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 March 31, 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 May 3, 2021, the registrant had outstanding 114,588,212 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 and commercialization of other vaccines containing our CpG 1018™ adjuvant, including any potential vaccine for COVID-19, our ability to manufacture sufficient supply of CpG 1018 to meet potential future demand in connection with new vaccines, including any potential COVID-19 vaccine, and to meet regulatory requirements, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, liquidity and cash needs, as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," or "intend," or the negative of these terms or other variations or comparable terminology.

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

This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners. References herein to "we," "our," "us," "Dynavax" or the "Company" refer to Dynavax Technologies Corporation and 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 the marketplace. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.
- 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 CpG 1018, including collaborations to develop a vaccine for COVID-19, our collaborators generally have primary responsibility for the development, conduct of clinical trials, and for seeking and obtaining regulatory approval, 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 are inadequate; we may be unable to realize any commercial benefit from the development of a vaccine containing CpG 1018.
- 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 product 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 problems 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.
- We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B or continue to sell significant quantities of CpG 1018, and if we are unable to achieve and 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, we will 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 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 CpG 1018, 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, 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 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 have limited experience in manufacturing our product candidates in commercial quantities. With respect to HEPLISAV-B, we have switched to a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture sufficient supply in this presentation.
- 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 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 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.
- The term loan agreement we entered into in February 2018 imposes significant operating and financial restrictions on us that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.
- 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)

	March 31, 2021 (unaudited)	December 31, 2020 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 79,055	$ 32,073
Marketable securities available-for-sale	153,619	132,963
Accounts and other receivables, net	83,994	22,661
Inventories, net	68,846	63,689
Prepaid manufacturing	32,642	29,423
Prepaid expenses and other current assets	9,377	9,206
Total current assets	427,533	290,015
Property and equipment, net	30,696	30,567
Operating lease right-of-use assets	25,799	26,583
Goodwill	2,197	2,297
Restricted cash	226	237
Other assets	3,668	3,573
Total assets	$ 490,119	$ 353,272
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,154	$ 3,312
Accrued research and development	2,890	2,805
Accrued liabilities	16,083	19,099
Warrant liability	31,737	10,736
Deferred revenue	52,202	38,212
Other current liabilities	3,356	3,247
Total current liabilities	109,422	77,411
Long-term debt, net of debt discount of $1,016 and $1,094 at March 31, 2021 and December 31, 2020, respectively	179,889	179,811
Long-term deferred revenue	64,350	-
Long-term portion of lease liabilities	33,795	34,789
Other long-term liabilities	2,901	2,568
Total liabilities	390,357	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– 4 shares at March 31, 2021 and December 31, 2020	-	-
Common stock: $0.001 par value; 278,000 shares authorized at March 31, 2021 and December 31, 2020; 114,563 shares and 110,190 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	114	110
Additional paid-in capital	1,393,947	1,352,374
Accumulated other comprehensive (loss) gain	(1,126)	273
Accumulated deficit	(1,293,173)	(1,294,064)
Total stockholders' equity	99,762	58,693
Total liabilities and stockholders' equity	$ 490,119	$ 353,272

See accompanying notes.

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

	Three Months Ended March 31	
	2021	2020
Revenues:		
Product revenue, net	$ 82,885	$ 10,514
Other revenue	450	405
Total revenues	83,335	10,919
Operating expenses:		
Cost of sales - product	24,625	2,354
Cost of sales - amortization of intangible assets	-	2,298
Research and development	7,758	4,653
Selling, general and administrative	22,423	20,926
Total operating expenses	54,806	30,231
Income (loss) from operations	28,529	(19,312)
Other income (expense):		
Interest income	47	590
Interest expense	(4,712)	(4,731)
Sublease income	2,022	1,926
Change in fair value of warrant liability (Note 10)	(25,552)	8,610
Other	557	322
Net income (loss)	891	(12,595)
Net income (loss) per share attributable to common stockholders		
Basic	$ 0.01	$ (0.15)
Diluted	$ 0.01	$ (0.25)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:		
Basic	112,035	85,477
Diluted	113,469	85,648

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

	Three Months Ended March 31,	
	2021	2020
Net income (loss)	$ 891	$ (12,595)
Other comprehensive income (loss), net of tax:		
Change in unrealized gain on marketable securities available-for-sale	(9)	291
Foreign currency translation adjustments	(1,390)	(479)
Total other comprehensive loss	(1,399)	(188)
Total comprehensive loss	$ (508)	$ (12,783)

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 March 31, 2021	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at December 31, 2020	110,190	$ 110	4	$ -	$ 1,352,374	$ 273	$ (1,294,064)	$ 58,693
Exercise of warrants	750	1	-	-	7,927	-	-	7,928
Issuance of common stock upon exercise of stock options and restricted stock awards, net	640	-	-	-	387	-	-	387
Issuance of common stock under Employee Stock Purchase Plan	104	-	-	-	383	-	-	383
Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (see Note 10)	2,879	3	-	-	28,153	-	-	28,156
Stock compensation expense	-	-	-	-	4,723	-	-	4,723
Total other comprehensive loss	-	-	-	-	-	(1,399)	-	(1,399)
Net income	-	-	-	-	-	-	891	891
Balances at March 31, 2021	114,563	$ 114	4	$ -	$ 1,393,947	$ (1,126)	$ (1,293,173)	$ 99,762

