested as of the date of such termination.

For clarity, the Equity Vesting Benefit will also apply to any stock award granted in substitution for an equity award granted by the Company to Employee by a surviving or acquiring entity in a Change of Control.

(d) **Option Extended Exercise Period Benefit**. In the event of an Involuntary Termination or a Retirement, Employee will be permitted to exercise all stock options granted by the Company to Employee, to the extent that such stock options are outstanding and vested as of the date of such termination (including any stock options that become vested pursuant to Section 2(c) above), for a period ending on the following, as applicable (the "***Option Extended Exercise Period Benefit***"):

(i) if such Involuntary Termination is a Non-Change of Control Termination, the Option Extended Exercise Period Benefit will end on the earlier of (i) one (1) year following the termination of Employee's "Continuous Service" (as defined in the Company's applicable equity plan) (or, if Employee is entitled to exercise such stock option until a later date in accordance with the terms of the stock option agreement, such later date) and (ii) the end of the original full term of such stock option, as specified in the stock option agreement;

(ii) if (x) such Involuntary Termination is a Change of Control Termination and (y) such stock option is assumed or continued, or substituted with a similar stock award, in connection with the Change of Control applicable to such Change of Control Termination, the Option Extended Exercise Period Benefit will end on the earlier of (i) three (3) years following the termination of Employee's "Continuous Service" (as defined in the Company's applicable equity plan) (or, if Employee is entitled to exercise such stock option until a later date in accordance with the terms of the stock option agreement, such later date) and (ii) the end of the original full term of such stock option, as specified in the stock option agreement; and

(iii) in the event of a Retirement, the Option Extended Exercise Period Benefit will end on the earlier of (i) one (1) year following the termination of Employee's "Continuous Service" (as defined in the Company's applicable equity plan) (or, if Employee is entitled to exercise such stock option until a later date in accordance with the terms of the stock option agreement, such later date) and (ii) the end of the original full term of such stock option, as specified in the stock option agreement.

For clarity, the Option Extended Exercise Period Benefit will also apply to any stock award granted in substitution for an equity award granted by the Company to Employee by a surviving or acquiring entity in a Change of Control.

(e) **No Duplication of Benefits**. For the avoidance of doubt, in no event will Employee be entitled to receive any benefits under Section 2 for both a Non-Change of Control Termination, a Change of Control Termination and/or a Retirement.

(f) **Modification of Stock Options**. Employee acknowledges that Sections 2(c) and 2(d) above, if applicable, amend the terms of Employee's currently outstanding stock options granted by the Company to Employee, and as a result, some or all of such stock options may cease, as of the date of this Agreement and/or as of the date of Employee's termination of employment with the Company, to be treated as incentive stock options, in accordance with applicable law.

3. **Other Terminations**. If Employee's employment with the Company terminates due to Cause, Employee's death or Disability, or any other reason (other than due to an Involuntary Termination or a Retirement), then Employee shall not be entitled to receive any benefits under Section 2. The Company, in its sole discretion, will determine the reason for Employee's termination of employment (including, but not limited to, whether such termination is due to Cause or Employee's Disability).

4. **Release**. In order to be eligible to receive any benefits under Section 2, Employee must (i) execute and return the general waiver and release provided by the Company, the terms of which will comply with applicable law and be determined by the Company, in its sole discretion (the "***Release***"), to the Company within the applicable time period set forth therein and (ii) not revoke the Release within the revocation period (if any) set forth therein; *provided, however*, that in no event may the applicable time period or revocation period extend beyond sixty (60) days following Employee's date of termination.

5. **Section 409A**. If any benefit provided under this Agreement is subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"), and the regulations and other guidance thereunder or any state law of similar effect ("***Section 409A***"), and such benefit otherwise is payable in connection with Employee's termination of employment with the Company, then such benefit will not be payable unless such termination constitutes a "separation from service" (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) ("***Separation from Service***"). It is intended that (i) each installment of any benefit payable under this Agreement be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), and (ii) all payments of any such benefits satisfy, to the greatest extent possible, the exemptions from the application of Section

