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, 2021

or

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

For the transition period from to .

Commission file number: 001-34207

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 1, 2021, the registrant had outstanding 119,952,132 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 support the development, manufacture and commercialization of other vaccines containing our CpG 1018® adjuvant, including any potential vaccine for COVID-19 stemming from our multiple collaborations, our ability to manufacture sufficient supply of CpG 1018 to meet potential future demand in connection with new vaccines, 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 its subsidiaries.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found in the more detailed discussion that follows this summary, and the below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described herein as part of your evaluation of an investment in our securities:

- HEPLISAV-B has been launched in the United States, and approved in the European Union, and there is significant competition in these marketplaces. 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.
- Our business and operations have been and may continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic. While we have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop a vaccine for COVID-19, our collaborators generally have primary responsibility for the development, conduct of clinical trials, for seeking and obtaining regulatory approval, and for the manufacture and commercialization of any approved vaccine, and 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 adjuvant are inadequate; we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018 adjuvant.
- Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.
- 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 products or product candidates on commercially reasonable terms.
- We are subject to ongoing United States Food and Drug Administration (“FDA”) and European Medicines Agency (“EMA”) 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 regulatory issues with HEPLISAV-B.
- 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 limit our marketing claims, we may be unable to generate significant revenues, if any.
- 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.
- Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Conversion of the Convertible Notes (defined below) may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.
- Despite recent profitability, we have incurred annual net losses in each year since our inception and anticipate that we could continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and/or continue to sell significant quantities of our CpG 1018 adjuvant, and if we are unable to sustain profitability, the market value of our common stock will likely decline. Until we are able to generate significant revenues or achieve profitability through product sales on a consistent basis, we could require substantial additional capital to finance our operations.
- 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 and product candidates.
- 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.
- 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 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.

- 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.
- HEPLISAV-B and most of our earlier stage programs, including our CpG 1018 adjuvant, rely on oligonucleotide toll-like receptor ("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.
- As we plan for broader commercialization of HEPLISAV-B and for expanded capacity to manufacture our CpG 1018 adjuvant, our financial commitments to increase supply capacity might outpace actual demand for our products. Also, if we are unable to maintain our production operations in Dusseldorf and our existing supplier for CpG 1018 adjuvant, we would have to establish alternate qualified manufacturing capabilities, which could result in significant additional operating costs and delays in developing and commercializing HEPLISAV-B and any approved or potential vaccine utilizing CpG 1018. There can be no assurance that we or other third parties will be able to produce CpG 1018 at a cost, quantity and quality sufficient to support our existing or any future collaborations.
- We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture HEPLISAV-B. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we and our collaborators have limited experience in manufacturing our products and product candidates in commercial quantities. With respect to HEPLISAV-B, we use a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our or our contract manufacturer's ability to provide sufficient supply in this presentation.
- As we continue to grow as a commercial organization and enter into supply agreements with customers and collaborators, those supply agreements will have obligations to deliver product for which we are reliant upon third parties to manufacture on our behalf.
- HEPLISAV-B is subject to regulatory 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.
- A key part of our business strategy for products in development is to establish collaborative relationships to help fund or manage 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 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.
- As we focus on commercialization of HEPLISAV-B, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.
- 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.
- 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 face product liability exposure, which, if not covered by insurance, 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. Significant disruptions of information technology systems or breaches of data security could also adversely affect our business.
- 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.

- 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.
- 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.

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2021 (unaudited)	December 31, 2020 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 246,351	$ 32,073
Marketable securities available-for-sale	167,804	132,963
Accounts and other receivables, net	200,362	22,661
Inventories, net	67,297	63,689
Prepaid manufacturing	109,763	29,423
Prepaid expenses and other current assets	61,093	9,206
Total current assets	852,670	290,015
Property and equipment, net	34,251	30,567
Operating lease right-of-use assets	26,772	26,583
Goodwill	2,171	2,297
Restricted cash	224	237
Other assets	3,623	3,573
Total assets	$ 919,711	$ 353,272
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,596	$ 3,312
Accrued research and development	3,935	2,805
Accrued liabilities	87,910	19,099
Warrant liability	72,017	10,736
Deferred revenue	358,588	38,212
Other current liabilities	2,889	3,247
Total current liabilities	528,935	77,411
Long-term debt, net of debt discount of $1,094 at December 31, 2020	-	179,811
Convertible Notes, net of debt discount of $5,277 at September 30, 2021 (see Note 7)	220,223	-
Long-term deferred revenue	67,969	-
Long-term portion of lease liabilities	34,929	34,789
Other long-term liabilities	79	2,568
Total liabilities	852,135	294,579
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock: $0.001 par value		
Authorized: 5,000 shares; Issued and outstanding:	-	-
Series B Convertible Preferred stock– no shares and 4 shares at September 30, 2021 and December 31, 2020, respectively	-	-
Common stock: $0.001 par value; 278,000 shares authorized at September 30, 2021 and December 31, 2020; 119,787 shares and 110,190 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	120	110
Additional paid-in capital	1,386,114	1,352,374
Accumulated other comprehensive (loss) gain	(1,528)	273
Accumulated deficit	(1,317,130)	(1,294,064)
Total stockholders' equity	67,576	58,693
Total liabilities and stockholders' equity	$ 919,711	$ 353,272

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,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	$ 106,996	$ 13,276	$ 242,558	$ 26,195
Other revenue	1,274	138	1,814	806
Total revenues	108,270	13,414	244,372	27,001
Operating expenses:				
Cost of sales - product	60,090	4,031	99,560	7,352
Cost of sales - amortization of intangible assets	-	-	-	2,500
Research and development	6,186	8,521	21,111	19,058
Selling, general and administrative	26,926	21,538	70,932	61,418
Gain on sale of assets (Note 5)	(1,000)	(6,851)	(1,000)	(6,851)
Total operating expenses	92,202	27,239	190,603	83,477
Income (loss) from operations	16,068	(13,825)	53,769	(56,476)
Other income (expense):				
Interest income	39	269	134	1,190
Interest expense	(1,676)	(4,794)	(9,497)	(14,257)
Sublease income	2,022	1,926	5,714	5,779
Loss on debt extinguishment (Note 8)	-	-	(5,232)	-
Change in fair value of warrant liability (Note 11)	(45,121)	21,245	(68,576)	4,200
Other	238	(420)	622	(209)
Net (loss) income	(28,430)	4,401	(23,066)	(59,773)
Net (loss) income per share attributable to common stockholders				
Basic	$ (0.24)	$ 0.04	$ (0.20)	$ (0.61)
Diluted	$ (0.24)	$ (0.15)	$ (0.20)	$ (0.65)
Weighted-average shares used in computing net (loss) income per share attributable to common stockholders:				
Basic	116,903	109,816	114,540	97,589
Diluted	116,903	111,973	114,540	98,577

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	$ (28,430)	$ 4,401	$ (23,066)	$ (59,773)
Other comprehensive (loss) income, net of tax:				
Reclassification of realized gain on available-for-sale securities recognized in interest income	-	(108)	-	(21)
Change in unrealized gain (loss) on marketable securities available-for-sale	(18)	(75)	11	30
Foreign currency translation adjustments	(797)	1,256	(1,812)	1,356
Total other comprehensive (loss) income	(815)	1,073	(1,801)	1,365
Total comprehensive (loss) income	$ (29,245)	$ 5,474	$ (24,867)	$ (58,408)

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, 2021	Shares	Par Amount	Shares	Par Amount	Capital	(Loss) Income	Deficit	Equity
Balances at June 30, 2021	114,756	$ 114	4	$ -	$ 1,372,679	$ (713)	$ (1,288,700)	$ 83,380
Issuance of common stock upon exercise of stock options and restricted stock awards, net	582	2	-	-	3,980	-	-	3,982
Issuance of common stock upon exercise of warrants	196	-	-	-	3,625	-	-	3,625
Conversion of preferred stock	4,140	4	(4)	-	(4)	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	113	-	-	-	458	-	-	458
Stock compensation expense	-	-	-	-	5,376	-	-	5,376
Total other comprehensive loss	-	-	-	-	-	(815)	-	(815)
Net loss	-	-	-	-	-	-	(28,430)	(28,430)
Balances at September 30, 2021	119,787	$ 120	-	$ -	$ 1,386,114	$ (1,528)	$ (1,317,130)	$ 67,576
Nine Months Ended September 30, 2021								
Balances at December 31, 2020	110,190	$ 110	4	$ -	$ 1,352,374	$ 273	$ (1,294,064)	$ 58,693
Issuance of common stock upon exercise of stock options and restricted stock awards, net	1,415	2	-	-	5,315	-	-	5,317
Issuance of common stock upon exercise of warrants	946	1	-	-	11,552	-	-	11,553
Conversion of preferred stock	4,140	4	(4)	-	(4)	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	217	-	-	-	841	-	-	841
Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (see Note 11)	2,879	3	-	-	28,153	-	-	28,156
Issuance of capped call options	-	-	-	-	(27,240)	-	-	(27,240)
Stock compensation expense	-	-	-	-	15,123	-	-	15,123
Total other comprehensive loss	-	-	-	-	-	(1,801)	-	(1,801)
Net loss	-	-	-	-	-	-	(23,066)	(23,066)
Balances at September 30, 2021	119,787	$ 120	-	$ -	$ 1,386,114	$ (1,528)	$ (1,317,130)	$ 67,576

	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

See accompanying notes.

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

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (23,066)	$ (59,773)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,280	3,166
Amortization of right-of-use assets	2,013	1,906
Gain on disposal of property and equipment and from lease termination	-	(76)
Amortization of premium (accretion of discounts) on marketable securities	442	193
Realized gain on available-for-sale securities	-	(56)
Loss on debt extinguishment	5,232	-
Change in fair value of warrant liability	68,576	(4,200)
Stock compensation expense	15,123	9,968
Cost of sales - amortization of intangible assets	-	2,500
Non-cash interest expense	2,546	2,129
Tenant improvements provided by the landlord	-	908
Gain on sale of assets	(1,000)	(6,851)
Changes in operating assets and liabilities:		
Accounts and other receivables, net	(177,701)	(22,137)
Inventories, net	(3,608)	(17,701)
Prepaid manufacturing	(80,340)	-
Prepaid expenses and other current assets	(51,887)	(11,406)
Other assets	(50)	106
Accounts payable	(545)	(1,433)
Lease liabilities	(2,416)	(2,131)
Deferred revenue	320,376	21,712
Long-term deferred revenue	67,969	-
Accrued liabilities and other liabilities	70,087	6,668
Net cash provided by (used in) operating activities	215,031	(76,508)
Investing activities		
Acquisition of technology licenses	-	(7,000)
Purchases of marketable securities	(164,927)	(171,982)
Proceeds from maturities and redemptions of marketable securities	129,655	117,650
Proceeds from sales of marketable securities	-	20,902
Purchases of property and equipment, net	(6,441)	(3,303)
Proceeds from sale of assets, net of transaction costs	1,000	2,859
Net cash used in investing activities	(40,713)	(40,874)
Financing activities		
Proceeds from issuance of common stock, net	28,156	108,537
Proceeds from issuance of Convertible Notes, net	219,822	-
Purchases of capped call options	(27,240)	-
Repayment of long-term debt	(190,194)	-
Proceeds from warrants exercises	4,258	-
Proceeds from exercise of stock options and restricted stock awards, net	5,317	224
Proceeds from Employee Stock Purchase Plan	841	672
Net cash provided by financing activities	40,960	109,433
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1,013)	763
Net increase (decrease) in cash, cash equivalents and restricted cash	214,265	(7,186)
Cash, cash equivalents and restricted cash at beginning of period	32,310	40,100
Cash, cash equivalents and restricted cash at end of period	$ 246,575	$ 32,914
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 6,965	$ 12,149
Non-cash investing and financing activities:		
Purchases of property and equipment, not yet paid	$ 1,561	$ -
Right-of-use assets obtained in exchange of lease liabilities (modification)	$ 2,468	$ 364

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 focused on developing and commercializing novel vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We also manufacture and sell CpG 1018®, the adjuvant used in HEPLISAV-B. We are working to develop CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis, plague and universal influenza.

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, 2020 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, 2020, 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 subsidiaries, Dynavax GmbH located in Düsseldorf, Germany and Dynavax India LLP in India. 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, 2021, we had cash, cash equivalents and marketable securities of $414.2 million. In May 2021, we issued $225.5 million in 2.50% convertible senior notes due 2026 ("Convertible Notes"). We used approximately $190.2 million of the net proceeds to retire our previous loan agreement with CRG Servicing LLC (see Note 8) and $27.2 million of the net proceeds to pay the costs of the capped call transactions (the "Capped Calls") (see Note 7). As of September 30, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.3 million (see Note 7). The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and nine months ended September 30, 2021, we recorded net loss of $28.4 million and $23.1 million, respectively. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development of our CpG 1018 adjuvant and clinical trials and other development. 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, 2021, 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.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that may affect the amounts reported in the condensed consolidated financial statements and accompanying notes, including amounts of revenues and expenses during the reported periods. 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. On an ongoing basis, we evaluate our estimates, judgments and methodologies. Significant estimates and assumptions in the condensed consolidated financial statements include those related to revenue recognition; accounts receivable; useful lives of long-lived assets, impairment of long-lived assets, including goodwill; valuation procedures for right-of-use assets and operating lease liabilities; valuation of inventory; fair value of warrants; balance sheet classification of Convertible Notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; contingencies and share-based compensation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from these estimates under different assumptions or conditions and could be further impacted by the COVID-19 pandemic. Changes in estimates are reflected in reported results in the period in which they become known.

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. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

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 three and nine months ended September 30, 2021 and 2020.

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 CpG 1018 adjuvant to certain of our collaboration partners for use in their development and/or commercialization of their respective COVID-19 vaccine candidates. We have determined that our collaboration partners in these arrangements meet the definition of customers under ASC 606. Therefore, we account for product sales of CpG 1018 adjuvant under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligations which include the transfer of control of our product to the collaboration partner, generally upon shipment or delivery. The timing between the recognition of revenue and the receipt of payment is less than one year. As such, we do not adjust the amount of consideration for the effects of a significant financing component. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contracts with our customers. 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, in accordance with ASC 606. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment.

Other Revenue

Other revenue includes 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.

Inventories, net

HEPLISAV-B Inventories, net

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 three and nine months ended September 30, 2021 and 2020, 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 United States Food and Drug Administration (“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.

CpG 1018 Inventories, net

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 three and nine months ended September 30, 2021 and 2020, there were no inventory reserves recognized.

Convertible Notes

We evaluate all conversion, repurchase and redemption features contained in a debt instrument to determine if there are any embedded features that require bifurcation as a derivative. We accounted for the Convertible Notes (see Note 7) as a long-term liability equal to the proceeds received from issuance, including the embedded conversion feature, net of the unamortized debt issuance and offering costs on the condensed consolidated balance sheets. The conversion feature is not required to be accounted for separately as an embedded derivative. We amortize debt issuance and offering costs over the contractual term of the Convertible Notes, using the effective interest method, as interest expense on the condensed consolidated statements of operations.

Capped Calls

We evaluate financial instruments under ASC 815. In May 2021, in connection with the issuance of the Convertible Notes, we entered into the Capped Calls (see Note 7). The Capped Calls cover the same number of shares of common stock that initially underlie the Convertible Notes (subject to anti-dilution and certain other adjustments). The Capped Calls meet the definition of derivative

under ASC 815. In addition, the Capped Calls meet the conditions in ASC 815 to be classified in stockholders' equity and are not subsequently remeasured as long as the conditions for the equity classification continue to be met.

Recent Accounting Pronouncements

Accounting Standards Update 2019-12

In December 2019, the FASB issued Accounting Standards Update ("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 adopted this ASU on January 1, 2021 and the adoption of this standard did not have a material impact on our consolidated financial statements.

Accounting Standards Update 2020-06

We adopted 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 on January 1, 2021 using the modified retrospective method. This ASU simplifies the accounting for convertible instruments and requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. Entities also need to recombine instruments that were previously separated into two units of account if separation is no longer required. The adoption of this ASU did not have a material impact on our condensed consolidated financial statements as there were no outstanding financial instruments that require recombination at January 1, 2021.

Accounting Standards Update 2016-13

In June 2016, the Financial Accounting Standards Board ("FASB") issued 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. For public business entities, excluding smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2019. Furthermore, the one-time determination of whether an entity is eligible to be a smaller reporting company shall be based on an entity's most recent determination as of November 15, 2019, in accordance with SEC regulations. Because we were a smaller reporting company based on the most recent determination as of November 15, 2019, this ASU and its subsequent updates, will be effective for fiscal years beginning after December 15, 2022. We are currently evaluating the impact this standard will have on our 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 three and nine months ended September 30, 2021.

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, 2021				
Assets				
Money market funds	$ 241,451	$ -	$ -	$ 241,451
U.S. treasuries	-	12,281	-	12,281
U.S. government agency securities	-	36,343	-	36,343
Corporate debt securities	-	119,180	-	119,180
Total assets	$ 241,451	$ 167,804	$ -	$ 409,255
Liabilities				
Warrant liability	$ -	$ -	$ 72,017	$ 72,017

	Level 1	Level 2	Level 3	Total
December 31, 2020				
Assets				
Money market funds	$ 23,128	$ -	$ -	$ 23,128
U.S. treasuries	-	32,579	-	32,579
U.S. government agency securities	-	40,321	-	40,321
Corporate debt securities	-	61,063	-	61,063
Total assets	$ 23,128	$ 133,963	$ -	$ 157,091
Liabilities				
Warrant liability	$ -	$ -	$ 10,736	$ 10,736

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, 2021, we used the following key assumptions to estimate the fair value of warrant liability:

Number of shares	4,895,100
Expected term	0.4 year
Expected volatility	0.8
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, 2021 (in thousands):

Balance at December 31, 2020	$	10,736
Increase in fair value of warrants exercised		4,776
Warrants exercised		(7,295)
Increase in the estimated fair value of warrant liability upon revaluation		63,800
Balance at September 30, 2021	$	72,017

Convertible Notes

As of September 30, 2021, the fair value of the Convertible Notes was $457.2 million. The fair value was estimated using a reputable third-party valuation model based on observable inputs and is considered Level 2 in the fair value hierarchy (see Note 7). estimate of fair value using their proprietary model

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, 2021	December 31, 2020	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 246,351	$ 32,073	$ 32,688	$ 39,884
Restricted cash	224	237	226	216
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 246,575	$ 32,310	$ 32,914	$ 40,100

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 5).

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2021				
Cash and cash equivalents:				
Cash	$ 4,900	$ -	$ -	$ 4,900
Money market funds	241,451	-	-	241,451
Total cash and cash equivalents	246,351	-	-	246,351
Marketable securities available-for-sale:				
U.S. treasuries	12,279	2	-	12,281
U.S. government agency securities	36,338	5	-	36,343
Corporate debt securities	119,145	35	-	119,180
Total marketable securities available-for-sale	167,762	42	-	167,804
Total cash, cash equivalents and marketable securities	$ 414,113	$ 42	$ -	$ 414,155
December 31, 2020				
Cash and cash equivalents:				
Cash	$ 7,945	$ -	$ -	$ 7,945
Money market funds	23,128	-	-	23,128
Corporate debt securities	1,000	-	-	1,000
Total cash and cash equivalents	32,073	-	-	32,073
Marketable securities available-for-sale:				
U.S. treasuries	32,548	31	-	32,579
U.S. government agency securities	40,313	14	(6)	40,321
Corporate debt securities	60,071	3	(11)	60,063
Total marketable securities available-for-sale	132,932	48	(17)	132,963
Total cash, cash equivalents and marketable securities	$ 165,005	$ 48	$ (17)	$ 165,036

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

	September 30, 2021	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 167,762	$ 167,804
Mature after one year through two years	-	-
	$ 167,762	$ 167,804

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.

There were no realized gains or losses from the sale of marketable securities during the three and nine months ended September 30, 2021. 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. All investments with unrealized losses at September 30, 2021 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, 2021	December 31, 2020
Raw materials	$ 30,332	$ 25,121
Work-in-process	9,956	30,293
Finished goods	27,009	8,275
Total	$ 67,297	$ 63,689

As of September 30, 2021 and December 31, 2020, included in finished goods inventory was $22.2 million and $6.7 million of HEPLISAV-B inventory, respectively. The remaining balance in finished goods inventory was CpG 1018. There was no CpG 1018 balance within raw materials and work-in-process inventory as of September 30, 2021 and December 31, 2020.

We recorded prepaid manufacturing costs related to prepayments made to third-party manufacturers of CpG 1018 adjuvant, of $109.8 million and $29.4 million as of September 30, 2021 and December 31, 2020, respectively. We expect these costs to be converted into inventory within the next twelve months.

5. 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”) for our corporate headquarters. 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.

In September 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 have received tenant improvement allowance totaling $8.1 million through September 30, 2021. 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, 2021 condensed consolidated balance sheets primarily relate to the Horton Street Master Lease. Lease expense related to the Horton Street Master Lease is included in operating expense in our condensed consolidated statements of operations.

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. For the three and nine months ended September 30, 2021, we recognized sublease income of $2.0 million and $5.7 million, respectively. For the three and nine months ended September 30, 2020, we recognized sublease income of $1.9 million and $5.8 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.

In September 2021, we entered into a commercial lease agreement in Düsseldorf, Germany (the "New Düsseldorf Lease"). The New Düsseldorf Lease is for the same space that we currently lease in Düsseldorf, Germany and with the same landlord. Our existing lease will continue until December 31, 2021, at which point the New Düsseldorf Lease will be in effect. We have determined that the New Düsseldorf Lease qualifies as a modification not accounted for as a separate contract. The New Düsseldorf Lease has an initial term of 10 years, beginning on January 1, 2022, 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 assets and liabilities as we did not consider it reasonably certain that we would exercise the options. Beginning on January 1, 2024, the base rent is subject to an annual increase at the same percentage of Consumer Price Index of Germany. We are also responsible for certain operating expenses and taxes throughout the life of the New Düsseldorf Lease. We used our estimated incremental borrowing rate of 10.1% to recognize the initial right-of-use asset for the New Düsseldorf Lease.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease expense	$ 1,535	$ 1,550	$ 4,665	$ 4,703

Cash paid for amounts included in the measurement of lease liabilities for the nine months ended September 30, 2021 and 2020 was $5.2 million and $5.1 million, respectively, was included in change in lease liabilities in our condensed consolidated statement of cash flows.