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months March 31, 2020	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at December 31, 2019	83,871	$ 84	5	$ -	$ 1,229,417	$ (2,387)	$ (1,218,824)	$ 8,290
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	728	1	-	-	(2)	-	-	(1)
Issuance of common stock under Employee Stock Purchase Plan	91	-	-	-	311	-	-	311
Issuance of common stock, net of issuance costs, in conjunction with an At Market Sales Agreement (see Note 10)	2,909	3	-	-	14,226	-	-	14,229
Stock compensation expense	-	-	-	-	1,778	-	-	1,778
Total other comprehensive loss	-	-	-	-	-	(188)	-	(188)
Net loss	-	-	-	-	-	-	(12,595)	(12,595)
Balances at March 31, 2020	87,599	$ 88	5	$ -	$ 1,245,730	$ (2,575)	$ (1,231,419)	$ 11,824

See accompanying notes.

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

	Three Months Ended March 31,	
	2021	2020
Operating activities		
Net income (loss)	$ 891	$ (12,595)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,106	1,014
Amortization of right-of-use assets	653	634
Gain on disposal of property and equipment and from lease termination	-	(76)
Amortization of premium (accretion of discounts) on marketable securities	221	(87)
Change in fair value of warrant liability	25,552	(8,610)
Stock compensation expense	4,723	1,778
Cost of sales - amortization of intangible assets	-	2,298
Non-cash interest expense	414	1,338
Tenant improvements provided by the landlord	-	908
Changes in operating assets and liabilities:		
Accounts and other receivables, net	(61,333)	751
Inventories, net	(5,157)	(6,767)
Prepaid manufacturing	(3,219)	-
Prepaid expenses and other current assets	(171)	(1,000)
Other assets	(95)	43
Accounts payable	(295)	(2,095)
Lease liabilities	(751)	(672)
Deferred revenue	78,340	-
Accrued liabilities and other liabilities	(2,847)	(3,728)
Net cash provided by (used in) operating activities	38,032	(26,866)
Investing activities		
Acquisition of technology licenses	-	(7,000)
Purchases of marketable securities	(72,016)	(17,985)
Proceeds from maturities and redemptions of marketable securities	51,130	37,900
Purchases of property and equipment, net	(1,747)	(2,352)
Net cash (used in) provided by investing activities	(22,633)	10,563
Financing activities		
Proceeds from issuance of common stock, net	28,156	14,229
Proceeds from exercise of warrants	3,377	-
Proceeds (tax withholding) from exercise of stock options and restricted stock awards, net	387	(1)
Proceeds from Employee Stock Purchase Plan	383	311
Net cash provided by financing activities	32,303	14,539
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(731)	(225)
Net increase (decrease) in cash, cash equivalents and restricted cash	46,971	(1,989)
Cash, cash equivalents and restricted cash at beginning of period	32,310	40,100
Cash, cash equivalents and restricted cash at end of period	$ 79,281	$ 38,111
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 4,296	$ 3,412
Non-cash investing and financing activities:		
Purchases of property and equipment, not yet paid	$ 411	$ 408

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 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 March 31, 2021, we had cash, cash equivalents and marketable securities of $232.7 million. As of March 31, 2021, the principal amount of our term loan was $180.9 million, including paid-in-kind interest. The term loan has a maturity date of December 31, 2023, unless earlier prepaid.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three months ended March 31, 2021, we recorded net income of $0.9 million. We incurred net loss of $12.6 million for three months ended March 31, 2020. 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 March 31, 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. Adequate financing may not be available to us on acceptable terms, or at all.

Use of Estimates

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

Summary of Significant Accounting Policies

Revenue Recognition

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

Product Revenue, Net – HEPLISAV-B

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

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

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

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, pharmacies and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. There have been no material adjustments to these estimates for the three months ended March 31, 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 our collaboration partners for use in their development and/or commercialization of COVID-19 vaccine. We have determined that our collaboration partners meet the definition of customers under ASC 606. Therefore, we accounted for our CpG 1018 sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer.

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

Collaboration and Manufacturing Service Revenue

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

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the three months ended March 31, 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.

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 months ended March 31, 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
March 31, 2021				
Assets				
Money market funds	$ 71,374	$ -	$ -	$ 71,374
U.S. treasuries	-	28,465	-	28,465
U.S. government agency securities	-	47,472	-	47,472
Corporate debt securities	-	77,682	-	77,682
Total assets	$ 71,374	$ 153,619	$ -	$ 224,993
Liabilities				
Warrant liability	$ -	$ -	$ 31,737	$ 31,737

	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 10. 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 March 31, 2021, we used the following key assumptions to estimate the fair value of warrant liability:

Number of shares	5,090,942
Expected term	0.9 year
Expected volatility	1.2
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 three months ended March 31, 2021 (in thousands):

Balance at December 31, 2020	$ 10,736
Increase in fair value of warrants exercised	3,172
Warrants exercised	(4,551)
Increase in the estimated fair value of warrant liability upon revaluation	22,380
Balance at March 31, 2021	$ 31,737

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):