409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company determines that any benefit payable under this Agreement constitutes "deferred compensation" under Section 409A and Employee is a "specified employee" (as such term is defined in Section 409A(a)(2)(B)(i) of the Code) as of the date of Employee's Separation from Service, then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (a) the commencement of such benefit payments will be delayed until the earlier of (1) the date that is six (6) months and one (1) day after such Separation from Service and (2) the date of Employee's death (such applicable date, the "***Delayed Initial Payment Date***"), and (b) the Company will (1) pay Employee a lump sum amount equal to the sum of any benefit payments that Employee otherwise would have received through the Delayed Initial Payment Date if the commencement of such benefit payments had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of such benefit in accordance with the applicable payment schedule set forth in this Agreement. In addition, if the Company determines that any benefit payable under this Agreement constitutes "deferred compensation" under Section 409A and Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which such Separation from Service occurs, then for purposes of such benefit, the Release will not be deemed effective any earlier than the latest permitted effective date set forth therein (which date, in all cases, will be in the subsequent calendar year).

6. **Definition of Terms**. The following terms referred to in this Agreement shall have the following meanings:

(a) **Cause**. "Cause" shall mean the occurrence of any of the following events: (i) Employee's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Company or affiliate documents or records; (ii) Employee's material failure to abide by the code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct) of the Company or an affiliate; (iii) Employee's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of the Company or an affiliate (including, without limitation, Employee's improper use or disclosure of confidential or proprietary information of the Company or an affiliate); (iv) any intentional act by Employee which has a material detrimental effect on the reputation or business of the Company or an affiliate; (v) Employee's repeated failure or inability to perform any reasonable assigned duties after written notice from the Company or an affiliate, and a reasonable opportunity to cure, such failure or inability; (vi) any material breach by Employee of any employment or service agreement between Employee and the Company or an affiliate, which breach is not cured pursuant to the terms of such agreement; or (vii) Employee's conviction (including any plea of guilty or nolo contendere) of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which impairs Employee's ability to perform his or her duties. Any determination by the Company that the employment of Employee was terminated with or without Cause for the purposes of this Agreement shall have no effect upon any determination of the rights or obligations of the Company or Employee for any other purpose.

(b) **Change of Control**. A "Change of Control" shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change of Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change of Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change of Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) over a period of twelve (12) months or less, individuals who, on the date of the Original Agreement, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; *provided*, *however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Agreement, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Agreement, the term Change of Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

(c) **Change of Control Termination**. A "Change of Control Termination" shall mean an Involuntary Termination that occurs upon or within twenty-four (24) months following a Change of Control.

(d) **Disability**. "Disability" shall mean the inability of Employee to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(e) **Entity**. An "Entity" shall mean a corporation, partnership, limited liability company or other entity.

(f) **Exchange Act Person**. An "Exchange Act Person" shall mean any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (the "***Exchange Act***")), except that "Exchange Act Person" shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the date of the Original Agreement, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

(g) **Good Reason**. "Good Reason" shall mean any of the following conditions arising without the consent of Employee: (i) a material reduction in Employee's base compensation (other than in connection with a general reduction in base compensation for most officers of the Company or the successor corporation); (ii) a material reduction in Employee's job duties, responsibilities, and requirements inconsistent with Employee's prior job duties, responsibilities, and requirements, or (iii) a relocation of Employee's principal place of employment that increases Employee's one-way commute by more than thirty-five (35) miles. Notwithstanding anything in this Agreement to the contrary, in order to qualify as a resignation for Good Reason, (x) Employee must provide written notice to the Company of the existence of any of the foregoing conditions that forms the basis for such resignation within ninety (90) days following its initial existence, (y) the Company must fail to remedy such condition within thirty (30) days following such notice, and (z) Employee's termination of employment with the Company must occur within sixty (60) days following the Company's failure to remedy such condition (and in no event later than one hundred eighty (180) days following the initial existence of such condition).

(h) **Involuntary Termination**. An "Involuntary Termination" shall mean a termination of Employee's employment with the Company as a result of either: (i) a termination by the Company without Cause and other than as a result of Employee's death or Disability; or (ii) Employee's resignation for Good Reason.

(i) **Non-Change of Control Termination**. A "Non-Change of Control Termination" shall mean any Involuntary Termination other than a Change of Control Termination.