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

	September 30, 2021	December 31, 2020
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 2,889	$ 3,247
Long-term portion of lease liabilities	34,929	34,789
Total operating lease liabilities	$ 37,818	$ 38,036

At September 30, 2021, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2021 (remaining)	$ 1,324	$ 1,768
2022	5,357	6,186
2023	5,518	5,652
2024	5,684	5,796
2025	5,854	5,945
Thereafter	33,742	34,444
Total	$ 57,479	59,791
Less:		
Present value adjustment		(21,973)
Total		$ 37,818

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

	September 30, 2021	December 31, 2020
Weighted average remaining lease term	9.2 years	9.1 years
Weighted average discount rate	10.1%	10.1%

Commitments

As of September 30, 2021, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 and for clinical research, totaled $149.3 million.

As of September 30, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.3 million (see Note 7). The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

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, 2021 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, 2021.

Sales of SD-101 Program

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 and $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 conjunction with our agreement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC ("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 September 2021, we received payment of $1 million from TriSalus for their meeting a pre-commercialization milestone. In connection with the milestone payment received from TriSalus and under our agreement with Holdings, we paid Holdings $0.5 million. For the three and nine months ended September 30, 2021, we recognized a gain on sale of SD-101 assets of $1 million in our condensed consolidated statements of operations. The $0.5 million payment to Holdings was included in selling, general and administrative expense in our condensed consolidated statements of operations for the three and nine months ended September 30, 2021.

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.

6. Collaboration, Development and Supply Agreements

Coalition for Epidemic Preparedness Innovations

In January 2021, we entered into an agreement (the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant ("CpG 1018 Materials"). The CEPI Agreement enables CEPI to direct the supply of CpG 1018 Materials to CEPI partner(s). CEPI partner(s) would purchase CpG 1018 Materials under separately negotiated agreements. The CEPI Agreement also allows us to sell CpG 1018 Materials to third parties if not purchased by a CEPI partner within a two-year term.

In exchange for reserving CpG 1018 Materials and agreeing to sell CpG 1018 Materials to CEPI partner(s) at pre-negotiated prices, CEPI agreed to provide payments in the form of an interest-free, unsecured, forgivable loan (the "Advance Payments") of up to $99.0 million. We are obligated to repay the Advance Payments, in proportion to quantity sold, if and to the extent we receive payments from sales of CpG 1018 Materials reserved under the CEPI Agreement. If the vaccine programs pursued by CEPI partner(s)

are unsuccessful and no alternative use is found for CpG 1018 Materials reserved under the CEPI Agreement, the applicable Advance Payments will be forgiven at the end of the two-year term.

In May 2021, we entered into the first Amendment to the CEPI Agreement. This Amendment provided for the manufacture and reservation of an additional specified quantity of CpG 1018 adjuvant. In exchange for reserving an additional specified quantity of CpG 1018 adjuvant, CEPI agreed to provide additional Advance Payments of up to $77.4 million, together with the initial CEPI Agreement, for total Advance Payments of up to $176.4 million.

We determined that the accounting of the Advance Payments is under the scope of ASC 606. The Advance Payments are to cover the costs of manufacture and to reserve CpG 1018 Materials, which is an output of our ordinary activities. As such, the Advance Payments are initially classified as long-term deferred revenue in our condensed consolidated balance sheets. We are obligated to repay CEPI, in proportion to quantity sold and within a certain period, upon receipt of payment from CEPI partner(s). Thus, when we deliver CpG 1018 Materials to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the Advanced Payments from long-term deferred revenue to accrued liabilities. We recognize the Advance Payments as revenue when the amount (or a portion thereof) is forgiven by CEPI when (i) the CpG 1018 Materials are not sold through to CEPI partner(s), (ii) there is no alternative use and (iii) the CpG 1018 Materials are destroyed.

Through September 30, 2021, we have received Advance Payments totaling approximately $129.4 million pursuant to the CEPI Agreement. As of September 30, 2021, Advance Payments totaling $68.0 million and $58.9 million, were recorded as long-term deferred revenue and accrued liabilities, respectively, in our condensed consolidated balance sheets. No revenue was recognized for the three and nine months ended September 30, 2021.

Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc.

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, “Clover”), for the commercial supply of CpG 1018 adjuvant, for use with Clover’s COVID-19 vaccine candidate, SCB-2019 (the “Clover Supply Agreement”). Under the Clover Supply Agreement, Clover has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Clover’s commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant (“Clover Product”). The Clover Supply Agreement also provides terms for Clover to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI.

Pricing for CpG 1018 adjuvant is variable depending on the destination where Clover ultimately sells Clover Product to. Pursuant to the Clover Supply Agreement, our initial invoicing is at the lowest price tier, with a true-up mechanism to issue additional invoice for the difference between the initial invoice price and the higher tiered price, if any. In addition, if the net selling price of such Clover Product exceeds a threshold specified in the Clover Supply Agreement, we are entitled to a royalty calculated as a percentage of the excess portion of such net selling price.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay the purchase price upon the earliest of (i) the true-up exercise, (ii) within a specified period after Clover delivers Clover Product to a customer, or (iii) Clover’s receipt of payment for Clover Product from a customer. For CpG 1018 adjuvant ordered by Clover outside the CEPI Agreement, Clover is obligated to pay a specified percentage of the purchase price, as set forth in a purchase order submitted by Clover, upon our acceptance of such purchase order, and the remainder of the purchase price upon the release of such CpG 1018 adjuvant.

We recognize revenue at the lowest price tier upon transfer of control of CpG 1018 adjuvant to Clover. The potential true-up amount and royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue. When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement, we recognize product revenue and a corresponding contract asset as our right to consideration is contingent on something other than the passage of time, as outlined above.

As of September 30, 2021, our contract asset balance of $52.4 million was included in other current assets in our condensed consolidated balance sheets. There was no contract asset balance at the beginning of the period. As of September 30, 2021, we recognized approximately $192.9 million in deferred revenue for a portion of Clover’s binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement. There was no deferred revenue recognized for a portion of Clover’s binding commitment to purchase CpG 1018 adjuvant that was reserved for Clover under the CEPI Agreement. For the three and nine months ended September 30,2021, we recognized CpG 1018 product revenue of $52.4 million and $58.2 million, respectively.

Biological E. Limited

In July 2021, we entered into an agreement (the “Bio E Supply Agreement”) with Biological E. Limited (“Bio E”), for the commercial supply of CpG 1018 adjuvant, for use with Bio E’s subunit COVID-19 vaccine candidate, CORBEVAX™. Under the Bio E Supply Agreement, Bio E has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E’s commercialization of its CORBEVAX vaccine (“Bio E Product”) with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides terms for Bio E to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI.

Pricing for CpG 1018 adjuvant is variable depending on the destination where Bio E ultimately sells Bio E Product to. Pursuant to the Bio E Supply Agreement, our initial invoicing will be at the lowest price tier, with a true-up mechanism to issue additional invoice for the difference between the initial invoice price and the higher tiered price, if any. In addition, if the net selling price of such Bio E Product exceeds a threshold specified in the Bio E Supply Agreement, we are entitled to a royalty calculated as a percentage of the excess portion of such net selling price.

For CpG 1018 adjuvant reserved for Bio E under the CEPI Agreement, Bio E is obligated to pay, in full, the aggregate purchase price, as set forth in a purchase order submitted by Bio E, upon delivery of CpG 1018 adjuvant. For CpG 1018 adjuvant ordered by Bio E outside the CEPI Agreement, Bio E is obligated to pay a specified percentage of the purchase price, as set forth in a purchase order submitted by Bio E, upon our acceptance of such purchase order, and the remainder of the purchase price upon the delivery of such CpG 1018 adjuvant.

We recognize revenue at the lowest price tier upon transfer of control of CpG 1018 adjuvant to Bio E. The potential true-up amount and royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue.

As of September 30, 2021, we recognized approximately $110.2 million in deferred revenue for a portion of Bio E’s binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement. There was no deferred revenue recognized for a portion of Bio E’s binding commitment to purchase CpG 1018 adjuvant that was reserved for Bio E under the CEPI Agreement. For the three and nine months ended September 30,2021, we recognized CpG 1018 product revenue of $25.0 million and $25.9 million, respectively.

Medigen Vaccine Biologics

In February 2021, we entered into a Supply Agreement (“Medigen Supply Agreement”) with Medigen Vaccine Biologics (“Medigen”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen’s COVID-19 vaccine for delivery in the first and second quarters of 2021. Pursuant to the Medigen Supply Agreement, we recognized CpG 1018 product revenue of $6.9 million and $10.6 million in the first and second quarter of 2021, respectively.

In August 2021, we entered into a second supply agreement (“Medigen Supply Agreement No. 2”) to manufacture and supply additional specified quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021.

Under Medigen Supply Agreement No. 2, pricing for CpG 1018 adjuvant is variable depending on the destination where Medigen ultimately sells Medigen Product to. Pursuant to the Medigen Supply Agreement No. 2, we invoice Medigen based on the highest-tier price, with a true-up mechanism to issue credit to Medigen for the difference between the initial invoice price and the lower tiered price, if any. We invoice Medigen a specified percentage of the aggregate price of the order upon acceptance of the order and the remaining upon delivery. In addition, we are entitled to a royalty calculated as a percentage of the adjusted net sales.

We recognize revenue upon transfer of control of CpG 1018 adjuvant to Medigen at the highest-tiered price. The potential royalties are considered constrained. There is no significant financing component, as the timing between shipment and payment is expected to be within twelve months. Payments received or invoices issued before we transfer control of CpG 1018 adjuvant are recorded as deferred revenue.

Pursuant to the Supply Agreement No. 2, we recognized CpG 1018 product revenue of $6.9 million in the third quarter of 2021.

Valneva SE

In April 2020, we entered into a collaboration agreement ("Valneva Collaboration Agreement") with Valneva Scotland Limited (“Valneva”) to provide CpG 1018 adjuvant for use in the development of Valneva’s COVID-19 vaccine candidate ("VLA2001). The

Valneva Collaboration Agreement was amended in July 2020, to provide additional quantities of CpG 1018 adjuvant. In September 2020, we entered into a supply agreement (“Valneva Supply Agreement”) with Valneva to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the commercialization of VLA2001.

We concluded that the Valneva Collaboration Agreement and the Valneva 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 to provide CpG 1018 adjuvant to Valneva. Therefore, the Valneva Collaboration Agreement and the Valneva Supply Agreement should be combined and accounted for as a single arrangement.

Pursuant to the Valneva Supply Agreement, we received advanced payments to purchase specified quantities of CpG 1018 adjuvant which were recorded as deferred revenue until we deliver CpG 1018 adjuvant to Valneva. As of September 30, 2021, deferred revenue related to the Valneva Supply Agreement was $55.4 million. No CpG 1018 product revenue was recognized for the three months ended September 30, 2021. For the nine months ended September 30, 2021, we recognized CpG 1018 product revenue of $89.4 million.

In October 2021, we entered into a letter agreement with Valneva, amending the Valneva Supply Agreement. See Note 13.

Bill & Melinda Gates Foundation Grant

In July 2020, we entered into a grant agreement (the "BMGF 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 and we received $1.2 million of the grant from BMGF which we accounted for as deferred revenue in our condensed consolidated balance sheets since September 30, 2020.

In July 2021, the BMGF Grant Agreement expired. Pursuant to the BMGF Grant Agreement, we were not obligated to return the $1.2 million funding that we spent on grant-related activities. In the three and nine months ended September 30, 2021, we recognized $1.2 million as other revenue in our condensed consolidated statements of operations.

U.S. Department of Defense

In September 2021, we entered into an agreement with the U.S. Department of Defense ("DOD") for the development of a recombinant plague vaccine adjuvanted with CpG 1018 for approximately $22.0 million over two and a half years. Under the agreement, we will conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DOD's rF1V vaccine. We anticipate the Phase 2 trial will commence in 2022.

7. Convertible Notes

In May 2021, we issued $200.0 million aggregate principal amount of 2.50% convertible senior notes due 2026 in a private placement. The purchasers also partially exercised their option to purchase additional Convertible Notes in May 2021 and we issued an additional $25.5 million of the Convertible Notes. Total proceeds from the issuance of the Convertible Notes, net of debt issuance and offering costs of $5.7 million, were $219.8 million. We used $190.2 million of the net proceeds to repay, in full, our outstanding debt and other obligations under the Loan Agreement and $27.2 million of the net proceeds to pay the costs of the capped call transactions described below.

The Convertible Notes are general unsecured obligations and accrue interest at a rate of 2.50% per annum payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

The Convertible Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, at an initial conversion rate of 95.5338 shares of our common stock per $1,000 principal amount of the Convertible Notes, which is equivalent to an initial conversion price of approximately $10.47 per share of our common stock. The Convertible Notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding February 15, 2026, only under the following circumstances:

1. During any calendar quarter commencing after September 30, 2021 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

2. During the five business day period after any ten consecutive trading day period (the “measurement period”), in which the “trading price” (as defined the indenture governing the Convertible Notes) per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;
3. If we call such Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
4. Upon the occurrence of specified corporate events as set forth in the indenture governing the Convertible Notes.

On or after February 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders of the Convertible Notes may convert all or any portion of their Convertible Notes regardless of the foregoing circumstances. During the period from issuance to September 30, 2021, the conditions allowing holders of the Convertible Notes to convert have not been met and there were no changes to the initial conversion price of the Convertible Notes.

On October 1, 2021, the conditional conversion feature of the Convertible Notes was triggered as the last reported sale price of our common stock was more than or equal to 130% of the conversion price for at least 20 trading days in the period of 30 consecutive trading days ending on September 30, 2021 (the last trading day of the immediately preceding fiscal quarter), and therefore the Convertible Notes are currently convertible, in whole or in part, at the option of the holders between October 1, 2021 through December 31, 2021. Whether the Convertible Notes will be convertible following such period will depend on the continued satisfaction of this condition or another conversion condition in the future. As of November 4, 2021, we had not received any conversion notices. Since we have the election of repaying the Convertible Notes in cash, shares of our common stock, or a combination of both, we continued to classify the Convertible Notes as long-term debt on the condensed consolidated balance sheets as of September 30, 2021.

We may redeem for cash all or any portion of the Convertible Notes, at our option, on or after May 20, 2024 and prior to the 31st scheduled trading day immediately preceding the maturity date, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on the trading day immediately preceding the date on which we provide notice of redemption, at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If we undergo a fundamental change (as set forth in the indenture governing the Convertible Notes), noteholders may require us to repurchase for cash all or any portion of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to the fundamental change repurchase date. In addition, following certain corporate events (as set forth in the indenture governing the Convertible Notes) or if we deliver a notice of redemption prior to the maturity date, we will, in certain circumstances, adjust the conversion rate for a noteholder who elects to convert its notes in connection with such a corporate event or such notice of redemption.

As a result of adopting ASU 2020-06, we accounted for the Convertible Notes as a single liability. As of September 30, 2021, the Convertible Notes were recorded at the aggregate principal amount of $225.5 million less unamortized issuance costs of $5.3 million as a long-term liability on the condensed consolidated balance sheets. As of September 30, 2021, the fair value of the Convertible Notes was $457.2 million. See Note 2. The debt issuance costs are amortized to interest expense over the contractual term of the Convertible Notes at an effective interest rate of 3.1%.

The following table presents the components of interest expense related to Convertible Notes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stated coupon interest	$ 1,409	$ -	$ 2,145	$ -
Amortization of debt issuance cost	265	-	402	-
Total interest expense	$ 1,674	$ -	$ 2,547	$ -

Capped Calls

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers of the Convertible Notes and other financial institutions, totaling $27.2 million (the “Capped Calls”). The Capped Calls cover, subject to customary adjustments, the number of shares of our common stock that initially underlie the Convertible Notes (or 21,542,871 shares of our common stock). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments. Conditions that cause adjustments to the initial strike price of the

Capped Calls mirror conditions that result in corresponding adjustments to the conversion price of the Convertible Notes. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

For accounting purposes, the Capped Calls are considered separate financial instruments and not part of the Convertible Notes. As the Capped Calls transactions meet certain accounting criteria, we recorded the cost of the Capped Calls, totaling $27.2 million, as a reduction to additional paid-in capital within the condensed consolidated statements of stockholders' equity.

8. Long-Term Debt

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"). Net proceeds under the Loan Agreement were $173.3 million. The Term Loans under the Loan Agreement bore interest at a rate equal to 9.5% per annum. The Term Loans had a maturity date of December 31, 2023.

In May 2021, we repaid the principal on the Term Loans, in full, using the net proceeds from the Convertible Notes issuance. In connection with the early repayment of the Term Loans, in the second quarter of 2021, we recorded $5.2 million loss on debt extinguishment related to the amount we paid to terminate the Term Loans in excess of its carrying value at the time of the repayment. Our final payment of $190.2 million to CRG Servicing LLC satisfied all of our obligations under the Loan Agreement. With the full repayment of the Term Loans, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

No interest expense related to the Term Loans was recorded in the three months ended September 30, 2021. We recorded $4.8 million of interest expense related to the Term Loans during the three months ended September 30, 2020. We recorded $7.0 million and $14.2 million of interest expense related to the Term Loans during the nine months ended September 30, 2021 and 2020, respectively.

9. Revenue Recognition

Disaggregation of Revenues

The following table disaggregates our product revenue, net by product and geographic region and disaggregates our other revenues by geographic region (in thousands):

	Three Months Ended September 30, 2021			Three Months Ended September 30, 2020		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 22,707	$ -	$ 22,707	$ 11,599	$ -	$ 11,599
CpG 1018	-	84,289	84,289	-	1,677	1,677
Total product revenue, net	$ 22,707	$ 84,289	$ 106,996	$ 11,599	$ 1,677	$ 13,276
Other revenue	1,200	74	1,274	-	138	138
Total revenues	$ 23,907	$ 84,363	$ 108,270	$ 11,599	$ 1,815	$ 13,414

	Nine Months Ended September 30, 2021			Nine Months Ended September 30, 2020		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 44,698	$ -	$ 44,698	$ 24,518	$ -	$ 24,518
CpG 1018	-	197,860	197,860	-	1,677	1,677
Total product revenue, net	$ 44,698	$ 197,860	$ 242,558	$ 24,518	$ 1,677	$ 26,195
Other revenue	1,460	354	1,814	-	806	806
Total revenues	$ 46,158	$ 198,214	$ 244,372	$ 24,518	$ 2,483	$ 27,001

Revenues from Major Customers

The following table summarizes HEPLISAV-B product revenue from each of our three largest Customers (as a percentage of total HEPLISAV-B product revenue):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Largest Customer	22%	28%	21%	25%
Second largest Customer	20%	25%	21%	22%
Third largest Customer	19%	17%	18%	21%

The following table summarizes CpG 1018 product revenue from each of our two largest collaboration partners (as a percentage of total CpG 1018 product revenue):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Largest collaboration partner	62%	71%	45%	71%
Second largest collaboration partner	30%	25%	29%	25%

Contract Balances

The following table summarizes balances and activities in HEPLISAV-B product revenue allowance and reserve categories for the nine months ended September 30, 2021 (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, 2021:				
Accounts receivable reserves(1)	$ 2,836	$ 13,549	$ (12,369)	$ 4,016
Revenue reserve accruals(2)	$ 6,040	$ 8,962	$ (6,653)	$ 8,349

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

When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement to Clover, we recognize product revenue and a corresponding contract asset as our right to consideration is conditioned on something other than the passage of time. See Note 6 for further discussion.

Payments received or invoices issued before we satisfy our performance obligations are recorded as deferred revenue until we satisfy such performance obligations. Our deferred revenue activities are related to CpG 1018 product sales. The following table summarizes balances and activities in our deferred revenue accounts for the nine months ended September 30, 2021 (in thousands):

	Balance at Beginning of Period	Additions (1)	Subtractions (2)	Revenue recognized in the current period included in deferred revenue balance at the beginning of the period	Balance at End of Period
Nine months ended September 30, 2021:					
Deferred revenue	$ 38,212	$ 371,860	$ (13,272)	$ (38,212)	$ 358,588
Long-term deferred revenue	-	129,420	(61,451)	-	67,969

(1) Additions are primarily payments received or invoices issued before we satisfy our performance obligations.
(2) Subtractions are primarily revenues recognized in the period included in deferred revenue during the period and reclassification from long-term deferred revenue to accrued liabilities.

10. Net (Loss) Income Per Share

We compute net (loss) income per share of common stock using the two-class method required for participating securities. We consider Series B Preferred Stocks and warrants to be participating securities because holders of such shares have dividend rights in the event of our declaration of a dividend for common shares. Undistributed earnings allocated to participating securities are subtracted from net (loss) income in determining net (loss) income attributable to common stockholders.

Basic net (loss) income per share is computed by dividing net (loss) income attributable to common stockholders by the weighted-average number of shares of our common stock outstanding.

For the calculation of diluted net (loss) income per share, net (loss) income attributable to common stockholders for basic net (loss) income per share is adjusted by the effect of dilutive securities, including awards under our equity compensation plans and change in fair value of warrant liability. Diluted net (loss) income per share attributable to common stockholders is computed by dividing the resulting net (loss) income attributable to common stockholders by the weighted-average number of fully diluted common shares outstanding.

The numerators and denominators of the basic and diluted net (loss) income per share computations for our common stock are calculated as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator				
Net (loss) income	$ (28,430)	$ 4,401	$ (23,066)	$ (59,773)
Less: undistributed earnings allocated to participating securities	-	(367)	-	-
Net (loss) income attributable to common stockholders, basic	$ (28,430)	$ 4,034	$ (23,066)	$ (59,773)
Less: Removal of change in fair value of warrant liability	-	(21,245)	-	(4,200)
Net loss attributable to common stockholders, diluted	$ (28,430)	$ (17,211)	$ (23,066)	$ (63,973)
Denominator				
Weighted average common stock outstanding, basic	116,903	109,816	114,540	97,589
Effect of dilutive shares:				
Effect of dilutive warrants	-	2,157	-	988
Weighted average common stock outstanding, diluted	116,903	111,973	114,540	98,577

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Outstanding securities not included in diluted net (loss) income per share calculation:				
Stock options and stock awards	5,924	10,984	6,274	10,984
Series B Convertible Preferred Stock (as converted to common stock)	-	4,140	-	4,140
Warrants (as exercisable into common stock)	4,895	-	4,895	-
Convertible Notes (as converted to common stock)	21,543	-	21,543	-
Total	32,362	15,124	32,712	15,124

11. Common Stock, Preferred Stock and Warrants

Common Stock

As of September 30, 2021, there were 119,787,380 shares of our common stock outstanding.