	March 31, 2021	December 31, 2020	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 79,055	$ 32,073	$ 37,899	$ 39,884
Restricted cash	226	237	212	216
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 79,281	$ 32,310	$ 38,111	$ 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
March 31, 2021				
Cash and cash equivalents:				
Cash	$ 7,681	$ -	$ -	$ 7,681
Money market funds	71,374	-	-	71,374
Total cash and cash equivalents	79,055	-	-	79,055
Marketable securities available-for-sale:				
U.S. treasuries	28,448	17	-	28,465
U.S. government agency securities	47,462	17	(7)	47,472
Corporate debt securities	77,687	8	(13)	77,682
Total marketable securities available-for-sale	153,597	42	(20)	153,619
Total cash, cash equivalents and marketable securities	$ 232,652	$ 42	$ (20)	$ 232,674
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):

	March 31, 2021	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 137,849	$ 137,877
Mature after one year through two years	15,748	15,742
	$ 153,597	$ 153,619

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 months ended March 31, 2021 and 2020. All investments with unrealized losses at March 31, 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):

	March 31, 2021	December 31, 2020
Raw materials	$ 25,137	$ 25,121
Work-in-process	20,525	30,293
Finished goods	23,184	8,275
Total	$ 68,846	$ 63,689

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

On September 17, 2018, we entered into a lease ("Horton Street Master Lease") for office and laboratory space located at 5959 Horton Street, Emeryville, California ("Horton Street Premises"). Under the terms of the Horton Street Master Lease, we are leasing 75,662 square feet at the rate of $4.75 per square foot, paid on a monthly basis, starting on April 1, 2019 ("Commencement Date"). Rent is subject to scheduled annual increases, and we are also responsible for certain operating expenses and taxes throughout the life of Horton Street Master Lease. In connection with the Horton Street Master Lease, we have received tenant improvement allowance totaling $8.1 million through March 31, 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 March 31, 2021 condensed consolidated balance sheets primarily relate to the Horton Street Master Lease.

In connection with the organizational restructuring in May 2019, we did not occupy the Horton Street Premises and in July 2019, we entered into an agreement to sublease the Horton Street Premises to a third party ("Horton Street Sublease"). Under the terms of the Horton Street Sublease, we are subleasing the entire 75,662 rentable square feet at the rate of $5.50 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and the subtenant ("Subtenant") is responsible for certain operating expenses and taxes throughout the life of the Horton Street Sublease. The Horton Street Sublease term is until March 31, 2031, unless earlier terminated, concurrent with the term of our Horton Street Master Lease. The Subtenant has no option to extend the sublease term. Sublease income for the three months ended March 31, 2021 and 2020 were $2.0 million and $1.9 million, respectively. Sublease income is included in other income (expense) in our condensed consolidated statements of operations.

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

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

	Three Months Ended March 31,	
	2021	2020
Operating lease expense	$ 1,560	$ 1,592

Cash paid for amounts included in the measurement of lease liabilities for each of the three months ended March 31, 2021 and 2020 was $1.7 million and 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):

	March 31, 2021	December 31, 2020
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 3,356	$ 3,247
Long-term portion of lease liabilities	33,795	34,789
Total operating lease liabilities	$ 37,151	$ 38,036

At March 31, 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)	$ 3,915	$ 5,215
2022	5,357	6,240
2023	5,518	5,377
2024	5,684	5,521
2025	5,854	5,670
Thereafter	33,742	30,704
Total	$ 60,070	58,727
Less:		
Present value adjustment		(21,576)
Total		$ 37,151

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

	March 31, 2021	December 31, 2020
Weighted average remaining lease term	9.0 years	9.1 years
Weighted average discount rate	10.1%	10.1%

Commitments

On February 20, 2018, we entered into a $175.0 million term loan agreement (“Loan Agreement”) with CRG Servicing LLC. We borrowed $100.0 million under the Loan Agreement at closing and the remaining $75.0 million in March 2019 (collectively, “Term Loans”). At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through March 31, 2021, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans. Included in our total contractual obligations of $188.1 million is the principal amount of $175.0 million, paid-in-kind interest of $5.9 million and the backend facility fee of $7.2 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. See Note 7.

As of March 31, 2021, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 and for clinical research, totaled $90.9 million.

During 2004, we established a letter of credit with Deutsche Bank as security for our Düsseldorf lease in the amount of €0.2 million (Euros). The letter of credit remained outstanding through March 31, 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 March 31, 2021.

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 July 2020, we sold assets related to our SD-101 compound to TriSalus. We paid $2.5 million to Holdings in August 2020. We are obligated to pay Holdings 50% of the contingent pre-commercialization milestone payments that we may receive under the Asset Purchase Agreement. No liability has been recorded under this agreement as of March 31, 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 "Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 ("CpG 1018 Materials"). The 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 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 has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan of up to $99.0 million (the "Advance Payments"). 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 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 Agreement, the applicable Advance Payments will be forgiven at the end of the two-year term.

We have 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 classified as deferred revenue in our condensed consolidated balance sheets.

In February 2021, we received the first Advance Payment of $45.8 million from CEPI which we recorded as long-term deferred revenue. In March 2021, CEPI executed their option to reserve additional quantity of CpG 1018 Materials. Upon the exercise, we recorded $18.6 million of accounts receivable and long-term deferred revenue. As of March 31, 2021, long-term deferred revenue balance related to CEPI's Advance Payments was $64.4 million. No revenue was recognized for the three months ended March 31, 2021.