(j) **Own, Owned, Owner and Ownership**. A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(k) **Retirement**. A "Retirement" shall mean a termination of Employee's employment with the Company on or after March 31, 2021, but no later than December 31, 2021, as a result of Employee's resignation for any reason.

(l) **Subsidiary**. A "Subsidiary" shall mean with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

7. **Conflicts**. Employee represents that Employee's performance of all the terms of this Agreement will not breach any other agreement to which Employee is a party. Employee has not entered, and will not during the term of this Agreement enter, into any oral or written agreement in conflict with any of the provisions of this Agreement.

8. **Successors**. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation, or otherwise) shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Employee's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees, and legatees.

9. **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Employee shall be addressed to Employee at the home address that Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices

shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

10. Parachute Payments.

(a) If any payment or benefit Employee will or may receive from the Company or otherwise (a "***280G Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then any such 280G Payment pursuant to this Agreement (a "***Payment***") shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (*i.e*., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "***Pro Rata Reduction Method***").

(b) Notwithstanding any provision of Section 10(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g*., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not "deferred compensation" within the meaning of Section 409A.

(c) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the event described in Section 280G(b)(2)(A)(i) of the Code shall perform the foregoing calculations. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting such event, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the independent registered public accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to the Company and Employee within thirty (30) calendar days

after the date on which Employee's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by the Company or Employee) or such other time as requested by the Company or Employee.

(d) If Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 10(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Employee agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 10(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 10(a), Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

11. Miscellaneous Provisions.

(a) **No Duty to Mitigate**. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source.

(b) **Modification and Waiver**. No provision of this Agreement shall be modified, amended, waived, or discharged unless the modification, amendment, waiver, or discharge is agreed to in writing and signed by Employee and by the Company. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement; Other Agreements**. No agreements, representations, or understandings (whether oral or written and whether expressed or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes the Prior Agreement and any agreement of the same title and concerning similar subject matter dated prior to the date of this Agreement, and by execution of this Agreement both parties agree that the Prior Agreement and any such predecessor agreement shall be deemed null and void. Any equity awards granted by the Company to Employee prior to, on or after the date of this Agreement will be governed in accordance with their terms, except to the extent specifically modified by this Agreement. For the avoidance of doubt, nothing in this Agreement supersedes or replaces the terms of the Proprietary Information and Inventions Assignment Agreement between the Company and Employee, the terms of which remain in full force and effect.

(d) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions.

(e) **Severability**. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity

or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

(f) **Arbitration**. Any dispute or controversy arising under or in connection with this Agreement may be settled at the option of either party by binding arbitration in the County of Alameda, California, in accordance with the rules of the American Arbitration Association then in effect before a single arbitrator. The judgment may be entered on the arbitrator's award in any court having jurisdiction. Punitive damages shall not be awarded.

(g) **Legal Fees and Expenses**. The parties shall each bear their own expenses, legal fees, and other fees incurred in connection with this Agreement. This means the Company pays its own legal fees in connection with this Agreement and Employee is responsible for Employee's own legal fees in connection with this Agreement. However, the arbitrator may award legal fees and expenses in connection with any arbitration as deemed appropriate.

(h) **No Assignment of Benefits**. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment, or other creditor's process, and any action in violation of this Section 11(h) shall be void.

(i) **Employment Taxes**. All payments made pursuant to this Agreement will be subject to withholding of applicable income and employment taxes.

(j) **Assignment by Company**. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the Company; *provided, however*, that such assignee is the employer of Employee. In the case of any such assignment, the term "Company" when used in a section of this Agreement shall mean the corporation that actually employs Employee except that the term "Company" shall continue to mean Dynavax Technologies Corporation with regard to the definition of a Change of Control.

(k) **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

The parties have executed this Agreement on the date first written above.

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ Ryan Spencer

Title: Chief Executive Officer

Signature: /s/ Michael Ostrach

Address: as indicated in company personnel records

Exhibit 10.4

AMENDMENT NO. 3 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 3 TO TERM LOAN AGREEMENT, dated as of November 2, 2020 (this "***Agreement***"), is made among Dynavax Technologies Corporation, a Delaware corporation (the "***Borrower***"), the Subsidiary Guarantors party hereto, the Lenders party hereto and CRG Servicing LLC, as administrative agent and collateral agent (in such capacities, "***Agent***"), with respect to the Loan Agreement referred to below.