In August 2019, we sold 18,525,000 shares of our common stock, par value $0.001 per share, 4,840 shares of our Series B Convertible Preferred Stock, par value $0.001 per share (“Series B Preferred Stock”) and warrants to purchase up to an aggregate of

5,841,250 shares of our common stock in an underwritten public offering (the "Offering") for aggregate net proceeds of approximately $65.6 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 on the same terms as the other investors in the Offering. Following the Offering, Andrew A. F. Hack, M.D., Ph.D., a Managing Director of Bain Capital Life Sciences, was appointed to our board of directors.

In June 2021, Bain Capital Life Sciences and its affiliates sold warrants to purchase an aggregate of 2,916,250 shares of our common stock for aggregate consideration of $11.8 million, representing all of the warrants held by Bain Capital Life Sciences and its affiliates.

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.

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, 2021, we received net cash proceeds of $28.2 million resulting from sales of 2,878,567 shares of our common stock pursuant to the 2020 ATM Agreement. All of these shares were sold during the three months ended March 31, 2021. As of September 30, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

Preferred Stock

In August 2021, all of the 4,140 shares of Series B Preferred Stock were converted into 4,140,000 shares of common stock. As of September 30, 2021, there were no shares of Series B Preferred Stock outstanding.

Warrants

During the nine months ended September 30, 2021, 946,150 of our common stock warrants were exercised. As of September 30, 2021, 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, 2021 (in thousands)
August 12, 2019	4,895	February 12, 2022	$ 4.50	4,895

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.

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 be recognized as other income (expense) in the condensed consolidated statements of operations. At September 30, 2021, the estimated fair value of warrant liability was $72.0 million. For the three and nine months ended September 30, 2021, we recognized the increase in the estimated fair value of warrant liability of $45.1 million and $68.6 million, respectively, as expense in other income (expense) in our condensed consolidated statements of operations. 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

In January 2021, we adopted the Dynavax Technologies Corporation 2021 Inducement Award Plan ("2021 Inducement Plan"), pursuant to which we reserved 1,500,000 shares of common stock for issuance under the plan to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company. In June 2021, we amended the 2021 Inducement Plan ("Amended 2021 Inducement Plan") to increase the number of shares of common stock reserved under the 2021 Inducement Plan to 3,250,000.

In May 2021, the stockholders approved the amendment and restatement of our 2014 Employee Stock Purchase Plan (the "Amended and Restated 2014 Employee Stock Purchase Plan"). The maximum number of shares of common stock that may be issued under the Amended and Restated 2014 Employee Stock Purchase Plan is 1,850,000.

As of September 30, 2021, the 2018 Equity Incentive Plan, as amended, ("Amended 2018 EIP"), the Amended 2021 Inducement Plan and the Amended and Restated 2014 Employee Stock Purchase Plan are our active plans. 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.

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). Option activity under our stock-based compensation plans during the nine months ended September 30, 2021 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, 2020	8,505	$ 11.57		
Options granted	3,562	9.96		
Options exercised	(890)	6.10		
Options cancelled:				
Options forfeited (unvested)	(477)	7.92		
Options expired (vested)	(436)	18.22		
Balance at September 30, 2021	10,264	$ 11.37	4.33	$ 15,032
Vested and expected to vest at September 30, 2021	9,837	$ 11.43	4.23	$ 14,656
Exercisable at September 30, 2021	5,668	$ 13.32	2.80	$ 8,435

Restricted stock unit activity under our stock-based compensation plans during the nine months ended September 30, 2021 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, 2020	1,794	$ 7.23
Granted	1,797	9.43
Vested	(537)	8.85
Forfeited	(392)	8.22
Non-vested as of September 30, 2021	2,662	$ 8.24

We granted performance-based restricted stock unit ("PSU") to certain executives in February 2021. These PSUs vest upon a specified market condition. The summary of PSU activities for the nine months ended September 30, 2021 is as follows:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2020	-	$ -
Granted	297	8.40
Forfeited	(60)	8.40
Non-vested as of September 30, 2021	237	$ 8.40

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 of each RSU is determined at the date of grant using our closing stock price. The fair value of each PSU is estimated using the Monte Carlo simulation method on the date of grant. The weighted-average assumptions used in the calculations of these fair value measurements are as follows:

	Stock Options		Stock Options		Market-Based Performance Stock Unit ("PSUs")
	Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30, 2021
	2021	2020	2021	2020	
Weighted-average fair value per share	$ 7.91	$ 5.82	$ 6.85	$ 3.95	$ 8.40
Risk-free interest rate	0.7%	0.3%	0.6%	1.1%	From 0.03% to 1.92%
Expected life (in years)	4.5	4.5	4.5	4.5	2.9
Volatility	0.9	1.0	1.0	0.9	0.9

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 798	$ 778	$ 2,607	$ (21)
Selling, general and administrative	3,930	2,504	10,519	7,437
Cost of sales - product	124	137	448	452
Inventory	524	683	1,549	2,100
Total	$ 5,376	$ 4,102	$ 15,123	$ 9,968

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.

13. Subsequent Events

Amendment to CpG 1018 Adjuvant Supply Agreement with Valneva

In October 2021, we entered into a letter agreement (the "Valneva Amendment"), amending the Valneva Supply Agreement. Under the Valneva Amendment, we and Valneva agreed to the cancellation of the two then outstanding purchase orders for CpG 1018 adjuvant under the Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment and that we are entitled to retain the advance payments made by Valneva under such cancelled purchase orders which total approximately $36.4 million.

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, 2020.

Overview

We are a commercial stage biopharmaceutical company focused on developing and commercializing novel vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We also manufacture and sell CpG 1018, the adjuvant used in HEPLISAV-B. We are working to develop CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis, plague and universal influenza.

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 and we market it in the United States. 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. In addition, we received Marketing Authorization approval of HEPLISAV-B in February 2021 from the European Commission following a positive recommendation in December 2020 from the European Medicines Agency ("EMA") Committee for Medicinal Products ("CHMP") for Human Use for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. In May 2021, we entered into a commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany.

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, 2021, HEPLISAV-B product revenue, net was $22.7 million and $44.7 million, respectively.

In January 2021, we entered into an agreement (the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant. The agreement enables CEPI to direct the supply of CpG 1018 adjuvant to CEPI partner(s). In exchange for reserving CpG 1018 adjuvant, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan of up to $99.0 million. In May 2021, we entered into the first amendment (the "Amendment") to the CEPI Agreement. The Amendment provides for the manufacture and reservation of an additional specified quantity of CpG 1018 adjuvant. In exchange for reserving an additional specified quantity of CpG 1018 adjuvant, CEPI has agreed to provide additional advance payments of up to $77.4 million, for total funding of up to $176.4 million.

In July 2021, we entered into an agreement (the "Bio E Supply Agreement") with Biological E. Limited ("Bio E"), for the commercial supply of CpG 1018 adjuvant, for use with Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™. Under the Bio E Supply Agreement, Bio E has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides terms for Bio E to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI.

In February 2021, we entered into a Supply Agreement ("Medigen Supply Agreement") with Medigen Vaccine Biologics ("Medigen") to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen's COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant, MVC-COV1901, for delivery in the first and second quarters of 2021. In August 2021, we entered into a second supply agreement ("Medigen Supply Agreement No. 2") to manufacture

and supply additional specified quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021. In August 2021, Medigen launched MVC-COV1901. Medigen received Taiwan Emergency Use Authorization and approval for inclusion in Taiwan's COVID-19 vaccine immunization program in July 2021. In October 2021, MVC-COV1901, was recommended by an independent vaccine prioritization advisory group to be included in the World Health Organization ("WHO") Solidarity Trial Vaccines ("STv"). The recommendation came after the approval from WHO Ethics Review Committee and relevant regulatory authorities and ethics committees of Colombia, Mali and Philippines.

In the third quarter of 2020, we announced a commercial supply agreement (the "Valneva Supply Agreement") with Valneva Scotland Limited ("Valneva") to cover the supply of CpG 1018 adjuvant for its SARS-COV-2 vaccine candidate, VLA2001, in support of its supply agreement with the United Kingdom Government and subject to the terms of such agreement. In September 2021, Valneva received a termination notice from the United Kingdom Government in relation to such supply agreement. However, Valneva continues the clinical development of VLA2001 and the pivotal Phase 3 trial for VLA2001, COV-COMPARE, remains ongoing at Public Health England. In October 2021, Valneva reported that VLA2001 met both co-primary endpoints in the COV-COMPARE trial, and that VLA2001 was well-tolerated, demonstrating a statistically significant better tolerability profile compared to active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S).

In October 2021, we entered into a letter agreement (the "Valneva Amendment"), amending the Valneva Supply Agreement. Under the Valneva Amendment, we and Valneva agreed to the cancellation of the two then outstanding purchase orders for CpG 1018 adjuvant under the Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment and that we are entitled to retain the advance payments made by Valneva under such cancelled purchase orders which total approximately $36.4 million.

In June 2021, we entered into an agreement (the "Clover Supply Agreement") with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with its protein-based COVID-19 vaccine candidate, adjuvanted with our CpG 1018 adjuvant, SCB-2019. In September 2021, Clover reported that SCB-2019 achieved the primary and secondary efficacy endpoints, and with favorable safety profile, in a global Phase 2/3 clinical trial.

In September 2021, we entered into an agreement with the U.S. Department of Defense ("DOD") for the development of an improved recombinant plague vaccine adjuvanted with CpG 1018, whereby the DOD will provide funding of up to approximately $22.0 million over two and a half years. Under the agreement, we agreed to conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DOD's rF1V vaccine. We anticipate the Phase 2 trial will commence in 2022.

In the third quarter of 2020, we commenced selling our CpG 1018 adjuvant to certain of our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. For the three and nine months ended September 30, 2021, CpG 1018 product revenue, net, was $84.3 million and $197.9 million, respectively.

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 or current or newly discovered variants, 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 began restricting access to their facilities and focused on providing care to only the most severely affected patients, beginning in March 2020. As states began phasing out restrictions in the middle of 2020, medical centers have been operating under limited capacity or with 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 of HEPLISAV-B and is likely to continue to impact us until restrictions affecting us are lifted and the U.S. returns to more normal conditions. While we have seen utilization rates for adult vaccines generally, and HEPLISAV-B in particular, begin to increase again, their utilization still remains well below pre-COVID rates.

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 and continue to actively evaluate a return to the office at an appropriate time. In the conduct of our business activities, we are also taking actions to help protect the safety of patients and healthcare professionals. In the early stages of the pandemic, our field-based personnel reduced in-person customer interactions in healthcare settings and primarily used 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 began conducting a greater proportion of their work from their homes and are facing additional demands on their time during the COVID-19 pandemic. While 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, impacted the effectiveness of our sales personnel, we have gradually moved back to in-person interactions. With the rise of the delta variant, and related precautions, however, our customers' procurement activities and those of our collaborators continue to be impacted which could negatively affect our overall product sales.

Our HEPLISAV-B post-marketing follow-up has been completed. We conducted an observational comparative study of HEPLISAV-B to Engerix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018, concluded in November 2020 and final results were presented in April 2021. The results provided evidence that there is no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B. We expect data from the autoimmune portion of our observational study to be available in the first quarter of 2022. Our HEPLISAV-B dialysis study has also been completed. Final immunogenicity results of our dialysis study along with interim safety results were published in June 2021. Safety follow up was completed in September 2021 with no observed safety concerns.

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 toll-like receptor 9 ("TLR9") agonist adjuvant, CpG 1018, which is the adjuvant used in our HEPLISAV-B product. Since the first half of 2021, 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 or other vaccines. We and our contract manufacturers 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 or other vaccines.

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, 2021, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020 other than those described below:

Convertible Notes

We evaluate all conversion, repurchase and redemption features contained in a debt instrument to determine if there are any embedded features that require bifurcation as a derivative. We accounted for the issuance of the 2.50% convertible senior notes due

2026 (“Convertible Notes”) as a long-term liability equal to the proceeds received from issuance, including the embedded conversion feature, net of the unamortized debt issuance and offering costs on the condensed consolidated balance sheets. The conversion feature is not required to be accounted for separately as an embedded derivative. We amortize debt issuance and offering costs over the contractual term of the Convertible Notes, using the effective interest method, as interest expense on the condensed consolidated statements of operations.

Capped Calls

We evaluate financial instruments under ASC 815. In May 2021, in connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers of the Convertible Notes and other financial institutions (the “Capped Calls”). The Capped Calls cover the same number of shares of common stock that initially underlie the Convertible Notes (subject to anti-dilution and certain other adjustments). The Capped Calls meet the definition of derivative under ASC 815. In addition, the Capped Calls meet the conditions in ASC 815 to be classified in stockholders’ equity and are not subsequently remeasured as long as the conditions for the equity classification continue to be met.

Results of Operations

Revenues

Revenues consist of amounts earned from product sales and other revenues. Product revenue, net, includes sales of HEPLISAV-B and 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. We sell our CpG 1018 adjuvant to our collaboration partners for use in their development and/or potential commercialization of COVID-19 vaccines. 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.

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 2020 to 2021		Nine Months Ended September 30,		Increase (Decrease) from 2020 to 2021	
Revenues:	**2021**	**2020**	**$**	**%**	**2021**	**2020**	**$**	**%**
HEPLISAV-B	$ 22,707	$ 11,599	$ 11,108	96 %	$ 44,698	$ 24,518	$ 20,180	82 %
CpG 1018	84,289	1,677	82,612	4,926 %	197,860	1,677	196,183	11,698 %
Total product revenue, net	$ 106,996	$ 13,276	$ 93,720	706 %	$ 242,558	$ 26,195	$ 216,363	826 %
Other revenue	1,274	138	1,136	823 %	1,814	806	1,008	125 %
Total revenues	$ 108,270	$ 13,414	$ 94,856	707 %	$ 244,372	$ 27,001	$ 217,371	805 %

HEPLISAV-B revenue for the three and nine months ended September 30, 2021 increased, compared to the same periods of 2020, due to gains in market share and improvements in utilization of adult vaccines.

In September 2020, we began selling our CpG 1018 adjuvant to our collaboration partners for their use in development and/or potential commercialization of COVID-19 vaccines. In the three and nine months ended September 30, 2021, we continued to manufacture and ship CpG 1018 adjuvant pursuant to our supply and collaboration agreements.

Other revenue included grant revenue and collaboration revenue related to services performed under a collaboration agreement with Serum Institute of India Pvt. Ltd. Other revenue for the three and nine months ended September 30, 2021 increased, compared to the same periods of 2020, primarily due to the recognition of $1.2 million as revenue in connection with the termination of a certain grant agreement.

Cost of Sales – Product

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 and inventory costs to produce CpG 1018 adjuvant for our collaboration partners. 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 United States Food and Drug Administration ("FDA") in March 2018. Substantially all the inventory that was previously expensed to research and development has been sold to customers.

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

	Three Months Ended September 30,		Increase (Decrease) from 2020 to 2021		Nine Months Ended September 30,		Increase (Decrease) from 2020 to 2021	
Cost of Sales - Product	**2021**	**2020**	**$**	**%**	**2021**	**2020**	**$**	**%**
HEPLISAV-B	$ 10,544	$ 3,225	$ 7,319	227 %	$ 17,913	$ 6,546	$ 11,367	174 %
CpG 1018	49,546	806	48,740	6,047 %	81,647	806	80,841	10,030 %
Total cost of sales - product	$ 60,090	$ 4,031	$ 56,059	1,391 %	$ 99,560	$ 7,352	$ 92,208	1,254 %

For the three and nine months ended September 30, 2021, HEPLISAV-B cost of sales-product increased, as compared to the same periods in 2020, primarily due to higher sales volume and higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing. In addition, included in HEPLISAV-B cost of sales - product for each of the three and nine months ended September 30, 2021 was an excess capacity charge in connection with an expansion project at our manufacturing facility in Düsseldorf of $3.2 million.

In September 2020, we began selling our CpG 1018 adjuvant to our collaboration partners for their use in development and/or commercialization of COVID-19 vaccines. In the three and nine months ended September 30, 2021, we continued to manufacture and ship CpG 1018 adjuvant pursuant to our supply and collaboration agreements.

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 2020 to 2021		Nine Months Ended September 30,		Increase (Decrease) from 2020 to 2021	
Research and Development:	**2021**	**2020**	**$**	**%**	**2021**	**2020**	**$**	**%**
Compensation and related personnel costs	$ 2,314	$ 2,189	$ 125	6 %	$ 7,647	$ 6,412	$ 1,235	19 %
Outside services	3,074	5,381	(2,307)	(43)%	10,604	12,258	(1,654)	(13)%
Facility costs	-	173	(173)	(100)%	253	409	(156)	(38)%
Non-cash stock-based compensation	798	778	20	3 %	2,607	(21)	2,628	12514 %
Total research and development	$ 6,186	$ 8,521	$ (2,335)	(27)%	$ 21,111	$ 19,058	$ 2,053	11 %

For the nine months ended September 30, 2021, compensation and related personnel costs and non-cash stock-based compensation increased, as compared to the same periods in 2020, primarily due to higher headcount to support vaccine clinical and development activities. 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.

For the three and nine months ended September 30, 2021, the decrease in outside services, as compared to the same periods in 2020, was primarily due to winding down of our immuno-oncology study. In addition, outside services for the three and nine months ended September 30, 2020 included the cost of CpG 1018 adjuvant used in clinical trials.

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 2020 to 2021		Nine Months Ended September 30,		Increase (Decrease) from 2020 to 2021	
Selling, General and Administrative:	**2021**	**2020**	**$**	**%**	**2021**	**2020**	**$**	**%**
Compensation and related personnel costs	$ 11,389	$ 7,817	$ 3,572	46%	$ 29,765	$ 23,539	$ 6,226	26%
Outside services	8,020	7,700	320	4%	20,307	19,909	398	2%
Legal costs	487	722	(235)	(33)%	1,481	2,038	(557)	(27)%
Facility costs	3,100	2,795	305	11%	8,860	8,495	365	4%
Non-cash stock-based compensation	3,930	2,504	1,426	57%	10,519	7,437	3,082	41%
Total selling, general and administrative	$ 26,926	$ 21,538	$ 5,388	25%	$ 70,932	$ 61,418	$ 9,514	15%

For the three and nine months ended September 30, 2021, compensation and related personnel costs increased, as compared to the same periods in 2020, primarily, due to higher headcount. In addition, compensation and related personnel costs for the nine months September 30, 2021 included benefits for a former executive in connection with their retirement.

For the three and nine months ended September 30, 2021, outside services increased, as compared to the same periods in 2020, primarily due to an overall increase in commercial and marketing efforts. This increase was offset by the decrease in the amount we paid to Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC (“Holdings”). In connection with the sale of our immuno-oncology compound, SD-101, we paid $0.5 million to Holdings in September 2021 as compared to $2.5 million in September 2020.

For the three and nine months ended September 30, 2021, non-cash stock-based compensation increased, as compared to the same periods in 2020, primarily due to higher headcount and higher equity grant valuation. In addition, non-cash stock-based compensation included reversal of expenses related to cancellation of certain equity grants in the three months ended March 31, 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 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 and $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.

In September 2021, we received payment of $1 million from TriSalus for their meeting a pre-commercialization milestone. In the three and nine months ended September 30 2021, we recognized a gain on sale of SD-101 assets of $1 million in our condensed consolidated statements of operations.

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 terminated long-term debt agreement and Convertible Notes. Sublease income is recognized in connection with our sublease of office and laboratory space. Loss on debt extinguishment reflects the amount we paid to terminate our long-term debt in excess of its carrying value at the time of the extinguishment. 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 2020 to 2021		Nine Months Ended September 30,		Increase (Decrease) from 2020 to 2021	
	2021	2020	$	%	2021	2020	$	%
Interest income	$ 39	$ 269	$ (230)	(86)%	$ 134	$ 1,190	$ (1,056)	(89)%
Interest expense	$ (1,676)	$ (4,794)	$ (3,118)	(65)%	$ (9,497)	$ (14,257)	$ (4,760)	(33)%
Sublease income	$ 2,022	$ 1,926	$ 96	5%	$ 5,714	$ 5,779	$ (65)	(1)%
Loss on debt extinguishment	$ -	$ -	$ -	-	$ (5,232)	$ -	$ 5,232	-
Change in fair value of warrant liability	$ (45,121)	$ 21,245	$ (66,366)	(312)%	$ (68,576)	$ 4,200	$ (72,776)	(1,733)%
Other	$ 238	$ (420)	$ 658	(157)%	$ 622	$ (209)	$ 831	(398)%

Interest income for the three and nine months ended September 30, 2021 decreased, as compared to the same periods in 2020, primarily due to lower yields on our marketable securities portfolio. Interest expense for the three and nine months ended September 30, 2021 decreased, as compared to the same periods in 2020, due to the repayment of our long-term debt in May 2021, replaced by the issuance of Convertible Notes in May 2021 at a lower effective interest rate. In connection with the repayment of our long-term debt, we recorded a one-time loss on debt extinguishment of $5.2 million in the second quarter of 2021. The change in the fair value of warrant liability is primarily due to the increase in our stock price during the three and nine months ended September 30, 2021. 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, 2021, we had $414.2 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, 2021, 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.

Advanced payments received from CEPI to reserve a specified quantity of CpG 1018 are initially accounted for as long-term deferred revenue. When we deliver CpG 1018 adjuvant to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the advanced payments from long-term deferred revenue to accrued liabilities. As of September 30, 2021, advance payments totaling $68.0 million and $58.9 million were recorded as long-term deferred revenue and accrued liabilities, respectively, in our condensed consolidated balance sheets.