Valneva SE

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

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

Pursuant to the Supply Agreement, we receive advanced payments to purchase specified quantities of CpG 1018 adjuvant which are recorded as deferred revenue until we deliver the product to Valneva. In the first quarter of 2021, we recognized CpG 1018 product revenue, net of $64.9 million, of which $14.2 million was reported as deferred revenue as of December 31, 2020. As of March 31, 2021, deferred revenue related to the Supply Agreement was $51.0 million.

7. Long-Term Debt

On February 20, 2018, we entered into a $175.0 million Loan Agreement with CRG Servicing LLC. Net proceeds under the Loan Agreement were $173.3 million. The Term Loans under the Loan Agreement bear interest at a rate equal to 9.5% per annum. At March 31, 2021, the effective interest rate was 10.3%. At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through March 31, 2021, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $180.9 million, excluding debt discount of $1.0 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. The Term Loans and paid-in-kind interest will be entirely payable at maturity.

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

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

In January 2021, we entered into a fourth amendment to the Loan Agreement (the "Fourth Amendment"). The Fourth Amendment amended the Loan Agreement to, among other things, allow us to enter into the Agreement with CEPI and to perform our obligations thereunder.

The obligations under the Loan Agreement are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the Company and any future subsidiary guarantors, except for certain customary excluded property, and (ii) all of the capital stock owned by the Company and such future subsidiary guarantors (limited, in the case of the stock of certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, to 65% of the capital stock of such subsidiaries, subject to certain exceptions). The obligations under the Loan Agreement will be guaranteed by each of the Company's future direct and indirect subsidiaries (other than certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, subject to certain exceptions). The Loan Agreement contains customary covenants and requires us to comply with a $15.0 million daily minimum combined cash and investment balance covenant and a twelve-month period revenue requirement for sales of HEPLISAV-B and CpG 1018.

We recorded $4.7 million of interest expense related to the Term Loans during each of the three months ended March 31, 2021 and 2020.

8. Revenue Recognition

Our product revenue, net consisted of the following:

	Three Months Ended March 31,	
	2021	2020
HEPLISAV-B	$ 8,303	$ 10,514
CpG 1018	74,582	-
Total	$ 82,885	$ 10,514

All of our HEPLISAV-B sales were in the U.S. For the three months ended March 31, 2021 and 2020, our three largest Customers collectively represented approximately 75% and 68% of our HEPLISAV-B product revenue, respectively.

All of our CpG 1018 sales were outside the U.S. For the three months ended March 31, 2021, one customer represented approximately 87% of our CpG 1018 product revenue.

The following table summarizes balances and activity in HEPLISAV-B product revenue allowance and reserve categories for the three months ended March 31, 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
Three months ended March 31, 2021:				
Accounts receivable reserves(1)	$ 2,836	$ 1,962	$ (2,469)	$ 2,329
Revenue reserve accruals(2)	$ 6,040	$ 1,641	$ (1,533)	$ 6,148

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

9. Net Income (Loss) Per Share

We compute net income (loss) 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 income (loss) in determining net income attributable to common stockholders.

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

For the calculation of diluted net income (loss) per share, net income (loss) attributable to common stockholders for basic net income (loss) 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 income (loss) per share attributable to common stockholders is computed by dividing the resulting net income (loss) 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 income (loss) per share computations for our common stock are calculated as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2021	2020
Numerator		
Net income (loss)	$ 891	$ (12,595)
Less: undistributed earnings allocated to participating securities	(70)	-
Net income (loss) attributable to common stockholders, basic	$ 821	$ (12,595)
Less: Removal of change in fair value of warrant liability	-	(8,610)
Net income (loss) attributable to common stockholders, diluted	$ 821	$ (21,205)
Denominator		
Weighted average common stock outstanding, basic	112,035	85,477
Effect of dilutive shares:		
Stock-based compensation plans	1,434	-
Effect of dilutive warrants	-	171
Weighted average common stock outstanding, diluted	113,469	85,648

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

	March 31,	
	2021	2020
Outstanding securities not included in diluted net income (loss) per share calculation (in thousands):		
Stock options and stock awards	7,915	11,443
Series B Convertible Preferred Stock (as converted to common stock)	4,140	4,840
Warrants (as exercisable into common stock)	5,091	-
Total	17,146	16,283

10. Common Stock, Preferred Stock and Warrants

Common Stock

As of March 31, 2021, there were 114,563,212 shares of our common stock outstanding.

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

common stock, at a combined price of $3,000 per share and the accompanying warrant. Proceeds from the Offering were approximately $65.6 million, net of issuance costs of $4.5 million.

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

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

On March 11, 2020, we entered into a warrant exchange agreement with Bain Life Sciences Funds pursuant to which we agreed that we would, upon future notice from Bain Life Sciences Funds, exchange all or a portion of the common stock warrants held by Bain Life Sciences Funds for warrants to purchase a new Series C convertible preferred stock ("Series C Warrants"). Each share of Series C convertible preferred stock would be convertible into 1,000 shares of common stock, with a conversion price of $4.50 and would have substantially identical rights to our Series B Preferred Stock. As of March 31, 2021, Bain Life Sciences Funds have not exercised their rights to exchange common stock warrants with Series C Warrants.

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

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 three months ended March 31, 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. As of March 31, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

Preferred Stock

As of March 31, 2021, there were 4,140 shares of Series B Preferred Stock outstanding.