RECITALS

WHEREAS, the Borrower, the Subsidiary Guarantors from time to time party thereto, the Lenders from time to time party thereto and the Agent are parties to that certain Term Loan Agreement, dated as of February 20, 2018, as amended by that certain Waiver and Amendment, dated as of November 20, 2018, that certain Amendment No. 2 to Term Loan Agreement and Fee Letter, dated as of August 7, 2019 and effective as of August 7, 2019, that certain Consent, dated as of April 21, 2020 and that certain Consent, dated as of July 31, 2020 (as further amended, amended and restated, modified or otherwise supplemented from time to time, the "***Loan Agreement***"); and

WHEREAS, the parties hereto desire to amend the Loan Agreement on the terms and subject to the conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Agreement (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.03 of the Loan Agreement shall be applicable to this Agreement and are incorporated herein by this reference.

SECTION 2. Amendment. Subject to **Section 3**, Section 10.02 of the Loan Agreement is hereby amended and restated to read, in its entirety, as follows:

10.02 Minimum Revenue. Obligors shall have annual consolidated Revenue from sales of products (excluding upfront payments, milestones and other similar one-time payments received by any Obligor or any of its Subsidiaries) (for each respective calendar year, the "***Minimum Required Revenue***"):

(a) during the twelve month period beginning on July 1, 2019, of at least $30,000,000;

(b) [intentionally deleted];

(c) during the twelve month period beginning on July 1, 2021, of at least $75,000,000;

(d) during the twelve month period beginning on July 1, 2022, of at least $100,000,000.

(e) [intentionally deleted].

SECTION 3. Conditions to Effectiveness. The effectiveness of **Section 2** shall be subject to the satisfaction of each of the following conditions precedent:

(a) Agent shall have received, in form and substance reasonably satisfactory to it and Lenders, counterparts of this Agreement duly executed by Borrower, Agent and the Majority Lenders.

(b) The Borrower shall have paid or reimbursed Agent and Lenders for their reasonable out of pocket costs and expenses incurred in connection with this Agreement, including their reasonable and documented out of pocket legal fees and costs, pursuant to Section 13.03(a)(i)(z) of the Loan Agreement.

(c) The representations and warranties in **Section 4** shall be true in all material respects on the date hereof and on the date on which each of the foregoing conditions is satisfied.

SECTION 4. Representations and Warranties. Each Obligor hereby represents and warrants to Agent and each Lender as follows:

(a) Such Obligor has full power, authority and legal right to make and perform this Agreement and the Loan Agreement, as modified by this Agreement (the "***Amended Loan Agreement***"). Each of this Agreement and the Amended Loan Agreement is within such Obligor's corporate or equivalent powers and has been duly authorized by all necessary corporate or equivalent action and, if required, by all necessary shareholder action. This Agreement has been duly executed and delivered by such Obligor and each of this Agreement and the Amended Loan Agreement constitutes legal, valid and binding obligations of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). Each of this Agreement and the Amended Loan Agreement (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate any applicable law or regulation or the charter, bylaws or other organizational documents of such Obligor and its Subsidiaries or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, and (z) will not violate or result in an event of default under any material indenture, agreement or other

instrument binding upon any Obligor or any of its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person.

(b) No Default has occurred and is continuing or will result after giving effect to this Agreement.

(c) There has been no Material Adverse Effect since the date of the Loan Agreement.

(d) The representations and warranties made by or with respect to such Obligor in Section 7 of the Loan Agreement are true in all material respects (and, in all respects, for such representations and warranties that are by their terms already qualified as to materiality, material adverse effect or similar language), taking into account any changes made to schedules updated in accordance with Section 7.20 of the Loan Agreement, except that such representations and warranties that refer to a specific earlier date were true in all material respects on such earlier date (and, in all respects, for such representations and warranties that are by their terms already qualified as to materiality, material adverse effect or similar language).

SECTION 5. Reaffirmation. Each Obligor hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Agreement, except as expressly provided herein. By executing this Agreement, each Obligor acknowledges that it has read, consulted with its attorneys regarding, and understands, this Agreement.