As of September 30, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.3 million. The Convertible Notes bear interest at a rate of 2.50% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

For the nine months ended September 30, 2021, we received net cash proceeds of $28.2 million resulting from sales of 2,878,567 shares of our common stock pursuant to a 2020 At Market Sales Agreement with Cowen and Company, LLC (“2020 ATM Agreement”). All of these shares were sold during the three months ended March 31, 2021. As of September 30, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

During the nine months ended September 30, 2021, we generated $215.0 million of cash from our operations primarily due to our net loss of $23.1 million, of which $92.0 million consisted of non-cash items which included change in fair value of warrant liability, stock-based compensation, depreciation and amortization, amortization of right-of-use assets, provision for write-down of inventories, non-cash interest expense and accretion and amortization on marketable securities. By comparison, 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 $15.5 million consisted of non-cash items which included stock-based compensation, change in fair value of warrant liability, depreciation and amortization, amortization of intangible assets, non-cash interest expense, amortization of right-of-use assets and accretion and amortization on marketable securities. Cash provided by our operations during the nine months ended September 30, 2021 increased by $291.5 million compared to the same period in 2020. For the nine months ended September 30, 2021, we received advance payments from collaboration partners totaling $371.9 million to manufacture and supply CpG 1018 adjuvant for delivery in future dates. We classified such payments as deferred revenue until we satisfy our performance obligation to transfer control of CpG

1018 adjuvant to collaboration partners. Net cash provided by 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, 2021 and 2020, net cash used in investing activities was $40.7 million and $40.9 million, respectively. Cash used in investing activities during the first nine months of 2021 and 2020 included $35.3 million and $33.4 million of net purchases of marketable securities, respectively. During the first nine months of 2020, we paid $7.0 million of sublicense payment to Merck. In addition, for the nine months ended September 30, 2021 and 2020, we received $1 million and $2.9 million, respectively, from sale of SD-101 assets, net of transaction costs. Cash used in net purchases of property plant and equipment increased by $3.1 million during the first nine months of 2021 compared to the same period in 2020. The increase was, primarily, due to the ongoing facility expansion in the first nine months of 2021.

During the nine months ended September 30, 2021 and 2020, net cash provided by financing activities was $41.0 million and $109.4 million, respectively. Cash provided by financing activities for the first nine months of 2021 included net proceeds of $219.8 million from the issuance of our Convertible Notes, $28.2 million from our 2020 ATM Agreement, $6.2 million from options exercised and employee stock purchase plan, $4.3 million from warrants exercised, offset by $190.2 million repayment of our long-term debt and $27.2 million purchases of capped call options. 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 At Market Sales Agreement with Cowen and Company, LLC and $0.8 million from our 2020 ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and nine months ended September 30, 2021, we recorded net loss of $28.4 million and $23.1 million, respectively. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development of our CpG 1018 adjuvant and clinical trials and other development. 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 or future disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. 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, 2021, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 adjuvant and for clinical research, totaled $149.3 million.

Advanced payments received from CEPI to reserve a specified quantity of CpG 1018 are initially accounted for as long-term deferred revenue. When we deliver CpG 1018 adjuvant to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the advanced payments from long-term deferred revenue to accrued liabilities. As of September 30, 2021, advance payments totaling $68.0 million and $58.9 million were recorded as long-term deferred revenue and accrued liabilities, respectively, in our condensed consolidated balance sheets.

As of September 30, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.3 million. The Convertible Notes bear interest at a rate of 2.50% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2021. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

In May 2021, we repaid the principal on the term loans (the "Term Loans") under the term loan agreement (“Loan Agreement”) with CRG Servicing LLC in full. With the full repayment of the Term Loans, all security interests, covenants, liens and encumbrances under the Loan Agreement were permanently released.

In November 2013, we entered into a Commercial Manufacturing and Supply Agreement with Baxter Pharmaceutical Solutions LLC ("Baxter") that was amended in September 2021 (as amended, the "Baxter Agreement"). Baxter provides formulation, fill and finish services and produces pre-filled syringes ("PFS") of HEPLISAV-B for commercial use. Pursuant to the Baxter Agreement, we are obligated to purchase an annual minimum number of batches of PFS for each of the next five calendar years, and there are certain limits on the number of batches that Baxter is required to produce. As of September 30, 2021, our aggregate minimum commitment under the Baxter Agreement was $47.3 million which is included in the material non-cancelable purchase and other commitments in the first paragraph.

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, 2020.

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, 2021, 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, 2020.

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, including, but not limited to, statements concerning the effect of the COVID-19 pandemic on our business, our future efforts to obtain regulatory approval, achieve restructuring goals, advance our collaborations, manufacture and 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, 2020 that was filed with the Securities and Exchange Commission on February 25, 2021.

Risks Related to our Business and Capital Requirements

HEPLISAV-B has been launched in the United States, and approved in the European Union, and there is significant competition in these marketplaces. 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 our 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. We have never launched a product in the European Union before, and despite the recent European approval of HEPLISAV-B, there can be no certainty that we will succeed in our European launch efforts. 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 fail to complete or maintain some or all of these important contracts on favorable terms or at all, or that in a potentially evolving reimbursement environment our efforts may fail to overcome established competition at favorable pricing or at all.

We converted our contracted U.S. field sales team into full-time Dynavax employees in the second quarter of 2019. Before then we had 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 focus on 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 actually 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 financial resources 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 mostly paused in-person customer interactions in healthcare settings and are generally using electronic communication, such as emails, phone calls and video conferences. Many healthcare 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 restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in mid-March 2020. As states began phasing out restrictions, medical centers began operating under limited capacity and strict social distancing rules. This has resulted in significantly reduced utilization of adult vaccines which began in the first quarter of 2020, including utilization of 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. While utilization rates have begun to improve more recently, there can be no assurance of the timing or likelihood for adult vaccine utilization rates to return to pre-COVID levels.

Governments influence the price of medicinal products in the European Union through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Even though we have been granted a marketing authorization in the European Union for HEPLISAV-B we are yet to obtain reimbursements and pricing approval in any European Union Member State. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other European Union Member States allow companies to fix their own prices for medicines, but monitor and control company profits. Any delay in being able to market our products in the European Union or elsewhere will adversely affect our business and financial condition.

If we, or our partners, are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the U.S. and elsewhere, 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 allowing or significantly reduced 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.

The overall impact has generally resulted in significantly reduced utilization of all adult vaccines, (other than recently approved COVID-19 vaccines) since the end of the first quarter of 2020, including HEPLISAV-B. This shift has significantly and adversely impacted our sales of HEPLISAV-B and our business and operating results since March 2020 and continues to pose a headwind for our HEPLISAV-B business. This reduced HEPLISAV-B 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. Prolonged disruptions would likely materially and negatively impact our business, operating results and financial condition.

Current 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 such restrictions are increased or 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 or abroad. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B or CpG 1018 adjuvant 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, and the duration of such impact, brought by COVID-19 may be difficult to assess or predict, a widespread pandemic could also potentially 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 COVID-19 pandemic continues to rapidly evolve, and new variants of the virus continue to emerge. While some vaccines have been recently approved, it is not clear whether, which, or to what extent these vaccines will protect against current or future variants of the virus. The extent to which the COVID-19 pandemic impacts our business, our future sales of HEPLISAV-B, sales of CpG 1018 adjuvant 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 and elsewhere, business disruptions and the effectiveness of actions taken in the United States and elsewhere 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 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 elsewhere in this “Risk Factors” section.

As we continue to focus on the commercialization of HEPLISAV-B and our CpG 1018 adjuvant, 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 CpG 1018, 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, or secure sufficient or timely supply from third party service and product providers, 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 our CpG 1018 adjuvant, 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 CpG 1018 advanced adjuvant, 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 contract manufacturing organizations (“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 adjuvant 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 the adjuvant does not materialize in the volumes we are expecting.

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 obligations, 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.

Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.

A substantial portion of our revenue for the foreseeable future may depend on sales of CpG 1018 adjuvant, which are difficult to predict. For example, as of September 30, 2021, we received advanced payments from certain of our customers to purchase specified quantities of CpG 1018 adjuvant which were recorded as deferred revenue until we deliver CpG 1018 and meet all criteria to recognize revenue. In accordance with our stated revenue policy, we expect to record revenue for these contracts upon meeting all of the criteria for revenue recognition under Accounting Standards Codification 606, which includes, among other criteria, the transfer of control for CpG 1018 adjuvant to our customer. The occurrence and timing of such transfer of control can be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. We expect that our visibility into future revenue relating to sales of CpG 1018 adjuvant, including volumes, prices and timing, will continue to be limited and could result in significant, unexpected fluctuations in our quarterly and annual operating results.

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, sales of CpG 1018 accounted for 82% of our overall revenue, and one CpG 1018 customer accounted for 45% of our revenue, during the nine months ended September 30, 2021. If orders from our top customers or the number of CpG 1018 collaborations are reduced or discontinued, our revenue in future periods may materially decrease. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Similarly, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on any particular past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our products 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 products or product candidates in commercial quantities. With respect to HEPLISAV-B, we use a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture or have manufactured 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 rely on a contract manufacturer to do so. Our contract manufacturer is the only approved provider that we have, and there can be no assurance that we or they 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 (i) our CpG 1018 adjuvant for HEPLISAV-B and for our collaborators and (ii) our pre-filled syringe presentation. 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 adjuvant, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in manufacturing HEPLISAV-B, or CpG 1018, and developing and

commercializing our and our collaborators' 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 our products or our and our collaborators' product candidates and could result in significant expense.

We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop vaccines 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 adjuvant or otherwise are inadequate, we may be unable to realize recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant.

As part of our business, we are working to develop our CpG 1018 adjuvant 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 vaccine development, the results of clinical trials, whether a vaccine will be approved for use, the extent of competition, government actions and whether a vaccine can be successfully manufactured and commercialized. As a result, these collaborative efforts may not be as successful as we expect, or at all.

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 our adjuvant. 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 and commercialization of a vaccine could be delayed, and may not occur at all. For example, as of September 30, 2021, only one of our collaborators has received approval from an applicable regulatory authority for any vaccine for COVID-19 containing our adjuvant. We also rely on a single supplier to produce our CpG 1018 adjuvant, and are in the process of establishing an alternate qualified supplier. If we were unable to maintain our existing supplier for the adjuvant, we would have to establish and maintain 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 sufficient adjuvant at a cost, quantity and quality similar to that available from our current third-party supplier, or at all, and even if we are successful in adding an additional supplier, there is no guarantee such supplier will be able to manufacture compliant supplemental quantities sufficient to support commercial demand, to the extent it materializes, and in the timeframes required.

Our adjuvant has no composition of matter patent protection. We have filed patent applications claiming compositions and methods of use of CpG 1018 adjuvant for COVID-19 and other vaccines. Such patents may or may not be allowed. 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 adjuvant. If we are unable to adequately obtain or enforce our proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant, and we may not have the ability to prevent others from developing or commercializing a vaccine containing the adjuvant. 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.

Furthermore, restrictive government actions related to potential waivers of intellectual property rights in the case of national emergencies or in other circumstances, such as imposition of compulsory licenses related to COVID-19 vaccines, as well as other regulatory initiatives, may result in a general weakening of our or our collaborators' intellectual property protection or otherwise diminish or eliminate our or our collaborators' ability to realize any commercial benefit from the development of a COVID-19 vaccine containing CpG 1018. This may, in turn, adversely impact the demand for CpG 1018, which would have a material adverse effect on our business, results of operations, and financial condition.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third-party payors, which may make it difficult or impossible to sell certain of our products 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 we believe 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. Even if favorable

coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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.

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 adjuvant that may be required in the event that our CpG 1018 adjuvant 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. We may seek such grants in the future. These grants and others, 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 and 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 that is included 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 our control over the manufacturing and distribution of grant-funded products. Failure to agree with such requirements, may result in us 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. In 2020, we announced the sale of assets related to our SD-101 program. Additionally, we are seeking strategic alternatives for of the remaining assets in 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 the assets that remain in 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 assets upon favorable terms within an advantageous timeframe and recognize significant value for these assets, if any at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative involving our immuno-oncology assets 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 and EMA 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 regulatory issues 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 were required to conduct an observational comparative study of HEPLISAV-B to Engerix-B to assess occurrence of acute myocardial infarction, or AMI. This study was initiated in August 2018, concluded in November 2020 and final results were presented in April 2021, with the study report being prepared for submission to the FDA. We are also committed to conducting 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 and/or complete these studies to the satisfaction of the 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.

Similar post-marketing obligations and commitments exist in the European Union. For example, we are required to submit periodic safety update reports, or PSURs, to the EMA and to keep an up to date risk management plan that takes into account new information that may lead to a significant change in the risk/benefit profile of HEPISLAV-B. Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can result in significant financial penalties.

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 in the United States and the European Union. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices ("cGMP"), good clinical practices ("GCP"), ICH guidelines, and good laboratory practices ("GLP"). 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 limit 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 U.S. and European approvals of HEPLISAV-B 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 United States. 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 manufactured by VBI Vaccines Inc. ("VBI") is approved in Israel, and recently completed Phase 3 trials in the United States, Europe and Canada.

We are also in competition with companies developing vaccines and vaccine adjuvants, generally, including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Seqirus, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson and VBI.

Existing and potential competitors or other market participants 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.

Despite recent profitability, we have incurred annual net losses in each year since our inception and anticipate that we could continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and/or continue to sell significant quantities of our CpG 1018 adjuvant, and if we are unable to sustain profitability, the market value of our common stock will likely decline.*

We have generated limited revenue from the sale of products and, prior to January 1, 2021, have incurred losses in each year since we commenced operations in 1996. Our net loss for the nine months ended September 30, 2021 was $23.1 million compared to net loss of $59.8 million for the nine months ended September 30, 2020. As of September 30, 2021, 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. While new sales of CpG 1018 adjuvant may generate revenue during the pandemic, there is no guarantee that such revenues will be sustainable in the long term. The timing for uptake of our products in the U.S. has further increased losses related to commercialization. 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 on an annual basis or that if we are able to reach profitability that it will be sustainable for any period of time.

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

As of September 30, 2021, we had $414.2 million in cash, cash equivalents and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and nine months ended September 30, 2021, we recorded net loss of $28.4 million and $23.1 million, respectively. As of September 30, 2021, we had an accumulated deficit of $1.3 billion. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable and past results are not a reliable indicator of future performance. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development of our CpG 1018 adjuvant and clinical trials and other development. 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.

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.

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 products or product candidates.

We may seek to introduce HEPLISAV-B, or any other product candidates we may develop, to various additional markets outside the U.S. and Europe. 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 and the European Union, 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.

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 (and other regulatory agency) 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 if they are completed. 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 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 regulatory 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 otherwise unavailable for 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.

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.

HEPLISAV-B is subject to regulatory 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 products and 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 or product candidates, 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 products or 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.

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 to 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 or manage 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 commercialize the 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.

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.

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 False Claims Act, and Civil Monetary Penalties 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- 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 on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors 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 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.

It remains unclear how various state, federal, and international privacy and cybersecurity law will affect our business. For example, we don't know 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.

Internationally, the General Data Protection Regulation ("GDPR") requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition. Also, mechanisms for legally transferring information under the GDPR remain unclear. At present, there are few if any viable alternatives to the standard contractual clauses, or SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

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.

Enacted or future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may have an adverse effect on our operations and business.*

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 have been executive, legal and political challenges to certain aspects of ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by ACA. Concurrently, Congress 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 ("Tax Act") included 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 eliminated the health insurer tax. The Bipartisan Budget Act of 2018 ("BBA") among other things, amended 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". 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare reform measures will impact the ACA and our business.

Other legislative changes have also been proposed and adopted since the ACA 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 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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.

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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. 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.

We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business. However, 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

In connection with our work with the Department of Defense, we have become a defense contractor, and are therefore subject to new administrative burdens and control requirements in connection with the maintenance of that relationship.*

In September of 2021, we entered into an agreement with the department of defense relating to the conduct of a clinical trial in connection with the development of an improved plague vaccine. In connection with this agreement we became subject to new administrative and control requirements, including certain reporting obligations as well as a requirement to develop, implement and maintain an ITAR compliance program, among other things. Further, if our efforts result in an improved plague vaccine and we enter into a supply agreement for finished plague vaccines with the DoD, we expect that such a supply contract would impose additional administrative, control, compliance and other obligations. We have limited experience developing and administering such programs. Development and maintenance of such programs can be burdensome and costly and there can be no guarantee that we will be able to maintain compliance with all of the terms of such an agreement. Failure to comply with these requirements could have a significant reputational or financial impact on our business and on our stock price.

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.

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 products, 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 administrative proceedings related to our intellectual property which causes us to incur certain legal expenses. If we become involved in any litigation and/or other significant 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 or other 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 products or product candidates will decrease, and we may be unable to realize any commercial benefit from the development of a vaccine containing our CpG 1018 adjuvant.

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, or other disclosures which impact patentability, 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, our HEPLISAV-B and CpG 1018 adjuvant have 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 HEPLISAV-B and 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 HEPLISAV-B and CpG 1018. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that expire in 2032. 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 recurring 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 also uncertain. We may be particularly affected by this uncertainty since several of our product candidates or our collaborators' vaccine candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection, if any. For example, while many countries such as the U.S. 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 now or in the future;
- 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;
- other parties may design around technologies we have licensed, patented or developed; and
- pending patent applications or issued patents may be challenged by third parties in proceedings, such as inter partes review ("IPR"), pre- and post-grant oppositions, and post grant review ("PGR").

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 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 or other 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;
- 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 products or 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;
- the volume of trading in our common stock;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance; and
- industry conditions and general financial, economic and political instability, as well as developments with respect to the COVID-19 global pandemic, including but not limited to regulatory initiatives, such as the imposition of compulsory licenses related to COVID-19 vaccines, that may result in a general weakening of intellectual property protections.

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.

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 & Company, LLC, 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.

Risks Related to the Convertible Notes

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.*

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the $225.5 million in 2.50% convertible senior notes due 2026 ("Convertible Notes"), depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the notes for cash upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes.*

Holders of the Convertible Notes will have the right, subject to certain conditions and limited exceptions, to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. Moreover, we will be required to repay the Convertible Notes in cash at their maturity unless earlier converted, redeemed or repurchased. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture governing the Convertible Notes or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture governing the Convertible Notes would constitute a default under the indenture governing the Convertible Notes. A default under the

indenture governing the Convertible Notes or the occurrence of a fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes could constitute an event of default under any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Convertible Notes may adversely affect our financial condition and operating results.*

As of October 1, 2021, the conditions allowing holders to convert all or any portion of their Convertible Notes have been met, and holders of Convertible Notes are entitled to convert their Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Conversion of the Convertible Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.*

The conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. As of October 1, 2021, the conditions allowing holders to convert all or any portion of their Convertible Notes have been met. Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock.

Certain provisions in the indenture governing the notes may delay or prevent an otherwise beneficial takeover attempt of us.*

Certain provisions in the indenture governing the notes may make it more difficult or expensive for a third party to acquire us. For example, the indenture governing the notes will require us, subject to certain exceptions, to repurchase the notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its notes in connection with a make-whole fundamental change. A takeover of us may trigger the requirement that we repurchase the notes and/or increase the conversion rate, which could make it more costly for a potential acquirer to engage in such takeover. Such additional costs may have the effect of delaying or preventing a takeover of us that would otherwise be beneficial to investors.

The Capped Calls may affect the value of the Convertible Notes and our common stock.*

In connection with the issuance of the Convertible Notes, we have entered into Capped Calls with the option counterparties. The Capped Calls cover, subject to customary adjustments, the number of shares of common stock that initially underlie the Capped Calls. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

In connection with establishing their initial hedges of the Capped Calls, we have been advised that the option counterparties and/or their respective affiliates entered into various derivative transactions with respect to our common stock concurrently with or shortly after the pricing of the Convertible Notes and/or purchased shares of our common stock concurrently with or shortly after the pricing of the Convertible Notes. In addition, the option counterparties and/or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions following the pricing of the Convertible Notes and prior to the maturity of the Convertible Notes (and are likely to do so on each exercise date of the Capped Calls, which are expected to occur during the 30 trading day period beginning on the 31st scheduled trading day prior to the maturity date of the Convertible Notes, or following any termination of any portion of the Capped Calls in connection with any repurchase, redemption or early conversion of the Convertible Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Convertible Notes.

General Risk Factors

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.

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 data 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 GDPR, resulting in significant penalties; increased costs; loss of revenue; expenses of computer or forensic investigations; material fines and penalties; compensatory, special, punitive or statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; or injunctive relief. 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. In 2020, we 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.

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

None.

ITEM 5. OTHER INFORMATION

Amendment to CpG 1018 Adjuvant Supply Agreement with Valneva

On September 13, 2021, Valneva SE, an affiliate of Valneva, announced that the UK Government had terminated its supply agreement with Valneva Austria GmbH for VLA2001, resulting in a reduction of Valneva's requirements of CpG 1018 for use in the commercialization of vaccines containing VLA2001 and CpG 1018.

On October 29, 2021, Dynavax Technologies Corporation (the "Company") entered into a letter agreement (the "Amendment") with Valneva Scotland Limited and Valneva Austria GmbH (collectively, "Valneva"), amending the Supply Agreement between the Company and Valneva dated September 12, 2020, for the commercial supply of the Company's novel toll-like receptor 9 agonist adjuvant, CpG 1018, for use with Valneva's inactivated SARS-CoV-2 vaccine candidate, VLA2001 (the "Supply Agreement").

Under the Amendment, the Company and Valneva agreed to the cancellation of the two then outstanding purchase orders for CpG 1018 under the Supply Agreement that had not been fulfilled as of the date of the Amendment and that the Company is entitled to retain the advance payments made by Valneva under such cancelled purchase orders.