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

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

Warrants

In the first quarter of 2021, 750,308 of our common stock warrants were exercised. As of March 31, 2021, the following common stock warrants were outstanding:

Warrants Issuance Date	Shares Issuable (in thousands)	Expiration Date	Exercise Price per Share	Outstanding as of March 31, 2021 (in thousands)
August 12, 2019	5,091	February 12, 2022	$ 4.50	5,091

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

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

The warrants will be revalued at each reporting period using the Black-Scholes model and the change in the fair value of the warrants will recognized as other income (expense) in the condensed consolidated statements of operations. At March 31, 2021, the estimated fair value of warrant liability was $31.7 million. For the three months ended March 31, 2021, we recognized the increase in the estimated fair value of warrant liability of $25.6 million as expense in other income (expense) in our condensed consolidated statements of operations.

11. 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.

As of March 31, 2021, the 2018 Equity Incentive Plan, as amended, ("Amended 2018 EIP"), the 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 three months ended March 31, 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	1,996	9.36		
Options exercised	(119)	4.16		
Options cancelled:				
Options forfeited (unvested)	(171)	7.50		
Options expired (vested)	(164)	19.67		
Balance at March 31, 2021	10,047	$ 11.15	4.26	$ 17,816
Vested and expected to vest at March 31, 2021	9,693	$ 11.26	4.18	$ 17,184
Exercisable at March 31, 2021	5,967	$ 13.44	3.05	$ 8,975

Restricted stock unit activity under our stock-based compensation plans during the three months ended March 31, 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	1,796	9.43
Vested	(533)	8.88
Forfeited	(120)	8.50
Non-vested as of March 31, 2021	2,937	$ 8.22

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 three months ended March 31, 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	(30)	8.40
Non-vested as of March 31, 2021	267	$ 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		Market-Based Performance Stock Unit ("PSUs")
	Three Months Ended March 31,		Three Months Ended March 31, 2021
	2021	2020	
Weighted-average fair value per share	$ 6.72	$ 3.58	$ 8.40
Risk-free interest rate	0.5%	1.4%	From 0.03% to 1.92%
Expected life (in years)	4.5	4.5	2.9
Volatility	1.0	0.9	0.9

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

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 872	$ (1,573)
Selling, general and administrative	3,144	2,442
Cost of sales - product	170	136
Inventory	537	773
Total	$ 4,723	$ 1,778

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. Stock-based compensation for the three months ended March 31, 2020 included reversal of expenses related to cancellation of certain equity grants in the first quarter of 2020.

12. Subsequent Events

CEPI Amendment

On May 3, 2021, we entered into the first Amendment (the "Amendment") to the Agreement with CEPI. The Amendment provides for the manufacture and reservation of an additional specified quantity of CpG 1018 adjuvant (the "Extra Reserved Material") and helps to accelerate the Company's efforts to further increase its available inventory of CpG 1018 adjuvant. In exchange for the Company's reserving additional CpG 1018 adjuvant pursuant to the Amendment, in addition to the $99.0 million previously provided under the Agreement, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan in an amount equivalent to the anticipated manufacturing costs of all material reserved by CEPI, which, for the Extra Reserved Material covered by the Amendment, is up to an additional $77.4 million, for a total of CEPI's funding under the Agreement of up to $176.4 million. We intend to establish an additional qualified source of supply for CpG 1018 adjuvant, including a portion of the Extra Reserved Material, which is expected to be available for release during the fourth quarter of 2021.

Amendment to CRG Loan Agreement

On May 3, 2021, we entered into a fifth amendment to the Loan Agreement with CRG (the "Fifth Amendment"). The Fifth Amendment amended the Loan Agreement to, among other things, allow us to enter into the Amendment with CEPI and to perform our obligations thereunder.

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 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. We expect to launch HEPLISAV-B in the European Union in late 2021, initially focusing on one or a few key countries where it would be commercially feasible to market HEPLISAV-B on our own or through third-parties.

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 months ended March 31, 2021, HEPLISAV-B product revenue, net was $8.3 million.

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 months ended March 31, 2021, CpG 1018 product revenue, net was $74.6 million.

In January 2021, we entered into an agreement with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018. The agreement enables CEPI to direct the supply of CpG 1018 to CEPI partner(s). In exchange for reserving CpG 1018, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan of up to $99.0 million. If the vaccine programs pursued by CEPI partner(s) are unsuccessful and no alternative use is found for CpG 1018 reserved under the agreement, the applicable advance payments will be forgiven. No revenue was recognized for the three months ended March 31, 2021 under the CEPI agreement.

On May 3, 2021, we entered into the first Amendment (the "Amendment") to the agreement with CEPI. The Amendment provides for the manufacture and reservation of an additional specified quantity of CpG 1018 adjuvant (the "Extra Reserved Material") and helps to accelerate our efforts to further increase our available inventory of CpG 1018 adjuvant. In exchange for our reserving additional CpG 1018 adjuvant pursuant to the Amendment, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan in an amount equivalent to the anticipated manufacturing costs of all material reserved by CEPI, which, for the Extra Reserved Material covered by the Amendment, is up to an additional $77.4 million, for a total of CEPI's funding under the agreement of up to $176.4 million. We intend to establish an additional qualified source of supply for CpG 1018 adjuvant, including a portion of the Extra Reserved Material, which is expected to be available for release during the fourth quarter of 2021.