SECTION 6. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) **Governing Law**. This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Each Obligor agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the nonexclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 6** is for the benefit of Lenders and the Agent only and, as a result, neither the Agent nor any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, Agent and Lenders may take concurrent proceedings in any number of jurisdictions.

(c) **Waiver of Jury Trial**. EACH OBLIGOR, THE AGENT AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO

THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

SECTION 7. No Actions, Claims, Etc. Each Obligor acknowledges and confirms that it has no knowledge of any actions, causes of action, claims, demands, damages or liabilities of whatever kind or nature, in law or in equity, against any Secured Party, in any case, arising from any action or failure of any Secured Party to act under any Loan Document on or prior to the date hereof, or of any offset right, counterclaim or defense of any kind against any of its respective obligations, indebtedness or liabilities to Secured Party under any Loan Document. Each Obligor unconditionally releases, waives and forever discharges (a) any and all liabilities, obligations, duties, promises or indebtedness of any kind of Agent or any Lender to such Obligor, except the obligations required to be performed by Agent or any Lender under the Loan Documents on or after the date hereof, and (b) all claims, offsets, causes of action, suits or defenses of any kind whatsoever (if any), whether arising at law or in equity, whether known or unknown, which such Obligor might otherwise have against any Secured Party in connection with the Loan Documents or the transactions contemplated thereby, in the case of each of **clauses (a)** and **(b)**, on account of any past or presently existing condition, act, omission, event, contract, liability, obligation, indebtedness, claim, cause of action, defense, circumstance or matter of any kind. Each Obligor acknowledges that it may discover facts or law different from, or in addition to, the facts or law that it knows or believes to be true with respect to the claims released in this **Section 7** and agrees, nonetheless, that this release shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them. Each Obligor expressly acknowledges and agrees that all rights under Section 1542 of the California Civil Code are expressly waived. That section provides:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR."

SECTION 8. Miscellaneous.

(a) **No Waiver**. Nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, Agent and Lenders reserve all rights, privileges and remedies under the Loan Documents (including, without limitation, all such rights, privileges and remedies with respect to any Default, Event of Default or Material Adverse Effect, whether or not communicated to Lenders or Agent). Except as amended hereby, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as modified hereby.

(b) **Severability**. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and

enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Agreement (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Agreement constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart. Receipt by facsimile or other electronic transmission of any executed signature page to this Agreement shall constitute delivery of such signature page.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Agreement and the provisions of any other Loan Document, the provisions of this Agreement shall govern and prevail.

(g) **Loan Document**. This Agreement is a Loan Document.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the day and year first above written.

BORROWER:

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ Michael Ostrach
Name: Michael S. Ostrach
Title: Senior Vice President

AGENT:

CRG SERVICING LLC

By: /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

LENDERS:

CRG ISSUER 2017-1

By: CRG SERVICING LLC,
acting by power of attorney

By: /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

CRG PARTNERS III (CAYMAN) UNLEV AIV 1 L.P.

By: CRG PARTNERS III (CAYMAN) GP L.P.,
its General Partner

By: CRG PARTNERS III GP LLC,
its General Partner

By: /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

Witness: /s/ Nicole Nesson
Name: Nicole Nesson

CRG PARTNERS III-PARALLEL FUND “A” L.P.

By: CRG PARTNERS III-PARALLEL FUND “A” GP L.P.,
its General Partner

By: CRG PARTNERS III GP LLC,
its General Partner

By: /s/ Nathan Hukill
Name: Nathan Hukill
Title: Authorized Signatory

[Signature Page to Amendment No. 3]

Exhibit 31.1

Rule 13a-14(a) Certification of Principal Executive Officer

CERTIFICATIONS

I, Ryan Spencer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ RYAN SPENCER

Ryan Spencer
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2020

Exhibit 31.2

Rule 13a-14(a) Certification of Principal Financial Officer

CERTIFICATIONS

I, Michael Ostrach, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: November 5, 2020

Exhibit 32.1

Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Ryan Spencer, Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020 (the "Periodic Report"), to which this Certificate is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 5th day of November, 2020.

By: /s/ RYAN SPENCER

Ryan Spencer
Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Michael Ostrach, Chief Financial Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020 (the "Periodic Report"), to which this Certificate is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(ii) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 5th day of November, 2020.

By: /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Dynavax Technologies Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.