Pursuant to the Amendment, Valneva submitted, and the Company accepted, a new purchase order for a specified quantity of CpG 1018 for delivery in 2022 (the "New Purchase Order"), which Valneva has the right, in its sole discretion, to cancel by written notice to the Company on or before December 1, 2021. In addition, under the Amendment, the Company agreed to deliver notice to Valneva as to whether or not the Company can reasonably extend the shelf life of the CpG 1018 previously delivered to Valneva, and if the Company notifies Valneva that the Company has determined not to extend such shelf life, Valneva has the option, exercisable within a specified period after receipt of such notice, to submit one additional purchase order for an additional specified quantity of CpG 1018 for delivery in 2022 (the "Optional Purchase Order"). Other than the New Purchase Order and, if applicable, the Optional Purchase Order, Valneva has no right to submit any additional purchase orders for CpG 1018 under the Supply Agreement.

Under the Amendment, the Company acknowledged and agreed that it is deemed to have received advance payment of a specified percentage of the price of the CpG 1018 under the New Purchase Order and, if Valneva submits the Optional Purchase Order, the Company will be deemed to have received advance payment of a specified percentage of the price of the CpG 1018 under the Optional Purchase Order. The remainder of the price of the CpG 1018 under the New Purchase Order (unless cancelled on or before December 1, 2021), and, if Valneva submits the Optional Purchase Order, the remainder of the price of the CpG 1018 under the Optional Purchase Order, will be payable by Valneva upon delivery of such CpG 1018.

Under the Amendment, the parties amended the term of the Supply Agreement to expire, unless earlier terminated as permitted by the Supply Agreement, upon delivery of the CpG 1018 ordered under the New Purchase Order, except that if Valneva submits the Optional Purchase Order in accordance with the Amendment, the term will expire, unless earlier terminated as permitted by the Supply Agreement, upon delivery of the CpG 1018 ordered under the Optional Purchase Order.

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	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, and 3.9					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.3	Form of Warrant to Purchase Common Stock	4.1	8-K	August 8, 2019	001-34207	
4.4	Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021	4.1	8-K	May 13, 2021	001-34207	
4.5	Form of Global Note, representing Dynavax Technologies Corporation's 2.5% Convertible Senior Notes due 2026	4.2	8-K	May 13, 2021	001-34207	
10.1^	Supply Agreement dated July 1, 2021 by and between Company and Biological E. Limited	10.7	10-Q	August 4, 2021	001-34207	
10.2	Commercial Lease Agreement dated September 13, 2021 by and between Onyx Düsseldorf S.à r.l. and Dynavax GmbH					X
10.3^	First Amendment to Commercial Manufacturing and Supply Agreement dated September 10, 2021 by and between Baxter Pharmaceutical Solutions LLC and Dynavax Technologies Corporation					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

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)

+ Indicates management contract, compensatory plan or arrangement.

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because the Registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential.

* 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 4, 2021

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

Date: November 4, 2021

By: /s/ KELLY MACDONALD
Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer)

Date: November 4, 2021

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

Exhibit 10.2

COMMERCIAL LEASE

between

Onyx Düsseldorf S.à r.l.
2-4, Rue Eugène Ruppert
2453 Luxembourg
Luxembourg,

a limited liability company (*société à responsabilité limitée*) established and existing under the laws of the Grand Duchy of Luxembourg and registered with the Commercial Register of Luxembourg (*registre de commerce et des sociétés*) under RCS No. 111201,

represented by its sole managing director Mileway DirectorCo S.A.,

which, in turn, is represented as indicated in the signature line either by a managing director having sole power of representation or by one of the authorised representatives Nellie Esparza, Veronique Colson and Anna Cirka, who have sole power of representation by virtue of a Power of Attorney dated 28 July 2021, a copy of which is attached to this Lease as **Appendix I**,

– hereinafter referred to as "**Landlord**" –

and

Dynavax GmbH
Eichsfelder Straße 1-11
40595 Düsseldorf
Germany,

VAT identification number: 119436703

represented by either of the following managing directors having sole power of representation, Dr Eric Frings or Dr Andreas Richter

– hereinafter referred to as "**Tenant**" –

– Landlord and Tenant hereinafter also referred to each as a "**Party**" and jointly as the "**Parties**"–

regarding commercial space in the property located at

Eichsfelder Straße 1-11, 40595 Düsseldorf, Germany

Contents

1 Leased Premises

1.1 The Landlord is the owner of the property with the postal address Eichsfelder Straße 1-11, 40595 Düsseldorf, Germany ("**Property**"). The following areas, whose total size (excluding the parking spaces) is approximately 5,626 m² (together, the "**Leased Premises**") and which are marked in colour in **Appendix 1.1**, shall be let to the Tenant for commercial use:

(a) hall and office space (B1-B4) ca. 3,900 m² (marked in red);

(b) hall and office space (A5a and A5b) ca. 1,726 m² (marked in red); and

(c) car parking spaces 55 parking spaces (nos. 31-36, 65-68, 80-107, 130, 134, 135, 138-151).

1.2 Because of possible measurement errors, the indicated area sizes shall not determine the Leased Premises. The dimensions of the leased space shall be determined by the number and descriptions of the leased areas. The Tenant is familiar with the Leased Premises. If there are deviations in area sizes, these shall not affect the Parties' rights and obligations under this Lease.

1.3 A lease dated 27 December 2006 (no. 9.2077.11.03) together with a first addendum dated 1/5 July 2019, a second addendum dated 30 July/11 August 2020 and a third addendum dated 11 November/3 December 2020 (hereinafter together, the "**Former Lease**") existed between the Parties in relation to the Leased Premises. The Parties are familiar with that Former Lease and refrain from attaching it to this Lease.

1.4 The Landlord and the Tenant agreed in a fourth addendum to the Former Lease to cancel the Former Lease in relation to the Leased Premises with effect as of 31 December 2021, midnight, and the Landlord and the Tenant hereby enter into a new tenancy in accordance with the provisions of this Lease. From the Lease Commencement Date, as defined in clause 3.1 of this Lease, the tenancy shall be governed exclusively by the provisions of this Lease.

1.5 In light of the conclusion of this Lease, the Landlord refrains at this point from demanding the fulfilment of any obligations to remove structural changes on the occasion of the cancellation of the Former Lease. Any Servicing, Maintenance or Corrective Maintenance obligations that are due under the Former Lease must be fulfilled by the Tenant, even if they have arisen before 1 January 2022.

1.6 From the Lease Commencement Date, as defined in clause 3.1 of this Lease, the obligations to remove structural changes and the Servicing, Maintenance or Corrective Maintenance obligations shall then be governed by the provisions of this Lease. If and to the extent that the condition of the Leased Premises at the time of handover or on the Lease Commencement Date is relevant for this purpose, the condition of the Leased Premises at the time of handover of the Leased Premises to the Tenant under the Former Lease shall be decisive.

1.7 As the Tenant has already used the Leased Premises, the Leased Premises will not be handed over to the Tenant. The Tenant is familiar with the Leased Premises and, therefore, acknowledges that the condition of the Leased Premises is suitable for the Tenant's lease purposes and declares that the Leased Premises are in a condition that is as agreed in this Lease at the time of signing this Lease.

The Landlord does not owe any improvement work. This fact was taken into account by the Parties when determining the rent and the rent-free period.

The Tenant may create any facilities, fixtures and fittings and decorations that are required or desired for the operation of its business itself, at its own expense and its own risk. The Tenant shall obtain any permit that may be needed itself, at its own expense and its own risk, and shall indemnify the Landlord in this respect against any third-party claims. The Tenant shall be liable

for any damage suffered in connection with such facilities, fixtures and fittings and decorations and shall indemnify the Landlord against any claims asserted by third parties. Clause 14 of this Lease shall apply additionally.

1.8 The building envelope, the Roof and the existing outdoor areas shall only be included in this Lease *(mitvermietet)* if this has been expressly agreed in this Lease. If said areas are not included in this Lease *(mitvermietet)*, the Landlord reserves the right to let the Roof, the building envelope and the outdoor areas separately. An exception to this shall be made for the cooling water systems already installed on the Roof by the Tenant, which may remain on the Roof free of charge during the entire term of this Lease.

1.9 The Landlord shall have the right to change the location of the parking spaces that are included in this Lease *(mitvermietet)* at its reasonable discretion in accordance with Section 315 German Civil Code *(Bürgerliches Gesetzbuch – "BGB")*, taking into account the Tenant's interests, if the management of the Property so requires. In the event that the Landlord makes use of this right, the Tenant undertakes to enter into a "written form-compliant" *(schriftformkonform)* addendum to this Lease with the Landlord regarding such change. The change shall only become effective upon conclusion of the addendum.

1.10 Storing objects, of whatever kind, outside the Leased Premises is prohibited. Parking vehicles outside the Leased Premises is also prohibited, except for the purposes of immediate loading and unloading. Escape and rescue routes, as well as emergency access drives for fire brigade vehicles, must be kept clear at all times.

1.11 Except to the extent expressly otherwise provided in this Lease, the Leased Premises additionally do not include any operating equipment *(Betriebsvorrichtungen)* within the meaning of Section 68(2) no. 2 German Valuation Act *(Bewertungsgesetz)* or other movable assets (e.g. any office furniture or fixtures and fittings drawn in on any plans). In the event that the Leased Premises contain any such assets, the Landlord may, at any time, exclude these assets from this Lease. In this case, the Tenant shall be obliged to enter into a "written form-compliant" *(schriftformgerecht)* addendum with the Landlord regarding the exclusion of the operating equipment *(Betriebsvorrichtungen)* from this Lease. Furthermore, the Tenant shall be obliged, following a written request from the Landlord, to participate in the conclusion of a new lease regarding the operating equipment *(Betriebsvorrichtungen)* that meets the written form *(Schriftform)* requirement under Sections 550, 126 German Civil Code *(BGB)*. That new lease may not place the Tenant into a less favourable position economically than it is in under this Lease with regard to such existing operating equipment *(Betriebsvorrichtungen)*, if any. This clause 1.11 shall not apply to facilities or other objects owned by the Tenant or by a party (bank) furnished with security by the Tenant.

2 Lease purpose

2.1 The Leased Premises are let exclusively for use as a warehouse and as production space for biotechnical products and processes or, where space has been marked as office space for this purpose, for use as such. The Tenant must observe all technical and official orders that are addressed to the Tenant or relate to the Tenant's business, in particular any orders from the building authorities and the fire brigade. The Landlord shall not be liable for any further official permits, concessions, approvals or similar administrative acts that may be required due to circumstances the lie within the Tenant's business or person. The Tenant must obtain, and fulfil, any such required official permits, concessions, approvals or similar administrative acts at its own expense and its own risk.

The use of the Leased Premises in accordance with the aforesaid purpose must take place in such a way that there are no significant annoyances to other tenants of the Property. In particular,

goods must be stored in such a way as to rule out – or at least largely avoid – any pollution *(Immissionen)* (odour, dirt, etc.) of other rental areas. Smoking is strictly prohibited in all closed rooms *(geschlossene Räume)* on the Property and the Tenant must ensure that this prohibition is observed by its employees, suppliers, customers and other visitors.

2.2 The Leased Premises are located in a business park. The obligations *(Auflagen)* that are associated with this circumstance must be observed. This shall also apply to any business-related obligations *(Auflagen)* stipulated in building permits. The Leased Premises may not be used for residential purposes. The Tenant must observe the applicable noise control and environmental protection regulations.

2.3 The Landlord does not warrant that the Leased Premises can be heated to a certain temperature and/or that they will not heat up beyond a certain temperature. The Tenant is especially aware that the Leased Premises do not have air conditioning. In particular, the Landlord does not warrant that the Leased Premises can be heated, or cooled down, to a temperature that is in compliance with the provisions of the German Workplace Ordinance *(Arbeitsstättenverordnung)*.

2.4 The Landlord does not warrant that the Leased Premises generally comply with the provisions of the German Workplace Ordinance *(Arbeitsstättenverordnung)* or any other regulations protecting employees.

2.5 The existing supply networks for electricity, gas and water may only be used by the Tenant to an extent which does not cause a network overload. When inspecting the Leased Premises, the Tenant has verified that the existing supply networks suffice for the Tenant's purposes. The Tenant shall be liable for any damage sustained as a result of a network overload for which the Tenant is responsible. The Tenant shall have the right, even without obtaining the Landlord's consent, to carry out minor changes to the sub-distribution at the Tenant's own expense and, if necessary, extend the supply pipes or supply lines at the Tenant's own expense and its own risk if and to the extent that this is technically feasible and does not cause any additional costs to the Landlord. The Tenant shall professionally document these changes and present this documentation to the Landlord upon request.

2.6 Before setting up heavy objects (machinery, strongboxes, etc.), the Tenant must enquire with the Landlord whether the load on the floors *(Geschossdecken)* is permitted. If the Landlord does not have the relevant information, the Tenant must ascertain at its own expense that the load-bearing capacity *(Tragfähigkeit)* suffices and furnish the Landlord with supporting documents. The permitted load may not be exceeded. If it is nevertheless exceeded, the Tenant shall be liable for all resulting damage and consequential damage and shall be obliged to indemnify the Landlord against any third-party claims arising from this.

2.7 The Tenant shall, at its own expense, integrate the rooms that are used exclusively by the Tenant into the Landlord's locking system.

3 Term of the Lease

3.1 The tenancy shall commence on 1 January 2022 ("**Lease Commencement Date**") and shall be for a fixed term until 31 December 2031, midnight ("**Fixed Lease Term**").

3.2 During the Fixed Lease Term, the tenancy may not be terminated without good cause (no 'ordinary termination'). This shall not affect the right to terminate the tenancy without notice for good cause ('extraordinary termination').

3.3 The Parties clarify that the Landlord initially did not want to grant the Tenant a renewal option and that it only agreed at the Tenant's insistence after intensive negotiations to grant the Tenant two renewal options on the following terms:

The Tenant is hereby granted the option to provide the Landlord no later than twelve (12) months before the Fixed Lease Term or the previous Renewal Period, as applicable, is due to expire with written notice to renew the tenancy on the following terms, it being understood that the receipt by the Landlord of the notice to exercise this option shall be decisive in calculating the 12-month period:

a) Two times renewal of the tenancy for another five (5) years ("**Renewal Period**") on the current terms, unless otherwise agreed below.

b) The monthly rent for the respective Renewal Period shall, at minimum, be an amount equal to the agreed rent payable in the month before the respective Renewal Period commences (clause 5 below in conjunction with clause 7 below).

c) The Tenant expressly acknowledges that the Landlord shall have the right to raise the rent at the beginning of the respective Renewal Period to reflect the then applicable market price for similar office and storage buildings in a similar location, provided the Landlord has presented the Tenant no later than eighteen (18) months before the expiry of the Fixed Lease Term or the previous Renewal Period, as applicable, with an independent market price assessment commissioned by the Landlord and prepared by an internationally operating broker firm (e.g. JLL, CBRE or BNP Paribas) according to which the market price is at least 0.5% higher. Before instructing the broker firm, the Landlord shall propose three (3) broker firms to the Tenant for selection from which the Tenant may choose one broker firm. If the Tenant does not notify the Landlord of its selection within two (2) weeks after the receipt of the Landlord's proposal, the Landlord may select one of the proposed broker firms itself. The Tenant shall be free to additionally obtain its own market price assessment for information before exercising the option. However, the Landlord shall not be obliged to base the adjustment of the rent on any market price assessment that may have been obtained by the Tenant, but must at least take into account such an assessment at its reasonable discretion.

d) The renewal of the tenancy shall take effect upon the Tenant exercising the option as agreed in this Lease. If the Landlord asserts a legitimate claim for an increase in rent in accordance with clause 3.3 (c) above, both Parties shall be obliged to enter into an addendum to this Lease that meets the written form requirement and in which it is provided that the rent shall be adjusted at the beginning of the Renewal Period. Clause 7 (Indexation) below shall apply correspondingly to the adjusted rent.

e) The costs incurred by the Landlord in commissioning a broker firm that meets the above criteria shall be borne by the Parties in equal parts.

If the Tenant continues to use the Leased Premises after the term of this Lease has expired, the tenancy shall not be deemed renewed for an indefinite period of time. Section 545 German Civil Code *(BGB)* shall not apply.

4 Extraordinary termination

4.1 Either Party shall have the right of extraordinary termination in accordance with the statutory provisions.

4.2 Furthermore, the Landlord shall have the right to terminate the tenancy without notice if the lease security is not provided as agreed in this Lease (clause 6 below).

5 Rent

5.1 From the Lease Commencement Date, the total rent payable each month shall amount to:

Base rent for halls and office space (B1-B4, A5a and A5b)	EUR 47,500.00
Base rent	**EUR 47,500.00**
plus advance payment on Operating Costs	EUR 12,377.20
Total net rent	EUR 59,877.20
plus VAT at the rate applicable from time to time, currently 19%	EUR 11,376.67
Total rent	**EUR 71,253.87**

The Landlord grants the Tenant a rent-free period as provided below:

For the months of January 2022 to (and including) May 2022, no base rent shall be owed. The Operating Costs must, however, be paid during this period through the advance payments plus VAT thereon at the rate applicable from time to time. If any costs or cost limits are defined as a percentage of the base rent, the above-stated regular base rent shall nevertheless be used as a basis also during the rent-free period.

5.2 The total monthly rent shall be paid by no later than the third working day of each month in advance free of charge into a bank account whose details shall be provided separately by the Landlord. The rent shall be deemed paid in due time if it is received in the Seller's bank account by the aforesaid deadline. The Landlord shall issue to the Tenant a permanent invoice for the rent in which the details of the bank account applicable from time to time for the payment of the rent are stated.

5.3 The Tenant may not reduce the amount of the Landlord's claims by the amount of any counterclaim or exercise a right of retention unless the Tenant's counterclaim or the right of retention is undisputed *(unbestritten)* or has been established in a judgment that cannot be appealed against *(rechtskräftig festgestellt)*. Where this is not the case, the Tenant must assert a separate counterclaim. The above restrictions on set-offs and on the right of retention shall also apply after the term of this Lease has ended until the Leased Premises have been returned to the Landlord. The above shall not affect the Tenant's claims for repayment, if any, under Section 812 German Civil Code *(BGB)*. The above restrictions shall not affect the assertion of a right to reduce the rent; however, the Tenant must have notified the Landlord at least one month in advance of the defect that is the reason for reducing the rent *(Mietminderung)*.

5.4 If the Tenant is late *(in Verzug)* with the payment of the rent ('default'), the Tenant shall be obliged to pay at least default interest at the statutory rate, which is currently 9 percentage points above the basic interest rate *(Basiszinssatz)* pursuant to Section 247 German Civil Code *(BGB)*, and a lump sum of EUR 40.00 pursuant to Section 288(5) German Civil Code *(BGB)*. The right to assert further claims for damages shall remain unaffected.

6 Lease security

6.1 On the Lease Commencement Date, as defined in clause 3.1 above, the Tenant shall, concurrently with *(Zug um Zug)* the return of the lease security provided under the Former Lease, or concurrently with *(Zug um Zug)* the reduction of the lease security provided under the Former Lease to a reduced amount of EUR 33,840.72, as applicable, provide to the Landlord as security for all of the Landlord's direct and indirect claims arising from this tenancy, including any post-contractual claims, security in the amount of

EUR 213,761.61

(this amount corresponds to the total rent for three months, as per the Lease Commencement Date, not taking into account any rent-free periods).

6.2 The Tenant may choose whether to provide this security in the form of

(a) a (non-interest-bearing) cash deposit or

(b) an open-ended, irrevocable, unconditional and directly enforceable *(selbstschuldnerische)* guarantee from a bank, insurance company or savings bank that has its registered office or a branch in Germany in which the guarantor has waived the defences of failure to make a set-off (Section 770(2) German Civil Code *(BGB)*), except in the case of claims that are undisputed *(unbestritten)* or have been established in a judgment that cannot be appealed against *(rechtskräftig festgestellt)*, of failure to contest and of failure to pursue remedies (Sections 770(1), 771 German Civil Code *(BGB)*) *(Einreden der Aufrechnung, Anfechtung und Vorausklage)* and also the right to make a deposit *(Recht zur Hinterlegung)*.

6.3 If the total monthly rent increases by more than 10% in the course of the tenancy, the Tenant shall be obliged to appropriately increase the lease security without undue delay and in any case no later than four weeks after receipt of a written request from the Landlord.

6.4 After setting a reasonable deadline, the Landlord may draw on the security to satisfy due claims already during the tenancy. In the event that the security is rightfully drawn upon during the term of this Lease, the Tenant shall be obliged to replenish the security with the amount used. The agreements as to how to provide the security shall apply correspondingly to its replenishment.

6.5 As regards the Landlord's lien *(Vermieterpfandrecht)*, the statutory provisions shall apply. The Tenant undertakes to inform the Landlord without undue delay of any attachment of physical items that have been added to the Leased Premises.

6.6 In the event that the Leased Premises are sold, the Landlord shall have the right to transfer the lease security to the buyer – with debt-discharging effect *(schuldbefreiende Wirkung)* for the Landlord, as between Landlord and Tenant. The Tenant hereby gives its irrevocable consent to such transfer.

7 Indexation

7.1 The base monthly rent pursuant to clause 5.1 of this Lease shall change automatically as of 1 January of each year, for the first time as of 1 January 2024, without the need for a request or notification from either Party, by the same percentage by which the Consumer Price Index for Germany ("**Consumer Price Index**") that is determined by the German Federal Statistical Office *(Statistisches Bundesamt)* has changed on a monthly average (monthly indices) compared to 1 January of the respective previous year ("**Indexation Clause**").

7.2 If, when changing the base year of the index, the Federal Statistical Office subsequently withdraws index numbers already published for previous base years, the changes in rent that have already taken place shall not be corrected. Any future changes in rent shall then be based on the newly published index numbers.

7.3 In the event that the Consumer Price Index is replaced with another, similar index, including a European Index, in the future, that index shall automatically replace the current index for the purposes of this Lease. The German Price Clause Act *(Preisklauselgesetz – "PrKG")* shall apply additionally.

7.4 The Landlord is a non-resident *(Gebietsfremder)* within the meaning of Section 6 German Price Clause Act *(PrKG)* of 7 September 2007. The Parties therefore assume that the provisions of the German Price Clause Act *(PrKG)* do not apply to the agreed Indexation Clause, pursuant to Section 6 German Price Clause Act *(PrKG)*. If, contrary to expectations, this is not the case and the agreed Indexation Clause is not a permitted price clause pursuant to the provisions of the German Price Clause Act *(PrKG)* and the invalidity of the clause has been established pursuant to Section 8 German Price Clause Act *(PrKG)*, the Parties agree that the Indexation Clause shall

be reinterpreted as a reservation of the right to determine the obligation to be performed *(Leistungsvorbehalt)* in the sense of an adjustment clause.