COVID-19 Update

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

To date, we and our distribution partners have been able to continue to supply HEPLISAV-B throughout the United States, and currently do not anticipate any interruptions in supply. Due to the ongoing COVID-19 global pandemic, most medical centers have restricted access to their facilities and focused on providing care to only the most severely affected patients beginning in 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.

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

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 by the end of 2021. Our HEPLISAV-B dialysis study was also able to continue, because the dialysis treatment has been classified under "essential travel" exemptions. Final immunogenicity results of our dialysis study were presented in April 2021 and we expect the safety follow up to be completed during the fourth quarter of 2021. However, if the COVID-19 pandemic continues to persist for an extended period of time, we could experience significant disruptions to these or other studies, which could adversely affect our business and growth prospects.

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

We have been actively pursuing opportunities to collaborate with other organizations on the development of a COVID-19 vaccine, by leveraging our toll-like receptor 9 ("TLR9") agonist adjuvant, CpG 1018, which is the adjuvant used in our HEPLISAV-B product. In 2020, we announced multiple collaborations focused on COVID-19 and we continue to work to identify other programs where CpG 1018 can be utilized to enhance the immune response to a coronavirus vaccine. We and our contract 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.

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 three months ended March 31, 2021, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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 commercialization of COVID-19 vaccine. 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 March 31,		Increase (Decrease) from 2020 to 2021	
Revenues:	**2021**	**2020**	**$**	**%**
HEPLISAV-B	$ 8,303	$ 10,514	$ (2,211)	(21)%
CpG 1018	74,582	-	74,582	-
Total product revenue, net	$ 82,885	$ 10,514	$ 72,371	688%
Other revenue	450	405	45	11%
Total revenues	$ 83,335	$ 10,919	$ 72,416	663%

HEPLISAV-B revenue for the three months ended March 31, 2021 decreased, compared to the same period of last year, due to lower sales volume. Adult vaccine utilization (except for COVID-19 vaccines) continued to be impacted in the three months ended March 31, 2021 due to the COVID-19 vaccine rollout.

In the three months ended September 30, 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 months ended March 31, 2021, we continued to manufacture and ship CpG 1018 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.

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 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):

Cost of Sales - Product	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020	Increase (Decrease) from 2020 to 2021 $	Increase (Decrease) from 2020 to 2021 %
HEPLISAV-B	$ 2,745	$ 2,354	$ 391	17%
CpG 1018	$ 21,880	$ -	$ 21,880	-
Total cost of sales - product	$ 24,625	$ 2,354	$ 22,271	946%

HEPLISAV-B cost of sales-product increased primarily due to higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing. The increase was partially offset by lower sales volume.

In the three months ended September 30, 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 months ended March 31, 2021, we continued to manufacture and ship CpG 1018 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):

Research and Development:	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020	Increase (Decrease) from 2020 to 2021 $	Increase (Decrease) from 2020 to 2021 %
Compensation and related personnel costs	$ 3,202	$ 2,197	$ 1,005	46%
Outside services	3,422	3,935	(513)	(13)%
Facility costs	262	94	168	179%
Non-cash stock-based compensation	872	(1,573)	2,445	155%
Total research and development	$ 7,758	$ 4,653	$ 3,105	67%

Compensation and related personnel costs and non-cash stock-based compensation increased primarily due to higher headcount. The increase in compensation and related personnel costs was partially offset by the decrease in business travel due to COVID-19 travel restrictions. In addition, non-cash stock-based compensation in the three months ended March 31, 2020 included reversal of expenses related to cancellation of certain equity grants.

The decrease in outside services was primarily due to the winding down of our immuno-oncology programs.

Total research and development expenses were higher in the three months ended March 31, 2021, due to development activities at our Dusseldorf facility focused on process improvements.

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):

Selling, General and Administrative:	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020	Increase (Decrease) from 2020 to 2021 $	Increase (Decrease) from 2020 to 2021 %
Compensation and related personnel costs	$ 9,204	$ 8,300	$ 904	11%
Outside services	6,588	6,625	(37)	(1)%
Legal costs	486	734	(248)	(34)%
Facility costs	3,001	2,825	176	6%
Non-cash stock-based compensation	3,144	2,442	702	29%
Total selling, general and administrative	$ 22,423	$ 20,926	$ 1,497	7%

Compensation and related personnel costs increased due to higher headcount and an accrual of benefits for a former executive in connection with his retirement, offset by the decrease in business travel due to COVID-19 travel restrictions.

Non-cash stock-based compensation increased due to higher headcount. 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.

Other Income (Expense)

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

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020	Increase (Decrease) from 2020 to 2021 $	Increase (Decrease) from 2020 to 2021 %
Interest income	$ 47	$ 590	$ (543)	(92)%
Interest expense	$ (4,712)	$ (4,731)	$ (19)	0%
Sublease income	$ 2,022	$ 1,926	$ 96	5%
Change in fair value of warrant liability	$ (25,552)	$ 8,610	$ (34,162)	(397)%
Other	$ 557	$ 322	$ 235	73%

Interest income for the three months ended March 31, 2021 decreased, as compared to the same periods in 2020, primarily due to lower yields on our marketable securities portfolio. The change in the fair value of the warrant liability is primarily due to increase in our stock price. The change in other is primarily due to foreign currency transactions and related fluctuations in the value of the Euro compared to the U.S. dollar.

Liquidity and Capital Resources

As of March 31, 2021, we had $232.7 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 March 31, 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.

Pursuant to the CEPI agreement, advanced payments received from CEPI to reserve a specified quantity of CpG 1018 totaling $64.4 million were recorded as long-term deferred revenue in our condensed consolidated balance sheets.

Pursuant to the supply agreement with Valneva Scotland Limited ("Valneva"), we received advanced payments to purchase specified quantities of CpG 1018 adjuvant which were recorded as deferred revenue. As of March 31, 2021, deferred revenue related to the supply agreement totaling $51.0 million was recorded in our condensed consolidated balance sheets

In February 2018, we entered into a term loan agreement with CRG Servicing LLC. At March 31, 2021, the principal amount of the term loan was $180.9 million, excluding debt discount of $1.0 million. The loan and the related unpaid interest and fees are due in December 2023.

For the three months ended March 31, 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"). As of March 31, 2021, we had $120.5 million remaining under the 2020 ATM Agreement.

During the three months ended March 31, 2021, we generated $38.0 million of cash from our operations primarily due to our net income of $0.9 million, of which $32.7 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, non-cash interest expense and accretion and amortization on marketable securities. By comparison, during the three months ended March 31, 2020, we used $26.9 million of cash for our operations primarily due to our net loss of $12.6 million, of which $1.7 million consisted of non-cash items which included change in fair value of warrant liability, amortization of intangible assets, stock-based compensation, non-cash interest expense, depreciation and amortization, amortization of right-of-use assets and accretion and amortization on marketable securities. Cash used in our operations during the first three months of 2021 increased by $64.9 million. For the three months ended March 31, 2021, we received an advance payment from CEPI in the amount of $45.8 million which was recorded as deferred revenue. 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 three months ended March 31, 2021, net cash used in investing activities was $22.6 million, compared to $10.6 million of net cash provided by investing activities in the same period of last year. During the first three months of 2021, net purchases of marketable securities was $20.9 million, compared to $19.9 million of net proceeds from maturities and redemptions of marketable securities in the same period of last year. During the first three months of 2020, we paid $7.0 million of sublicense payment to Merck. Cash used in net purchases of property plant and equipment decreased by $0.6 million during the first three months of 2021 compared to the same period in 2020. The decrease was, primarily, due to the installation of facility improvements in the first three months of 2020.

During the three months ended March 31, 2021 and 2020, net cash provided by financing activities was $32.3 million and $14.5 million, respectively. Cash provided by financing activities for the first three months of 2021 included net proceeds of $28.2 million from our 2020 ATM Agreement and $3.4 million from warrants exercised. Cash provided by financing activities in the first three months of 2020 included net proceeds of $14.2 million from the issuance of common stock under our 2017 ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three months ended March 31, 2021, we recorded net income of $0.9 million. We incurred net loss of $12.6 million for three months ended March 31, 2020. We cannot be certain that sales of our products, and the revenue from our other activities will not fall short of our projections or be delayed. 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.

Contractual Obligations

As of March 31, 2021, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B, CpG 1018 adjuvant and for clinical research, totaled $90.9 million.

There were no other material changes to the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 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 three months ended March 31, 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 our business, our future efforts to obtain regulatory approval, achieve restructuring goals, advance our collaborations, 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 the marketplace. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.

We have established sales, marketing and distribution capabilities and commercialized HEPLISAV-B in the U.S. Successful commercialization of HEPLISAV-B will require significant resources and time and, while Dynavax personnel are experienced with respect to marketing of healthcare products, because HEPLISAV-B is the company's first marketed product, the potential uptake of the product in distribution and the timing for growth in sales, if any, is unpredictable and we may not be successful in commercializing HEPLISAV-B. 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 that in a potentially evolving reimbursement environment our efforts may fail to overcome established competition at favorable pricing.

We converted our contracted 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 receive HEPLISAV-B.

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

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

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

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

In addition, due to the ongoing COVID-19 global pandemic, most medical centers 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 since the end of 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.

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

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

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

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

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.

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 continue for a substantial period of time, they could impact personnel at our manufacturing facility in Germany and third-party manufacturing facilities in the United States. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B sufficient to meet demand.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact, 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 have been discovered. 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 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 CpG 1018, 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 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, or at all.

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

As our commercial business begins to expand in connection with commercial sales of HEPLISAV-B and CpG 1018, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain quantities and meeting certain quality thresholds, among other things, all within specified timeframes. If, for any reason, whether due to reliance on third-party manufacturers or otherwise, we are unable to deliver timely, compliant products to our customers in quantities that meet our contractual obligation, we could be subject to lost revenue, contractual penalties, suits for damages, harm to our reputation or other problems that could materially and adversely affect our business.