8 Operating Costs and sustainability

8.1 From the time of the handover, the Tenant shall bear the Operating Costs attributable to the Leased Premises and, on a pro rata basis, the Operating Costs attributable to the Property as a whole, plus VAT at the statutory rate applicable from time to time.

8.2 For the purposes of this Lease, "**Operating Costs**" shall mean – to the extent that the Leased Premises and/or the Property have, now or in the future, the relevant structures or fixtures and fittings – the operating costs as defined in Section 2 German Operating Costs Ordinance *(Betriebskostenverordnung – "BetrKV")*, as amended from time to time, including the "other operating costs" pursuant to Section 2 no. 17 German Operating Costs Ordinance *(BetrKV)* which are listed below. The Parties are in agreement that Section 2 German Operating Costs Ordinance *(BetrKV)* has been drafted for residential leases and is to be understood in a broader sense in the case of a tenancy regarding commercial space.

The "other operating costs" within the meaning of Section 2 no. 17 German Operating Costs Ordinance *(BetrKV)* include in particular the following (additional) costs:

(a) the cost of commercial and technical property management in the amount actually incurred, at maximum an amount equal to 5% of the base annual rent applicable from time to time (without taking into account any rent-free periods);

(b) the cost of the insurance policies taken out by the Landlord, in particular, buildings insurance, including damage caused by bursting or leaking water pipes *(Leitungswasserschäden)*, insurance against damage caused by natural forces *(Elementarschaden)*, third-party liability insurance *(Haftpflicht)* and terrorism insurance;

(c) the cost of insurance against loss of rent *(Mietausfall)* (cost allocation limited to an amount equal to 1% of the net base annual rent);

(d) the costs for the operation (including any required inspections and operating current), Servicing, Corrective Maintenance and Maintenance of the common areas, common installations and common facilities, including the outdoor facilities and parking spaces, which are located **outside** the Leased Premises as well as of any areas, installations and facilities within the Leased Premises for which the Tenant does not bear the burden of upkeep *(Erhaltungslast)*, in particular:

- advertising facilities, signage;
- manually and power-operated doors, gates and gate systems, in each case including all the appurtenant loading technology, such as loading bridges, dock shelters, etc., as well as the appurtenant locking systems, access control systems, door intercom systems, etc.;
- lifting technology, such as lifting platforms, crane systems, crane runways, conveyer systems, etc.;
- passenger and goods lifts, moving escalators and moving walkways, etc.;
- barrier systems, cashier systems;
- fire protection gates and doors, fire detection systems, smoke detection and extraction systems, fire extinguishers, fire extinguishing installations, safety lighting, sprinkler systems, lightening protection systems, fire alarm and fire extinguishing systems, hydrants, hose boxes;

- air conditioning systems, ventilation systems, cooling technology, sun protection systems, such as blinds, films, etc.;
- emergency power generators including tanks, backup batteries;
- security systems, in particular, burglar alarm systems, surveillance systems, etc.;
- electrical installations, including medium-voltage installations and all sub-distribution boards;
- measurement, regulation and control technology, in particular consumption recording devices (including the cost of leasing such devices);
- waste disposal systems, such as waste sorting and waste compression systems, etc., lifting systems, groundwater pumps;
- cosmetic repairs to common areas;
- other common installations and facilities of a structural or technical nature.

The allocation of costs to the Tenant for the aforesaid Maintenance and Corrective Maintenance shall be limited each year to an amount equal to 8% of the respective base annual rent (without taking into account any rent-free periods). The above provisions shall not apply to the Maintenance and Corrective Maintenance of “Roof and Structure”, which shall be carried out by the Landlord at the Landlord’s own expense;

(e) the cost of cleaning the common facilities, the common restrooms and their sanitary installations, the car parking facilities as well as any other parking areas, the private and public roads, the other outdoor facilities (including street cleaning and snow clearing and gritting) as well as all general glass surfaces (including the appurtenant ancillary surfaces, in particular the skylight domes);

(f) the upkeep of green areas (including renewing plants and woody plants) and any other land owned;

(g) the cost of guarding the property, including the necessary personnel;

(h) the cost of a fire safety officer;

(i) rainwater charges;

(j) drinking water analysis;

(k) the cost of Servicing the Roof (but not the cost of Corrective Maintenance or Maintenance), including the removal of moss and the cleaning of the Roof covering, cleaning of the guttering;

(l) land tax, even in the event that this cost item should no longer be listed in the German Operating Costs Ordinance *(BetrKV)* in the future.

8.3 The Tenant shall also bear current Operating Costs that are associated with the management of the Leased Premises and the Property if and to the extent that such costs only arise newly in the future. The Landlord shall have the right to additionally allocate such newly arising costs to the Tenant from the time that they arise. In order to limit the economic risk for the Tenant, such new costs shall be limited to an amount equal to 10% of the contractually agreed Operating Costs (this means that the Tenant shall only have to bear an amount equal to up to 10% of the total Operating Costs that were to be borne by the Tenant under this Lease pursuant to the respective previous statement of Operating Costs). To the extent permitted by law, the advance payments on the Operating Costs shall be appropriately supplemented and/or their amount adjusted.

8.4 The Tenant shall bear all consumption costs for the Leased Premises, including the electricity costs. To the extent that a contract can be entered into directly between Tenant and provider (regarding the supply of energy, water, etc.), the Tenant shall be obliged to enter into an agreement directly with the providers. In this case, the Tenant shall directly bear the costs incurred. The Tenant shall, therefore, be obliged to pay without undue delay any Operating Costs and additional costs billed directly to the Tenant by the providers. If it is not possible for the Tenant to purchase electricity directly from the provider on the Property (for example, because there is no separate electricity supply to each tenant that could be recorded by the provider), the electricity supply shall be provided by the Landlord and the cost billed to the Tenant as part of the statement of Operating Costs.

8.5 If the Tenant's business leads to an accumulation of packaging or other materials that take a lot of space in the waste containers, the Tenant shall bear the cost of any additional waste containers that the Landlord requests or purchases at its reasonable discretion.

8.6 Should an interim reading of usage recording devices become necessary, the Tenant shall bear the necessary costs. The same shall apply if any change-of-user fees are incurred. The Tenant shall be obliged to ensure that consumption meters and other measuring devices are accessible at all times. In the event that water is consumed for commercial purposes, the Tenant must, at its own expense, install an intermediate water meter.

8.7 The Tenant shall make a monthly advance payment on the Operating Costs or, if and to the extent that flat-rate compensation has been agreed for the Operating Costs, a monthly flat rate in the amount agreed in clause 5.1 of this Lease plus VAT at the statutory rate applicable from time to time.

8.8 The Landlord may adjust the amount of any agreed advance payment at its reasonable discretion with effect for the future if the statement of Operating Costs results in a credit balance or in an additional claim, or in the event of an increase or reduction in Operating Costs.

8.9 Adjustments to an agreed flat rate for Operating Costs shall be made in accordance with the rules set out in Section 560(1) German Civil Code *(BGB)* and shall be permitted in the event there is a change in the Operating Costs, including land tax, that are mentioned in the German Operating Costs Ordinance *(BetrKV)*, as amended from time to time, or upon new Operating Cost items being included in the German Operating Costs Ordinance *(BetrKV)*. If land tax is deleted from the German Operating Costs Ordinance *(BetrKV)*, there shall be no reduction of the flat rate for Operating Costs.

8.10 As a rule, the Landlord shall carry out a settlement of accounts in relation to the advance payments on the Operating Costs once a year, without this being a preclusion period. The Operating Costs invoiced to the Tenant shall be in the proportion to which the agreed size of the Leased Premises pursuant to clause 1.1 of this Lease bears to the total rental space of the Property or of the building in which the Leased Premises are located, as applicable, except to the extent that the Operating Costs can be or are invoiced based on consumption or based on a flat rate agreed in this Lease or that other allocation criteria are more appropriate at the Landlord's reasonable discretion (cf. clause 8.11 below). For the avoidance of doubt, this shall also apply in the event that a (sub-)meter recording the amount of electricity consumed does not exist for the Leased Premises. The Landlord shall have the right to allocate the consumption-based additional costs, such as the cost of irrigation/water supply and drainage (excluding the charges for surface water/sealed surfaces) or of waste collection, only to those areas of the Property that are actually used if and to the extent that these costs have been incurred solely in respect of these areas actually used. The heating and hot water costs shall be calculated and invoiced as provided in the German Heating Costs Ordinance *(Heizkostenverordnung)*.

8.11 The Landlord may, at its reasonable discretion, combine the buildings which are located on the Property or properties that are locally connected to the Leased Premises into economic or accounting units. This shall only apply to the extent that the buildings are managed uniformly. The determination and allocation of Operating Costs within the framework of economic or accounting units shall not be limited to jointly incurred Operating Costs. It does not matter for the formation of an economic or accounting unit if the buildings are not used in a uniform manner or if there are significant differences in the buildings' mutual usage value. The Landlord may also decide at its reasonable discretion whether and which of the Operating Costs to allocate to groups of users according to the type and scope of use or consumption.

8.12 The Landlord shall have the right, within the limits defined by the statutory requirements, to change the allocation formula at its reasonable discretion based on objective considerations if an appropriate allocation of costs or compelling reasons of proper management so require. Adjustments to the allocation formula may only be made with effect for the future, that is, for settlement periods that have not yet commenced at the time of receipt by the Tenant of the corresponding change notice from the Landlord. At the request of either Party, the Parties shall enter into a "written form-compliant" *(schriftformkonform)* addendum regarding the change to the allocation formula.

8.13 The statement of Operating Costs shall be deemed accepted by the Tenant if the Tenant does not object in writing within two months of the receipt of the statement of Operating Costs – whereby an objection shall be deemed made in due time if received by the Landlord before the expiry of the aforesaid period – and the Landlord has informed the Tenant of this deadline and of the consequences of failure to object or of a late objection in the statement of Operating Costs. Upon request, the Tenant shall be allowed to inspect the documents on which the statement is based.

8.14 Any credit balances or additional claims resulting from an advance payment on Operating Costs and determined in the statement of Operating Costs shall be mutually settled without undue delay, which means within two months, as a rule. If the Tenant is in arrears with the rent at the time the statement is completed, the Landlord may reduce a credit balance determined in the statement by the outstanding amount of rent.

8.15 The Tenant acknowledges that it is very important to the Landlord that the Property is ecologically efficient and sustainable and that the Property's environmental performance is good. The Landlord and the Tenant are in agreement that they wish to promote and improve the environmental compatibility of the Leased Premises. They agree to cooperate in order to develop suitable strategies for how to improve the environmental compatibility of the Property and the Leased Premises. Observing the requirements under data protection law (such as the EU General Data Protection Regulation and the German Metering Point Operation and Data Communication in Intelligent Energy Networks Act *(Gesetz über den Messstellenbetrieb und die Datenkommunikation in intelligenten Energienetzen – "MsbG")*, the Landlord and the Tenant shall furnish each other with the environmental and consumption data that they have in relation to the Leased Premises so that such data can be exchanged between them or with third parties. To the extent that the consent of connection users needs to be obtained in order to use personal data, the Tenant shall grant such consent or, where the Tenant itself is not the connection user, obtain such consent from the connection users or, alternatively, anonymise the data. The Landlord shall provide the Tenant with the information needed to obtain the connection users' consent. Except where they are subject to a statutory disclosure obligation, the Landlord and the Tenant shall treat as confidential any data that is disclosed in accordance with this clause, and they shall use such data only for the following purposes: (a) monitoring and improving the environmental performance of the Property and/or of the Leased Premises and/or (b) measuring the environmental performance of the Property and/or of the Leased Premises based on agreed targets. If the Landlord or the Tenant passes on the jointly used data to third parties as agreed, it must be

ensured that the obligation is imposed on these third parties to treat the data as confidential and use it only for the purposes set out in this clause.

8.16 The Landlord may, at its discretion but in accordance with the provisions of the German Metering Point Operation and Data Communication in Intelligent Energy Networks Act *(MsbG)*, install recording devices in order to measure the energy/fuels/water or other utilities supplied to the Property and the Leased Premises. This must be done in compliance with the applicable requirements under data protection law. The Landlord shall have the right to enter, or have entered, the Leased Premises upon agreement in order to carry out the relevant work.

8.17 The Tenant shall be furnished with the statement of Operating Costs no later than 15 months after the settlement period has ended.

9 VAT

9.1 The Landlord has waived the exemption from VAT under Section 4 no. 12a) German VAT Act *(Umsatzsteuergesetz – "UStG")* for the letting in accordance with Section 9 German VAT Act *(UStG)* ("**Option for VAT**"). The Tenant is aware that the Landlord's Option for VAT is only permitted under the conditions specified in Section 9(2) German VAT Act *(UStG)*. The Tenant shall be obliged to use the Leased Premises exclusively to generate sales that are harmless *(unschädlich)* within the meaning of Section 9(2) German VAT Act *(UStG)*, as amended from time to time, or within the meaning of any other provisions or administrative instructions applicable from time to time.

9.2 Upon request, the Tenant shall furnish the Landlord at any time without undue delay with the documents that enable the Landlord to comply with its obligation under Section 9(2) German VAT Act *(UStG)* to provide supporting documents to the tax authorities. Should any circumstances arise on the part of the Tenant which affect the permissibility of the Landlord's Option for VAT, or should such circumstances be assumed to exist by the tax authorities in the context of a tax audit, the Tenant shall be obliged to so notify the Landlord without undue delay – if the relevant knowledge is obtained later, also with retroactive effect.

9.3 In the event that the sales generated in the Leased Premises prevent the Landlord's Option for VAT, the base rent payable by the Tenant shall increase – also subsequently, if appropriate – by the amount of VAT that would have been incurred if the Option for VAT had been valid, that is, currently by 19%. In that case, the Landlord shall correct the invoice(s) accordingly. In addition, the Tenant shall be obliged to compensate the Landlord for any further damage resulting from the breach of these obligations ("**Input Tax Loss**"). The Input Tax Loss shall especially be deemed to include the sum of (a) the input tax amounts from investments and current costs attributable to the Leased Premises directly and on a pro rata basis which were originally claimed by the Landlord and must be paid back to the tax office, (b) the interest payable to the tax office in this connection pursuant to Section 233a German Fiscal Code *(Abgabenordnung – "AO")*, as well as (c) any amounts of VAT from investments and current costs that will be attributable to the Leased Premises both directly and on a pro rata basis and cannot be deducted as input tax. The Tenant is expressly advised that the Landlord has claimed and/or will claim the input tax from the acquisition, manufacturing and upkeep costs relating to the Leased Premises and that the Landlord will suffer considerable damage if the Tenant fails to observe the above obligations.

9.4 In the event of Subletting, the provisions of clauses 9.1 to 9.3 above shall also apply correspondingly to the Subtenant and, if applicable, all further Subtenants. The Tenant, in turn, shall be obliged to opt for VAT for the Subletting and to impose the provisions of clauses 9.1 to 9.3 above on the Subtenant in the sublease in such a way that the Landlord has an independent right to demand compliance with said provisions (contract for the benefit of a third party), as well

as to use its influence to achieve that any further Subtenants are bound by corresponding obligations. Each other permission of use *(Gebrauchsüberlassung)* granted to third parties or subleasing *(Unterverpachtung)* shall also be deemed to constitute Subletting.

9.5 The Tenant shall be liable in addition to the Subtenant for any disadvantages suffered by the Landlord as a result of the violation of any of the above provisions. Should the Tenant and/or, in the event of Subletting, the Subtenant breach any of the above obligations, the Tenant must compensate the Landlord for any and all damage, costs and other disadvantages resulting from such breach, in particular the Input Tax Loss.

9.6 The Landlord shall be obliged to issue to the Tenant proper invoices stating the VAT, except to the extent that this Lease in conjunction with documents determining the period of performance of the respective partial obligations (e.g. bank transfer orders regarding the payment of the rent), can be considered a permanent invoice. The Landlord shall be liable for any costs, damage or other disadvantages, in particular in terms of tax, suffered by the Tenant as a result of an improper invoice from the Landlord. The Tenant shall be obliged to check each invoice carefully upon receipt. To the extent that corrections to the invoice are required, the Tenant shall so notify the Landlord without undue delay in writing. The Landlord shall not be liable for any costs, damage or other disadvantages suffered by the Tenant as a result of late notification.

9.7 Any claims under this clause 9 shall be subject to statutory limitation. However, they shall not become time-barred earlier than six (6) months after the date on which the respective VAT assessment has become definitive and final *(endgültig bestandskräftig)*.

10 Cosmetic repairs, Maintenance, Corrective Maintenance, Servicing

10.1 The Landlord shall not be obliged to carry out cosmetic repairs within the Leased Premises.

During the term of this Lease and until the Leased Premises are returned, the Tenant shall be obliged, at its own expense, to properly and professionally carry out, or have carried out, cosmetic repairs within the Leased Premises **if and to the extent that such cosmetic repairs are due to the use of the Leased Premises since they were handed over to the Tenant** and that they are necessary according to the degree of actual wear and tear. This was taken into account by the Parties when determining the rent. If the Tenant fails to comply with the above obligation, the Landlord shall have the right, after setting a reasonable grace period, to arrange for the necessary work to be carried out at the Tenant's expense. **An improvement compared to the condition as per the Lease Commencement Date shall not be owed.** Cosmetic repairs include the wallpapering, painting or whitewashing of the walls and ceilings, the internal doors and the inside of the windows and external doors and the painting of the floors or, as an equivalent measure, the basic cleaning of floors (in particular, shampooing in the case of carpeting or the use of a cleaning agent and subsequent application of a protective emulsion in the case of parquet flooring). The Tenant shall be under no obligation, both during the term of the tenancy and when the tenancy ends, to carry out cosmetic repairs at regular intervals regardless of whether they are necessary.

10.2 The Tenant shall, at its own expense, carry out the Servicing, Maintenance and Corrective Maintenance within the Leased Premises and in respect of any installations and facilities that are used exclusively by the Tenant or serve exclusively the Tenant's business, with the exception of Roof and Structure, if and to the extent that the Landlord cannot enforce any warranty claims in relation to such work and the work has been necessitated by the Tenant's use of the above.

The Tenant's Corrective Maintenance obligation shall not apply to **(i)** the removal of damage or defects that were already present when the Leased Premises were handed over to the Tenant, **(ii)** the removal of damage that was caused by third parties or is not attributable to the Tenant's sphere of risk, and **(iii)** the Replacement of entire installations and facilities (not only parts thereof) at the end of their economic life.

The Tenant shall be liable for the proper and professional execution of any Corrective Maintenance/Maintenance work. The Tenant hereby assigns any warranty claims against the firms carrying out the work to the Landlord by way of security; the Landlord accepts this assignment. Subject to the condition precedent of termination of the tenancy, the Tenant then assigns the warranty claims to the Landlord without any restriction, i.e. no longer only by way of security; the Landlord accepts this assignment.

10.3 The Tenant must additionally bear of cost of Servicing, Maintenance and Corrective Maintenance of any installations and facilities added by the Tenant. Upon request, the Landlord shall assign to the Tenant any claims against third parties, in particular, warranty claims and claims for damages. The Landlord may demand that the burden of upkeep *(Erhaltungslast)* of facilities according to the above be, in whole or in part, transferred to the Landlord. To the extent that the Landlord makes use of this right, the costs shall be allocated to the Tenant in connection with the statements of Operating Costs. In addition, the Parties shall without undue delay enter into a written form-compliant *(schriftformkonform)* addendum to this Lease.

10.4 In all other cases, the Landlord shall carry out the Servicing, Maintenance and Corrective Maintenance and allocate the costs to the Tenant within the limits defined by the agreements on the additional costs. The Servicing, Maintenance and Corrective Maintenance of Roof and Structure shall be carried out by the Landlord at the Landlord's own expense.

10.5 For the purposes of this Lease, "**Maintenance**" shall mean any measures to properly remove structural or other defects resulting from the wear and tear that is due to use as agreed in this Lease, aging and weathering which become necessary during the period of use to ensure that the intended use continues to be possible.

For the purposes of this Lease, "**Corrective Maintenance**" shall mean any measures to remove damage that has already been sustained, that is, measures to restore the Leased Premises to their contractually agreed, proper condition, in particular by repairing damage or replacing parts, installations and facilities that are beyond repair or unworthy of repair ("**Replacement**").

For the purposes of this Lease, "**Servicing**" shall mean the regular verification of serviceability and operational safety, including adjustments to the settings, by an expert.

For the purposes of this Lease, "**Roof**" shall mean the roof structure with the roofing and the appurtenant plumbing work (guttering), including any projecting and side roofs as well as glass roofs and the accesses to and exits from the roof.

For the purposes of this Lease, "**Structure**" shall mean the load-bearing parts of the building (foundations, but excluding the flooring applied to the foundation, and the external masonry, including any pipes laid therein or underneath up to the point where they leave the wall, load-bearing walls, columns, pillars, as well as ceilings) and the façades together with the façade cladding (to the extent that such cladding is firmly connected to the external masonry). For the avoidance of doubt, for the purposes of this Lease, the term "Roof" shall especially exclude any movable awnings and blinds, glazing, windows and window frames, mechanical or automatic doors and gates, including any locks, locking systems and fittings, loading ramps and loading bridges, inventory, building services or work on the land.

11 Subletting

11.1 Any subletting or other grant of permission to use the Leased Premises, in whole or in part, ("**Subletting**") to third parties ("**Subtenants**") shall only be permitted with the Landlord's prior written consent. The Landlord hereby grants its consent to any Subletting to the Tenant's affiliated companies *(verbundene Unternehmen)*, as defined in Sections 15 et seq. German Stock Corporation Act *(Aktiengesetz – "AktG")*.

11.2 The consent to such Subletting may be refused for good cause *(aus wichtigem Grund)*, in particular for reasons relating to the third party personally or to the type of use (e.g. violation of the Landlord's obligations to grant other tenants protection from competition, the Landlord's reputation, or types of use that would be detrimental to the Property, such as sex shops or gambling halls). The Landlord may grant its consent subject to reasonable conditions.

11.3 If the rent payable by the Subtenant (net without Operating Costs) is higher than the base rent owed by the Tenant from time to time (in the event that the Subletting concerns only part of the Leased Premises, the base rent attributable to the relevant part of the Leased Premises), the Tenant shall be obliged to pay 50% of the excess amount of rent payable by the Subtenant (net, without Operating Costs) plus statutory VAT to the Landlord. This payment shall always be due together with the total rent.

11.4 The Tenant hereby assigns to the Landlord all of the Tenant's claims against the Subtenant, including the lien, by way of security; the Landlord accepts this assignment. The Tenant shall continue to have the right, until revoked by the Landlord, to collect all due claims arising from the sub-tenancy.

11.5 The agreements in this Lease regarding VAT shall apply correspondingly to any Subletting.

11.6 The Tenant shall be liable for any fault *(Verschulden)* of the Subtenant as provided in Section 278 German Civil Code *(BGB)*, applied correspondingly.

12 Protection from competition

The Tenant is not granted protection from competition, or protection regarding a particular range of products *(Sortimentsschutz)*.

13 Structural changes by the Landlord

13.1 The Landlord shall have the right to carry out upkeep and modernisation work on the Leased Premises and the Property if such work is necessary or appropriate *(zweckmäßig)*. The Tenant undertakes to tolerate such work and not interfere with its execution. The right of termination under Section 555e German Civil Code *(BGB)* in the event of modernisation work shall be excluded.

13.2 When carrying out construction work, the Landlord shall have due regard to the Tenant's interests. Except in emergencies, the Landlord shall inform the Tenant in a timely manner, at the latest one week before the work commences. The Tenant's general access rules must be observed in this context; in particular, the Tenant shall have the right to demand the signing of a confidentiality agreement. Delays due to circumstances for which the Landlord is not responsible *(nicht zu vertreten)* shall not give rise to any claims of the Tenant against the Landlord.

14 Structural changes and advertising by the Tenant

14.1 Any structural changes to the Leased Premises by the Tenant shall require the Landlord's prior written consent. Before such consent is given, the Tenant must, in particular, present the Landlord with the execution planning. The Landlord's consent may only be refused for good cause *(aus wichtigem Grund)*. At the request of the Landlord, any work carried out without the Landlord's consent must be removed by the Tenant without undue delay at the Tenant's own expense and the Leased Premises restored to their original state, unless the Landlord would have been obliged to grant its consent. The Landlord shall have the right, after issuing a warning and setting a reasonable deadline to no avail, to take the required measures at the Tenant's expense by way of substitute performance *(Ersatzvornahme)*.

14.2 In particular, the Landlord may make its consent conditional upon:

(a) the Tenant bearing any increases in the insurance premiums that are payable under the insurance policies taken out by the Landlord for the Leased Premises which are due to the construction work planned by the Tenant; or

(b) the acceptance *(Abnahme)* of the construction work being carried out by Tenant and Landlord jointly, and on the structural changes fitting in with the appearance of the Property and of the Leased Premises; or

(c) the Tenant examining the changes for their environmental compatibility and furnishing the results of this examination to the Landlord.

14.3 If the Landlord gives its consent to the structural changes planned by the Tenant, the Tenant shall be obliged, before implementing these structural changes, to obtain at its own expense any official permits that may be required (in particular, building and change-of-use permits) and fulfil at its own expense any official obligations *(Auflagen)* and requirements. If the relevant permits etc. are denied, this shall not give rise to any rights of the Tenant against the Landlord. In particular, the Tenant shall have no right in this connection to reduce the rent or terminate this Lease for good cause *(aus wichtigem Grund)*.

Irrespective of whether consent to the structural changes has been obtained, the Tenant shall be liable for the proper and professional execution of the construction work. The Tenant hereby assigns any warranty claims against the firms carrying out the work to the Landlord by way of security; the Landlord accepts this assignment. Subject to the condition precedent of termination of the tenancy, the Tenant then assigns the warranty claims to the Landlord without any restriction, i.e. no longer only by way of security; the Landlord accepts this assignment.

Furthermore, the Tenant must bear all future costs that are incurred by the Tenant or the Landlord as a result of the structural changes carried out by the Tenant, in particular due to changes in statutory or official regulations (e.g. expansion of fire safety regulations).

14.4 Upon request, the Landlord must be provided with copies of the execution documents and permits.

14.5 The interests of the remaining tenants of the Property and of the neighbours must be taken into account to the greatest extent possible when carrying out the work.

14.6 The Landlord's right to demand that the Leased Premises be, in whole or in part, restored to their former state at the Tenant's expense upon termination of the tenancy shall not be excluded as a result of the Landlord having given its consent to a structural change. If and to the extent not expressly otherwise agreed in writing *(Schriftform)* now or in the future, all changes to the Leased Premises that have been made by the Tenant must be removed again and the Leased Premises restored to their original state at the Tenant's expense upon termination of the contractual relationship if the Landlord so requires. The condition of the Leased Premises at the time of handover of the Leased Premises, as documented in the handover report, shall be decisive for the obligation to remove structural changes.

In deviation from the above, the removal of the mezzanine created in area B4 as a result of the "Aurora" project described in Appendix 14.9 and of the lift contained therein as well as the newly created stairs shall not be owed by the Tenant but shall be the responsibility of the Landlord at the Landlord's own expense. All loose fixtures *(lose Einbauten)* and laboratory-specific facilities shall be removed by the Tenant at the Tenant's own expense when the tenancy ends.

14.7 The agreements regarding structural changes shall apply correspondingly to any company and information signs, external advertising facilities, awnings or aerials of the Tenant. In addition, the Tenant must use the collective signage system and other common means of presentation, if available. These shall be designed in a uniform manner in accordance with the Landlord's

specifications. The Landlord shall endeavour in this respect to take into account the Tenant's wishes.

14.8 Any posters or stickers on the windows, whether inside or outside, shall only be permitted with the Landlord's prior written consent.

14.9 The Landlord hereby gives its consent to the work planned by the Tenant and set out in **Appendix 14.9**. The details and the conditions under which the Landlord grants this consent can be gathered from this Lease and, in particular, Appendix 14.9.

14.10 The Landlord shall grant the Tenant a building cost contribution of up to EUR 50,000 plus the payable VAT. This building cost contribution may only be used for the work set out in Appendix 14.9 to convert the existing lighting to LED lighting.

The Tenant may claim this amount from the Landlord by issuing an invoice that meets the requirements of Section 14a German VAT Act *(UStG)* and presenting the paid invoices from the tradespeople for the fully performed and essentially defect-free work or services – which work or services must have been accepted by the Tenant in consultation with the Landlord or with a third party commissioned by the Landlord. The building cost contribution shall be forfeited if and to the extent not claimed by 31 December 2023.

15 Liability, warranty

15.1 The Landlord's no-fault liability for initial defects in the quality of the Leased Premises pursuant to Section 536a(1), first alternative German Civil Code *(BGB)* shall be excluded; this does not apply to defects in title.

In addition, the Landlord shall only be liable:

(a) in the event of a wilful *(vorsätzlich)* or grossly negligent *(grob fahrlässig)* breach of duty by the Landlord or any of its vicarious agents *(Erfüllungsgehilfen)*;

(b) if the Landlord has warranted a particular characteristic of the Leased Premises *(zugesicherte Eigenschaft)* or has concealed a defect with fraudulent intent *(arglistig verschwiegen)*;

(c) in the event of a person's death, bodily injury or damage to health;

(d) in the event of a breach of essential contractual obligations ("**Cardinal Obligations**") by the Landlord or any of its vicarious agents *(Erfüllungsgehilfen)*. Cardinal Obligations are obligations that result from the nature of the Lease and thus lead to the purpose of the Lease being reasonably achieved. The fulfilment of the Cardinal Obligations is, therefore, a prerequisite for the proper performance of this Lease, which is why the Tenant regularly relies, and can rely, on compliance with them; or

(e) if and to the extent that the Landlord has insurance coverage for the relevant damage.

15.2 If and to the extent that the Landlord provides water, district heat, gas and electricity from the supply systems of providers, the Tenant shall not, in the event of the Landlord's liability for defective performance *(Leistungsstörung)*, assert claims for damages beyond those to which the Landlord is entitled vis-à-vis the respective provider according to the respective applicable provisions. The Tenant must report any damage without undue delay in writing both to the Landlord and directly to the supplying provider.

15.3 The description of the Leased Premises in brochures, models or other advertising media shall not define the agreed quality *(vereinbarte Beschaffenheit)* of the Leased Premises.

15.4 The Tenant must report any damage to the Leased Premises and the Property without undue delay to the Landlord. In the event of problems with or damage to the supply pipes or supply lines, the Tenant must see to it that they are switched off without undue delay and shall be obliged to notify the Landlord without undue delay. If the Tenant culpably *(schuldhaft)* fails to comply with these obligations or performs them incompletely or late, any disadvantage suffered by the Landlord as a result of this shall be borne by the Tenant. The Tenant shall have the burden to prove that the notification was made in a timely manner.

15.5 The general obligation to maintain security for persons and vehicles *(Verkehrssicherungspflicht)* within the Leased Premises shall be incumbent upon the Tenant.

15.6 All exclusions and limitations of liability that are contained in this Lease shall also apply in favour of the Landlord's vicarious agents *(Erfüllungsgehilfen)*.

16 Insurance

16.1 The Landlord shall have the right to insure the Property containing the Leased Premises at replacement value *(Neuwert)* against the risk of fire, damage caused by natural forces *(Elementarschäden)* or all risks (including risks of terrorism). The reimbursable costs shall be allocated to the Tenant by the Landlord as part of the statement of additional costs.

16.2 The Tenant shall be obliged to notify the Landlord without undue delay of any fixtures leading to an increase in value and of any change in risk within the meaning of insurance law. Any resulting increase in insurance premiums shall be borne solely by the Tenant.

16.3 The Tenant shall be obliged to take out the following insurance policies at its own expense in an amount customary in its line of business, maintain such insurance for the duration of this tenancy and furnish supporting documents to the Landlord upon request:

- public liability insurance *(Betriebshaftpflicht-Versicherung)* for personal injury, property damage and financial losses with a scope of cover customary in the Tenant's line of business.

The Tenant shall be free to obtain insurance against additional damage (e.g. by fire or water penetration) to the furniture and fittings and the goods in the Leased Premises. The Landlord recommends obtaining such additional insurance. If and to the extent that the Tenant refrains from obtaining insurance cover in this respect, the Tenant shall remove any such damage without undue delay at its own expense unless the Landlord is liable *(einstandspflichtig)*. The Tenant is additionally advised to obtain insurance which covers the loss of keys, key cards or other access authorisations because if a key or other access authorisation is lost, the entire locking system may need to be exchanged, which can result in significant costs being incurred.

17 Soil and Groundwater Contaminations

17.1 The Tenant shall be obliged to inform the Landlord of any harmful soil changes *(schädliche Bodenveränderungen)* or contaminated sites *(Altlasten)*, as defined in Sections 2(3) and 2(5) German Federal Soil Protection Act *(Bundes-Bodenschutzgesetz – "BBodSchG")*, and of any impairments of the groundwater ("**Soil and/or Ground Water Contaminations**") of which the Tenant becomes aware.

17.2 The Tenant shall be obliged, at its own expense, to remove any Soil and/or Ground Water Contaminations within the Leased Premises that have been caused by the Tenant during the term of this Lease and/or during the period of possession by the Tenant. This shall apply correspondingly to Soil and/or Ground Water Contaminations on the Property outside the Leased Premises if and to the extent that the Tenant is responsible *(zu vertreten hat)* for them. In all other cases, the Landlord shall have no claim against the Tenant for removal.

17.3 The Landlord shall have the burden to prove that the Soil and/or Ground Water Contaminations within the Leased Premises have been caused by the Tenant during the term of this Lease and/or during the period of possession by the Tenant.

17.4 If the Tenant fails to comply within a reasonable period of time with a request for removal from the Landlord, or if the term of this Lease has already ended, the Landlord may carry out the removal itself at the expense of the Tenant and claim the costs of such removal from the Tenant (also as an advance payment).

17.5 In the event that any claims are asserted under public or civil law due to Soil or Groundwater Contaminations on the Property, the Parties undertake to indemnify each other on first request and reimburse any costs already incurred if and to the extent that their being held liable conflicts with the liability rules set out in clause 17.2 above. This applies also and in particular to claims for compensation under Section 24(2) German Federal Soil Protection Act *(BBodSchG)* or similar claims for compensation in the event of an assertion of claims under water law.

17.6 Claims of the Tenant against the Landlord due to Soil or Groundwater Contaminations shall be excluded if and to the extent that the assertion of claims would conflict with the liability rule set out in clause 17.2 above.

17.7 The Tenant shall be obliged to observe all applicable regulations regarding the handling of hazardous substances *(Gefahrstoffe)* within the meaning of the German Hazardous Substances Ordinance *(Gefahrstoffverordnung)* ("**Hazardous Substances**") and indemnify the Landlord against all related risks and official requirements. The Tenant shall be obliged to make good any damage caused by a use of Hazardous Substances (including their safekeeping and storage) which is attributable to the Tenant. The Tenant shall be obliged to take out appropriate third-party liability insurance that also covers the handling of Hazardous Substances and maintain such insurance throughout the term of this Lease and furnish the Landlord at any time upon request by the latter with appropriate evidence thereof. The Tenant shall be obliged to notify the Landlord without undue delay and without a prior request to this effect of any changes to the third-party liability insurance that existed when this Lease commenced.

18 Entering the Leased Premises

18.1 The Landlord and/or its agents shall have the right to enter and inspect the Leased Premises at reasonable intervals during normal business hours in the presence of an employee of the Tenant after an announcement made sufficiently in advance. The Tenant's general access rules must be observed in this context; in particular, the Tenant shall have the right to demand the signing of a confidentiality agreement. In the event of imminent danger *(Gefahr im Verzug)*, the Leased Premises may be entered at any time, even without an announcement.

18.2 If notice has been given to terminate this Lease or the Landlord intends to sell the Leased Premises, the Landlord and/or its agents shall also have the right to inspect the Leased Premises during normal business hours together with prospective tenants or prospective buyers, as applicable, in the presence of an employee of the Tenant after an announcement made sufficiently in advance. The Tenant's general access rules must be observed in this context; in particular, the Tenant shall have the right to demand the signing of a confidentiality agreement.

18.3 The Tenant must ensure that the Leased Premises can also be entered when the Tenant is absent. During longer periods of absence (e.g. in the event of an annual holiday shutdown), the Tenant must deposit the keys in a place where they can be quickly reached and notify the Landlord accordingly.

19 Termination of the tenancy

19.1 Upon termination of the tenancy, the Tenant must return the Leased Premises to the Landlord in the condition as agreed in this Lease, taking into account wear and tear in accordance with this Lease. The condition is as agreed in this Lease if:

(a) the Leased Premises have been fully vacated and are clean-swept;

(b) all cosmetic repairs that are due within the meaning of this Lease have been professionally carried out;

(c) all upkeep work due (Maintenance and Corrective Maintenance work etc.) has been property carried out during the term of this Lease;

(d) all keys and key cards are being returned to the Landlord;

(e) any obligations to remove structural changes pursuant to clause 14 above have been performed;

(f) all external advertising facilities have been dismounted and the original state has been created again.

19.2 If the Tenant fails to perform its obligations arising out of and in connection with the termination of the tenancy, or if the Tenant is late with the performance of said obligations, the Landlord may – in the event that a calendar date has been determined for the return of the Leased Premises, even without a prior warning – create the condition owed at the Tenant's expense, in particular, have the Leased Premises vacated and cleaned and any cosmetic repairs, Servicing, Maintenance and Corrective Maintenance work carried out. Any further claims shall remain unaffected.

20 Sale of the Leased Premises

In the event that the Leased Premises are sold, the Tenant shall release the Landlord from all its obligations as landlord, provided that the buyer assumes these obligations. The Tenant hereby gives its consent to all provisions of this Lease, including any addendums, being transferred upon conclusion of a notarial purchase agreement regarding the Property and payment of the purchase price.

21 Final provisions/commitment period

21.1 The Parties are in agreement that the House Rules that are attached as **Appendix 21.1** shall form part of this Lease and the Tenant agrees to be bound by said House Rules.

21.2 The laws of the Federal Republic of Germany shall apply, without regard to any conflict of laws provisions.

21.3 The Parties confirm that this Lease contains all the agreements made between the Parties. All changes and additions, as well as the cancellation of this Lease and any notice of termination, shall require the written form *(Schriftform)*. Verbal additional agreements do not exist. Should any verbal additional agreements exist, however, they are hereby cancelled as a precaution.

21.4 Even if the Landlord employs a property manager for the technical and/or commercial management of the Property, the Landlord alone shall have the right to receive notices of termination or notices to exercise options regarding the tenancy. Irrespective of how the property manager may be acting when dealing with the Tenant, the property manager has no power of attorney from the Landlord to receive notices of termination from the Tenant, or notices to exercise options regarding the tenancy, except where such power of attorney is granted to the property manager expressly in writing.

21.5 The Parties are aware of the special statutory written form requirement under Sections 578, 550 sentence 1 in conjunction with Section 126 German Civil Code *(BGB)*. They undertake to combine this Lease and its Appendices into a single document in such a way that the requirements that need to be met in order to comply with the written form are fulfilled.

The Parties are aware of the rulings of the German Federal Court of Justice *(Bundesgerichtshof)* regarding the validity of clauses meant to "cure" failures to comply with the written form requirement *(Schriftformheilungsklauseln)* and confirm that they wish to adhere to this Lease and, if and to the extent possible, will in particular waive the right to plead lack of written form pursuant to Sections 578, 550 sentence 1 in conjunction with Section 126 German Civil Code *(BGB)* and also the right to terminate this Lease early on the grounds of non-compliance with the written form. This shall apply both to the (original) Lease along with its Appendices and to any future addendums, amendment and supplementary agreements.

The Parties are additionally aware of the rulings of the German Federal Court of Justice according to which a buyer of the piece of land who replaces the Landlord as a party to this Lease pursuant to Section 566 German Civil Code *(BGB)* will generally not be bound by the clause in the preceding paragraph that is meant to cure failures to comply with the written form requirement. For the avoidance of doubt, the Parties therefore stipulate that the clause that has been agreed in the preceding paragraph to cure failures to comply with the written form requirement is not intended to be binding upon such a buyer of the piece of land. To the extent that a party has replaced one of the Parties to this Lease pursuant to Sections 566, 578 German Civil Code *(BGB)* or based on any corresponding provisions of law, the statutory rights of that party shall, therefore, remain unaffected.

21.6 Should one or more provisions of this Lease be or become invalid, should this Lease contain any gap or should any of the contractual provisions turn out to be impracticable, this shall not affect the legal validity of the remaining provisions and/or of the tenancy as a whole. Section 139 German Civil Code *(BGB)* is expressly excluded, also in its function as a rule determining the burden of proof. In that case, the Parties shall be obliged to agree a new provision that corresponds to what was wanted in legal and economic terms.

21.7 At the request of the Landlord, the Tenant shall provide the Landlord with a current excerpt from the Commercial Register.

21.8 The Landlord shall have the right to disclose the data collected as part of this Lease to the asset manager and property manager for lease administration purposes. This manager may also be a third party. If any personal data is collected as part of this Lease, the Tenant shall ensure that the data subject has validly consented to his or her personal data being transferred to the asset manager and property manager for lease administration purposes as well as for the processing of such data by the asset manager and property manager for that purpose.

The Landlord shall have the right to disclose the data in relation to the contractual relationship to prospective buyers of the Property, as well as to banks in connection with the granting of loans or syndications. If any personal data is collected as part of this Lease, the Tenant shall ensure that the data subject has validly consented to his or her personal data being transferred to prospective buyers of the Property and to banks for the purposes of a purchase and/or for the purposes of granting a loan or syndication purposes as well as for the processing of the personal data by the prospective buyers and banks for the aforesaid purposes.

If and to the extent that personal data is transferred to a third country, that is, a country outside the European Union, the Landlord shall ensure that an adequate level of data protection exists or is established, as applicable, with the means provided for in the General Data Protection Regulation.

When processing personal data, the Landlord shall observe and comply with the provisions of the General Data Protection Regulation. Further details about the processing of data by the Landlord is available at: https://mileway.com/tppn/. In the event of Subletting, the Tenant shall ensure that it fulfils its own data protection obligations to its Subtenant.

21.9 At the request of the Landlord, the Tenant shall issue a declaration from which it can be gathered (e.g. by a prospective buyer of the Property) that the original Lease together with its addendums, if any, which must be named in the declaration, constitutes the entire lease agreement (so-called declaration of completeness *(Vollständigkeitserklärung)*).

21.10 The following Appendices shall form integral parts of this Lease and shall be deemed agreed:

Appendix I (Power of Attorney dated 28 July 2021)

Appendix 1.1 (Site plan of the Leased Premises)

Appendix 14.9 (Tenant's construction work)

Appendix 21.1 (House Rules)

21.11 If this Lease is initially signed by only one Party and is delivered or sent to the other Party for signature, this shall be deemed an offer to enter into this Lease which can be validly accepted by the other Party within a period of one month pursuant to Section 148 German Civil Code *(BGB)*. This period is due to the fact that the Landlord is based abroad, which leads to longer postal delivery times. The dates of the respective signatures shall be decisive. The first Party to sign this Lease may extend this period in writing or in text form *(Textform)*.

21.12 If one of the Parties is a body of persons or a legal person and this Lease is not signed on behalf of this Party by all of its authorised representatives jointly, the respective signatory hereby confirms that he or she is authorised to represent that Party and, where necessary, also represents the authorised representatives who are not themselves signatories.