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. We expect that our visibility into future 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 other 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 90% of our overall revenue, and one customer accounted for 78% of our revenue, during the quarter ended March 31, 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 HEPLISAV-B and our product candidates. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities. With respect to HEPLISAV-B, we have switched to a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our ability to manufacture sufficient supply in this presentation.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing HEPLISAV-B surface antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. The FDA approved our pre-filled presentation of HEPLISAV-B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV-B going forward. We have limited experience in manufacturing and supplying this presentation and 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 our CpG 1018 adjuvant for HEPLISAV-B and 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 and developing and commercializing our product candidates. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

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

We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop a vaccine for COVID-19. These collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 adjuvant or otherwise are inadequate, we may be unable to realize any 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 the vaccine will be approved for use, the extent of competition, government actions and whether a vaccine can be successfully 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 of a vaccine could be delayed, and may not occur at all. We also rely on a single supplier to produce our CpG 1018 adjuvant. If we were unable to maintain our existing supplier for the adjuvant, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing any potential adjuvanted

vaccines by our third-party collaborators. We or other third parties may not be able to produce 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 add an additional supplier, there is no guarantee such supplier will be able to manufacture 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. 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 any 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 our product or product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price, as well as the availability of coverage and adequate reimbursement, from third-party payors, in particular for HEPLISAV-B, where existing products are already marketed. In the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as 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 that may be required in the event that CpG 1018 is included in any approved and commercially-available novel vaccine, whether a COVID-19 vaccine or otherwise, we have applied for, and in some cases have received grants from various charitable and philanthropic organizations, including from Bill and Melinda Gates Foundation. These grants 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 in some cases, our control over the manufacturing and distribution of grant-funded products. Failure to agree with such requirements, may result in the Company not receiving some or all of the grant.

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

In the second quarter of 2019, we implemented a strategic restructuring that would focus our efforts on HEPLISAV-B, which included a reduction in our workforce and operations to focus resources on HEPLISAV-B commercialization and sales execution as

well as assess additional opportunities to leverage our CpG 1018 adjuvant. We recently announced the sale of assets related to our SD-101 program. Additionally, we are seeking strategic alternatives for 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 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 problems with HEPLISAV-B.

Our HEPLISAV-B regulatory approval in the United States is subject to certain post-marketing obligations and commitments to the FDA. For example, we 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. 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 these studies 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 limits our marketing claims, we may be unable to generate significant revenues, if any.

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

We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and CpG 1018, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

We have generated limited revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net income for the three months ended March 31, 2021 was $0.9 million and net loss for the three months ended March 31, 2020 was $12.6 million. As of March 31, 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 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 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, we will require substantial additional capital to finance our operations.

As of March 31, 2021, we had $232.7 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 months ended March 31, 2021, we recorded net income of $0.9 million. We incurred net loss of $12.6 million for three months ended March 31, 2020. As of March 31, 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. 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 continue to develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates we may develop outside the U.S., requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may seek to introduce HEPLISAV-B, or any other product candidates we may develop, 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 governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including with respect to our product candidates and those of our partners in combination agent studies:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- a product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether a product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- a product candidate or combination study may appear to be no more effective than current therapies;

- the quality or stability of a product candidate may fail to conform to acceptable standards;
- the inability to produce or obtain sufficient quantities of a product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- the inability to obtain regulatory approval to conduct a clinical trial;
- lack of adequate funding to continue a clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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

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

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

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

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 development and commercialization of our product candidates and research programs. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to continue to develop and commercialize those products and programs, if at all.

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;
- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;

- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

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

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

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

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

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

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

We rely on CROs, clinical sites and investigators for our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we maintain oversight over our clinical trials and conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third-party contractors to ensure that clinical trials are conducted properly and that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

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 penalty law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;
- the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education and Reconciliation Act of 2010 (collectively, “ACA”) which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians (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 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 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 December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate 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 instructs 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 unclear how the Supreme Court ruling, other such litigation, and the 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, 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

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

The biopharmaceutical patent environment outside the U.S. is 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 United States permit method of use patents relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving and may be unfavorably interpreted to prevent us from successfully prosecuting some or all of our pending patent applications relating to the use of CpG 1018. There are some countries that currently do not allow such method of use patents, or that significantly limit the types of uses that are patentable.

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

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed 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; and
- other parties may design around technologies we have licensed, patented or developed;
- 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 an Investment in our Common Stock

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

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

- impact of COVID-19 on our HEPLISAV-B 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; and
- the volume of trading in our common stock.

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

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

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

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

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

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

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

None.

ITEM 6. EXHIBITS

		Incorporated by Reference				
Exhibit Number	**Document**	**Exhibit Number**	**Filing**	**Filing Date**	**File No.**	**Filed Herewith**
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.5	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.6	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	
3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	May 29, 2020	001-34207	
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	3.1	8-K	August 8, 2019	001-34207	
3.10	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.3	Form of Series B Preferred Stock Certificate	4.3	10-Q	November 7, 2019	001-34207	
4.4	Form of Warrant to Purchase Common Stock	4.1	8-K	August 8, 2019	001-34207	
10.1	Dynavax Technologies Corporation 2021 Inducement Award Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Grant Notice and Restricted Stock Unit Award Agreement.	10.1	8-K	January 12, 2021	001-34207	
10.2^	Agreement, dated January 29, 2021, between the Company and Coalition for Epidemic Preparedness Innovations	10.31	10-K	February 25, 2021	001-34207	
10.3	Amendment No. 4 to Term Loan Agreement and Fee Letter, dated January 29, 2021, by and among Company, CRG Partners III L.P., CRG Partners III-Parallel Fund “A” L.P. and CRG Servicing LLC	10.32	10-K	February 25, 2021	001-34207	
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

\+ Indicates management contract, compensatory plan or arrangement.

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

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

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

SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: May 6, 2021

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

Date: May 6, 2021

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

Date: May 6, 2021

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

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: May 6, 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: May 6, 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 March 31, 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 6th day of May, 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 March 31, 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 6th day of May, 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.