Düsseldorf, 13.09.21	Luxembourg, 13.09.21
Place, date	Place, date
On behalf of the Tenant:	**On behalf of the Landlord:**
/s/ Andreas Richter	**/s/ Anna Cirka**
Name: Andreas Richter	Name: Anna Cirka
Position: Managing Director	Managing Director / power of attorney dated 28 July 2021

Exhibit 10.3

FIRST AMENDMENT TO COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

THIS FIRST AMENDMENT TO COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT (**"First Amendment"**) is entered into as of the 10th day of September, 2021 (**"First Amendment Effective Date"**), by and between **BAXTER PHARMACEUTICAL SOLUTIONS LLC**, a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403 (**"Baxter"**), and **DYNAVAX TECHNOLOGIES CORPORATION**, a Delaware corporation having a principal place of business at 2100 Powell Street, Suite 900, Emeryville, California 94608 (**"Dynavax"**).

WHEREAS, Baxter and Dynavax are parties to a Commercial Manufacturing and Supply Agreement dated November 22, 2013 (the **"Original Agreement"**);

WHEREAS, Baxter and Dynavax wish to amend certain provisions of the Original Agreement; and

WHEREAS, concurrently with entering into this First Amendment, Baxter and Dynavax are entering into an Amended and Restated Product Addendum for HEPLISAV-B® hepatitis B vaccine dated as of the First Amendment Effective Date (the "**Amended and Restated Product Addendum**").

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises hereinafter set forth, Baxter and Dynavax agree that the following amendment(s) shall be made to the Original Agreement, effective as of the First Amendment Effective Date:

1. The address of Dynavax's principal place of business set forth in the introductory paragraph is hereby amended and restated to read in its entirety as follows:

   "2100 Powell Street, Suite 900, Emeryville, California 94608"

2. The definition of **"Contract Requirements"** in Article 1 of the Original Agreement is hereby deleted in its entirety.

3. The definition of **"Contract Year"** in Article 1 of the Original Agreement is hereby deleted in its entirety.

4. All references in this First Amendment and in the Original Agreement to the term "Product Addendum" shall, as applicable to the HEPLISAV-B® hepatitis B vaccine Product, be deemed to refer to the Amended and Restated Product Addendum.

5. The definition of **"Purchase Order"** in Article 1 of the Original Agreement is hereby amended and restated to read in its entirety as follows:

   "**"Purchase Order"** shall mean a written order from Dynavax to Baxter which shall specify: (a) the quantity of Product ordered (expressed as a number of Batches) and the

size ([***] or [***], as applicable) of Batches; (b) shipping instructions; (c) requested delivery dates; and (d) delivery destinations."

6. Section 3.1 (Agreement to Purchase and Supply) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**3.1 Agreement to Purchase and Supply.** Pursuant to the terms and conditions of this Agreement, Dynavax shall purchase Product from Baxter and Baxter shall use good faith efforts to Produce and deliver Product to Dynavax in accordance with Article 4 of this Agreement."

7. Section 4.1.1 (Long Range Forecast) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**4.1.1 Long Range Forecast.** Within thirty (30) days from the Effective Date of this Agreement and prior to June 1 of each year thereafter, Dynavax will provide to Baxter in writing an annual forecast for the next five (5) calendar years during the Term of Dynavax's estimated demand for Product (the **"Long Range Forecast"**). The initial Long Range Forecast shall be included in the Product Addendum (pursuant to Exhibit D) and shall be considered the **"Initial Long Range Forecast"**. Baxter specifically agrees that such Long Range Forecasts submitted by Dynavax will be for general planning purposes only, and shall not be binding on Dynavax or Baxter."

8. Section 4.1.2 (Twelve Month Rolling Forecast) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**4.1.2 Forecasting.**

4.1.2.1 Twelve Month Rolling Forecast. Commencing one month after the First Amendment Effective Date, and on each December 1st, March 1st, June 1st and September 1st thereafter during the Term, Dynavax will provide to Baxter in writing a "**Twelve Month Rolling Forecast"** of the quantity of Batches Dynavax anticipates it will order for Production for the following twelve-month period (i.e., the Twelve Month Rolling Forecast submitted December 1st will be for the twelve month period beginning January 1st, the Twelve Month Rolling Forecast submitted March 1st will be for the twelve month period beginning April 1st, and so on). The total quantity of Batches of the first six (6) months (the first and second quarters) of each Twelve Month Rolling Forecast (**"Six Month Period"**) shall be considered [***]% binding on both: (a) Dynavax; and (b) Baxter, subject to Section 4.1.2.2 below. The total quantity of Batches of the third three months (the third quarter) of the Twelve Month Rolling Forecast shall be considered [***]%binding. Should the quantity forecasted in the third quarter be an odd number of Batches, then the binding forecast shall be [***]% of one less of the number of Batches forecasted. The quantity of Batches forecasted for the remaining three (3) months of the Twelve Month Rolling Forecast shall be for general planning purposes only, and shall not be binding on Dynavax or Baxter. Dynavax understands and agrees that its Twelve Month Rolling Forecast

for Product shall include Dynavax's monthly quantities of Product in only the months of January, February, March, April, May, October, November and December of each calendar year (**"Manufacturing Months"**). For the avoidance of doubt, Baxter is under no obligation to Produce any Product during the months of June, July, August and September of any calendar year.

4.1.2.2 Binding Six Month Period. Upon Baxter's receipt of each Twelve Month Rolling Forecast, Baxter will compare the quarterly quantities forecasted in the Six Month Period to the pro-rated portion (pro-rated based on the number of Manufacturing Months) of Baxter's Annual Order Maximum for such period. If (i) the quantities forecasted in the Six Month Period are equal to or less than the pro-rated portion of Baxter's Annual Order Maximum, then the quantities forecasted in such Six Month Period shall automatically be deemed confirmed by Baxter and will be [***]% binding on Baxter and Dynavax, and (ii) if such quantities are greater than the pro-rated portion of Baxter's Annual Order Maximum, Baxter will use commercially reasonable efforts to Produce the forecasted quantities in excess of the pro-rated portion and will confirm to Dynavax what quantities it is able to Produce, and such confirmed quantities will be [***]%binding on Baxter and Dynavax (such confirmed quantities under (i) or (ii), as applicable, the "**Binding Six Month Period**")."

9. Section 4.2.2 (Order Lead Time) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**4.2.2 Order Lead Time.** Dynavax shall not, without the written consent of Baxter, designate a delivery date in a Purchase Order earlier than [***]calendar days from the date Dynavax submits the Purchase Order. Within [***] calendar days from the date Dynavax submits a Purchase Order, Baxter shall provide a confirmation of receipt of such Purchase Order setting forth the Delivery Date that Baxter will meet. Upon Baxter's delivery of such confirmation (or, if no confirmation is delivered within [***] calendar days from the date Dynavax submits such Purchase Order, then upon the expiration of such [***]-day period), such Purchase Order shall become a **"Firm Purchase Order"** constituting a binding obligation of Dynavax to purchase, and of Baxter to Produce and deliver to Dynavax by the applicable Delivery Date set forth in Baxter's confirmation (or, if no confirmation is delivered, the Delivery Date designated in Dynavax's Purchase Order), the quantity of Product set forth in such Purchase Order. If Baxter is unable to meet the Delivery Date specified by Dynavax in its Purchase Order, Baxter will provide to Dynavax an alternative Delivery Date which shall not be more than [***] calendar days later than the initial Delivery Date designated by Dynavax in its Purchase Order."

10. Section 4.3 (Annual Obligation) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**4.3 Annual Obligation.** Subject to Section 4.4, Dynavax shall be obligated to order for Production (with the formulation and filling of all Batches to occur within the applicable calendar year) from Baxter a minimum number of Batches of Product in

each calendar year during the Term of this Agreement as specified in Exhibit B of the Product Addendum (as more fully defined below in this Section, the **"Annual Obligation"**), which Annual Obligation shall be pro-rated for any partial calendar year. For the avoidance of doubt, in each calendar year, Dynavax must order for Production (with the formulation and filling of all Batches to occur within the applicable calendar year) the greater of the Annual Obligation or the binding portion of the Twelve Month Rolling Forecasts. Within [***] days after the end of each calendar year, the Parties will determine the number of Batches of Product ordered by Dynavax for Production (as set forth above) in the then previous calendar year. Within [***] calendar days after such calculation, Dynavax shall pay Baxter for the difference between the aggregate Production Price of Product actually ordered by Dynavax for Production (with the formulation and filling of all Batches to occur within the applicable calendar year) pursuant to Sections 4.1 and 4.2 in the calendar year and the aggregate Production Price of the greater of (i) the Annual Obligation or (ii) the binding portions of the Twelve Month Rolling Forecasts."

11. Section 4.4 (Order Maximum) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**4.4 Annual Order Maximum.** Notwithstanding anything in this Article 4 to the contrary, in any calendar year during the Term of this Agreement, in no event shall Baxter be obligated to Produce more Product during the Manufacturing Months than the maximum number of Batches (as the case may be) as specified in Exhibit B of the Product Addendum (**"Annual Order Maximum"**). If Dynavax requests Baxter to Produce more than its Annual Order Maximum, Baxter will use commercially reasonable efforts to Produce such additional requested quantities. If the Dynavax requests changes (increase/decrease) in the annual order volume requiring changes in equipment and/or process, the Parties will reach agreement on the scope of the changes and associated costs prior to Baxter implementing such changes. As stated in Section 4.1.2 above, Baxter is under no obligation to Produce any Product during the months of June, July, August and September of any calendar year."

12. The following new Sections 4.5.3 and 4.5.4 are hereby added immediately after Section 4.5.2 of the Original Agreement:

"4.5.3 Yield Calculations. The formulas and calculations used by the Parties to determine the Yield Rate, the Expected Yield and Yield Reconciliation are defined and detailed in the Product Addendum.

4.5.4 Yield Rate Recalculations. If Production times, volumes, Batch sizes, manufacturing process changes or any other similar change should occur after the Yield Rate and Expected Yield are established, the impact of the changes will be evaluated and a new Yield Rate and Expected Yield will be established in accordance with Sections 4.5.1 and 4.5.2 above and the Product Addendum."

13. The first sentence only of Section 5.4 (Components) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"Based upon the Twelve Month Rolling Forecasts, Baxter and Dynavax shall develop a joint strategy for the purchase of primary packaging Components (backstop, syringe, stopper and plunger rod)."

14. The first sentence only of Section 7.1.2 of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"If the Parties dispute whether the Batch of Product is non-conforming, the dispute will be handled in accordance with Section 17 (Dispute Resolution) of the Quality Agreement."

15. Section 8.1 (Initial Term) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"**8.1 Term.** This Agreement shall commence on the Effective Date and shall continue through December 31, 2026 (the **"Initial Term"**), unless earlier terminated in accordance with Section 8.2 or Section 8.3 of this Agreement. This Agreement may be renewed for twenty-four (24) month renewal term(s), if agreed in writing by both Dynavax and Baxter at least eighteen (18) months prior to the expiration of the Initial Term or a renewal term, as the case may be. The Initial Term as may be extended is referred to herein as the **"Term"**."

16. Section 14.1 (Dynavax Indemnification) of the Original Agreement is hereby amended to replace "." at the end of paragraph (f) of such Section with ";" and to add the following immediately below paragraph (f) of such Section:

"except to the extent Baxter is obligated to indemnify Dynavax under Section 14.2 for any of the foregoing (a), (b), (d) or (f)."

17. Dynavax's contact information in Section 20.1 (Notices) of the Original Agreement is hereby amended and restated to read in its entirety as follows:

"If to Dynavax: **DYNAVAX TECHNOLOGIES CORPORATION**
2100 Powell Street, Suite 900
Emeryville, California 94608
Attn: General Counsel

Email legal@dynavax.com
Telefax No. (510) 848-1327
Telephone No. (510) 848-5100"

18. The phrase "this Agreement" as it appears in the Original Agreement or this First Amendment shall be deemed to refer to the Original Agreement, as modified by this First Amendment.

19. Except as modified by this First Amendment, the terms of the Original Agreement shall continue in full force and effect.

[Signatures on Next Page]

IN WITNESS WHEREOF, the parties have caused this First Amendment to be executed as of the First Amendment Effective Date by their duly authorized representatives.

BAXTER PHARMACEUTICAL SOLUTIONS LLC	**DYNAVAX TECHNOLOGIES CORPORATION**
By: /s/ Mike Nassif	By: /s/ David Novack
Name: Mike Nassif	Name: David Novack
Title: VP, BPS & Commercial Excellence	Title: President & Chief Operating Officer

EXHIBIT A to Amended and Restated Product Addendum for HEPLISAV-B® HEPATITIS B VACCINE

Product, Presentation and Commercial Batch Size

Product	Presentation
HEPLISAV-B® HEPATITIS B VACCINE	[***] standard syringe, with secondary package

Commercial Batch Size

Batch Size	[***] Batch size
Fill Volume	[***] mL fill, [***] syringe

Batch Size	[***] Batch size
Fill Volume	[***] mL fill, [***] syringe

EXHIBIT B to Amended and Restated Product Addendum for
HEPLISAV-B® HEPATITIS B VACCINE

Annual Obligation and Annual Order Maximum

Dynavax's Annual Obligation and Baxter's Annual Order Maximum for each calendar year during the Initial Term and any renewal term is set forth in the table below:

Calendar Year	Annual Obligation Number of Batches	Annual Order Maximum Number of Batches
2021	[***]	[***]
2022	[***]	[***]
2023*****	[***]	[***]
2024	[***]	[***]
2025	[***]	[***]
2026	[***]	[***]
Each calendar year in a renewal term	[***]	[***]

*For clarity, Dynavax's Annual Obligation for calendar year 2023 is [***] Batches at the [***] Batch size times the then current Unit price for the [***] Batch size (**"2023 Financial Obligation"**). In the event Dynavax orders for Production one or more [***]Batches in calendar year 2023, such [***] Batch(es) will count towards Dynavax's Annual Obligation and Baxter's Maximum Supply Obligation. If at the end of calendar year 2023 Dynavax has not met its 2023 Financial Obligation, Dynavax will pay Baxter the difference between the total dollar amount of the Batches Dynavax ordered for Production in calendar year 2023 and the 2023 Financial Obligation. For the avoidance of doubt, Baxter is under no obligation to Produce more than its Maximum Supply Obligation for calendar year 2023 or for any other calendar year.

EXHIBIT C to Amended and Restated Product Addendum for
HEPLISAV-B® HEPATITIS B VACCINE

Pricing

A. PRICING FOR [***] BATCH SIZE

Table 1: Commercial Pricing for ~[***] Batch Size

Volume[2]	Manufacturing Price + Finishing Price[1,3,4]
Up to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit

[1] The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Baxter separately. The Unit pricing is inclusive of the following secondary packaging materials (cartons, five (5) syringe blister packs with Tyvek lids, unit labels and inserts) with serialization.

[2] For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is "trued up" at the end of each calendar year (i.e. the first [***] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Baxter at [***] per Unit (as adjusted) and the second [***] will be charged at [***] per Unit (as adjusted) and so on even if Dynavax purchases over [***] Units of commercial Product in a calendar year).

[3] It is Dynavax's intention that no later than January 1, 2023, Baxter will no longer be Producing Product in the [***] Batch size and will be Producing Product only in the [***] Batch size. In the event Dynavax requests that Baxter continue Producing the [***] Batch size on or after January 1, 2023, for any reason, the Unit pricing for the [***] Batch size shall be increased as set forth in Table 2 of this Section A (PRICING FOR [***] BATCH SIZE) as of January 1, 2023. The [***] Batch size will not be Produced beyond June 30, 2024.

[4] Quoted Unit price assumes the following QC testing: appearance, pH, extractable volume, osmolality, bacterial endotoxin and sterility (membrane). In the event additional or different QC testing is required, the pricing referenced above may change.

Table 2: Commercial Pricing for [***] Batch Size effective January 1, 2023

Volume[2]	Manufacturing Price + Finishing Price[1,3]
Up to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit

1 The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Baxter separately. The Unit pricing is inclusive of the following secondary packaging materials (cartons, five (5) syringe blister packs with Tyvek lids, unit labels and inserts) with serialization.

2 For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is "trued up" at the end of each calendar year (i.e. the first [***] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Baxter at [***] per Unit (as adjusted) and the second [***] will be charged at [***]per Unit (as adjusted) and so on even if Dynavax purchases over [***] Units of commercial Product in a calendar year).

3 Quoted Unit price assumes the following QC testing: appearance, pH, extractable volume, osmolality, bacterial endotoxin and sterility (membrane). In the event additional or different QC testing is required, the pricing referenced above may change.

4 The [***] Batch size will not be Produced beyond June 30, 2024.

B. PRICING FOR [***] BATCH SIZE

Table 1: Pricing for ~[***] Batch Size (Non-GMP Pre PPQ Demonstration Batches and Process Validation Batches)

Batch Type	Batch Size	Price per Batch[1,3]
Non-GMP Pre PPQ Demonstration Batches[4]	Up to [***]PFS per batch	[***] USD
Process Validation Batches	Up to [***] PFS per batch	[***] USD

Table 2: Commercial Pricing for ~[***] Batch Size

Volume[2]	Manufacturing Price + Finishing Price[1,2,3]
Up to [***] Units per calendar year	[***] per Unit
[***] to [***] Units per calendar year	[***] per Unit
[***]to [***]Units per calendar year	[***] per Unit
[***]or more Units per calendar year	[***] per Unit

[1] The cost of the following primary and secondary packaging Components (syringes, stoppers, backstops, plunger rods) are not included in the Manufacturing Price + Finishing Price shown above and shall be invoiced by Baxter separately. The Unit pricing is inclusive of the following secondary packaging materials (cartons, five (5) syringe blister packs with Tyvek lids, unit labels and inserts) with serialization.

[2] For the avoidance of doubt, the volume pricing shown above is incremental or step pricing and not based on total volume which is "trued up" at the end of each calendar year (i.e. the first [***] Units of commercial Product purchased by Dynavax in any calendar year will be charged by Baxter at [***] per Unit (as adjusted) and the second [***] Units will be charged at [***] per Unit (as adjusted) and so on even if Dynavax purchases over [***] Units of commercial Product in a calendar year).

[3] Quoted Unit price assumes the following QC testing: appearance, pH, extractable volume, osmolality, bacterial endotoxin and sterility (membrane). In the event additional or different QC testing is required, the pricing referenced above may change.

[4] Non GMP batch price does not include analytical or QC testing. Scope of development or confirmation testing will be priced at a later date and mutually agreed to by the Parties in writing.

Note: All pricing in this Exhibit assumes automated inspection. In the event manual inspection is required, the pricing referenced above may change.

Exhibit D to Amended and Restated Product Addendum for
HEPLISAV-B® HEPATITIS B VACCINE

Initial Long Range Forecast

Calendar Year	Forecast (Number of Batches)
2021	[***]
2022	[***]
2023	[***]
2024	[***]
2025	[***]
2026	[***]

Exhibit E to Amended and Restated Product Addendum for
HEPLISAV-B® HEPATITIS B VACCINE

Yield Formulas and Calculations

Once the Yield Rate has been established for a Batch size as set forth in Section 4.5 of the Agreement, after the end of each calendar year thereafter, the Parties shall calculate the average Actual Batch Yield for the Batches of Product released during such calendar year and do a Yield Reconciliation, as defined below.

Definitions:

1. "Yield Rate" shall be defined as the average Actual Batch Yield for the first twenty (20) Batches of Commercial Product Produced (including secondary packaging) and released, including samples, for each Batch size.

2. "Expected Yield" shall be defined as [***] of the established Yield Rate.

3. "Actual Batch Yield" shall be defined as Syringes Produced (including secondary packaging) and released for a Batch, including samples, divided by the Theoretical Filled Units, multiplied by one-hundred.

4. "Bulk Solution Final Weight" is defined in the Master Batch Record.

5. "Yield Reconciliation" shall be defined as the Parties reconciling the average Actual Batch Yield as compared to the Expected Yield. The Yield Reconciliation is to be performed and reviewed by both Parties annually, no later than [***] days following the end of the applicable calendar year.

6. "Theoretical Fill" for a Batch shall be defined as the number of syringes that could have been filled utilizing the Bulk Solution Final Weight of the formulated solution minus total formulation loss divided by the Target Fill Weight as defined in the Master Batch Record.

7. "Syringes Produced" shall be defined as the actual number of good syringes filled and packaged, including samples, as defined in the Master Batch Record. Syringes Produced shall be used as the *numerator* in determining Actual Batch Yield.

8. "Target Fill Weight" shall be the weight, used in the Production of each Unit (syringe) of material as defined in the Master Batch Record.

General Information:

- For illustrative purposes, the primary Batch sizes are ~[***] and ~[***] for the Product.
- Yield Reconciliation shall be completed annually (within [***] of the end of each calendar year) and will include all Produced Batches released in the prior calendar year.

- Normal rules of rounding shall apply in all calculations.

Theoretical Fill:

- Bulk Solution Final Weight (kg) x 1000
- Target Fill Weight = [***]g
- Total formulation loss (g)
- Theoretical Fill = [Bulk Solution Final Weight (kg) x 1000 – Total formulation loss (g) ÷ Target Fill Weight (g)]

Actual Batch Yield: Calculated for each Batch released during a calendar year

Shall be calculated as follows:

- The *numerator* for Actual Batch Yield shall be the number of Syringes Produced.
- The *denominator* for Actual Batch Yield shall be the Theoretical Fill units.
- Displayed as a percent
- Expressed mathematically:

Actual Batch Yield = (Syringes Produced / Theoretical Fill) * 100

Expected Yield:

Shall be calculated as follows:

- Determine the Yield Rate for the first twenty (20) released commercial batches, including samples, excluding the Process Validation Batches.
- [***] of the Yield Rate becomes the Expected Yield.

Yield Reconciliation Reimbursement:

In the event the average Actual Batch Yield for all Batches Produced and released during a calendar year is less than the Expected Yield, Baxter will provide a credit to Dynavax for each Unit below the Expected Yield according to the following table:

Configuration	Reimbursement amount (per unit)
HEPLISAV-B® HEPATITIS B VACCINE	Capped at the applicable Unit price as shown in Exhibit C

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 4, 2021

Exhibit 31.2

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

CERTIFICATIONS

I, Kelly MacDonald, 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/ KELLY MACDONALD

Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer)

Date: November 4, 2021

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, 2021 (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 4th day of November, 2021.

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, Kelly MacDonald, 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, 2021 (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 4th day of November, 2021.

By: /s/ KELLY MACDONALD
Kelly MacDonald
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.