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 June 30, 2022

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 720
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 August 1, 2022, the registrant had outstanding 126,473,586 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, CpG 1018 adjuvant or any future product, our anticipated market opportunity and level of sales of HEPLISAV-B and CpG 1018 adjuvant, our ability to manufacture sufficient supply of HEPLISAV-B to meet future demand, our business, collaboration and regulatory strategy, our ability to successfully support the development, manufacture and commercialization of other vaccines containing our CpG 1018 adjuvant, including any current or potential vaccine or vaccine candidate for COVID-19 that stem from any of our collaborations, our ability to manufacture sufficient supply of CpG 1018 to meet potential future demand in connection with new vaccines, including COVID-19 vaccines, our ability to advance our other product candidates, such as our Tdap, shingles and plague programs, and to otherwise develop and expand our clinical research pipeline, meet regulatory requirements, including post-marketing obligations and commitments, 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 approved and launched in the United States and Germany, and approved more broadly in the European Union, and there is significant competition in these marketplaces. Since this is our first marketed product, the timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for HEPLISAV-B.
- Our business and operations have been and may continue to be adversely affected by the ongoing COVID-19 global pandemic. We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop vaccines for COVID-19. These collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 adjuvant or otherwise are inadequate, we may be unable to realize recurring commercial benefit from the development of any vaccines containing CpG 1018 adjuvant.
- Our financial results may vary significantly from quarter to quarter or may fall below the expectations of investors or securities analysts, each of which may adversely affect our stock price.
- We face uncertainty regarding coverage, pricing and reimbursement and the practices of third-party payors, which may make it difficult or impossible to sell certain of our products or product candidates on commercially reasonable terms.
- We are subject to ongoing United States Food and Drug Administration (“FDA”) and European Medicines Agency (“EMA”) post-marketing obligations concerning HEPLISAV-B, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated regulatory issues with HEPLISAV-B.
- If HEPLISAV-B or any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of HEPLISAV-B or any other products we develop, or limit our marketing claims, we may be unable to generate significant revenues, if any.
- Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors as a result of these disadvantages, we may be unable to generate sufficient or any revenues and our business will be harmed.
- Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Conversion of our Convertible Notes (defined below) may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.
- Despite recent profitability, we have incurred annual net losses in most years since our inception and anticipate that we could continue to incur significant losses for the foreseeable future unless we can successfully commercialize HEPLISAV-B and/or continue to sell significant quantities of our CpG 1018 adjuvant, and if we are unable to sustain profitability, the market value of our common stock will likely decline. Until we are able to generate significant revenues or achieve profitability through product sales on a consistent basis, we may 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. or Europe, requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our products or product candidates.
- 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 may have uncertain outcomes.
- 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 revenue from such product candidates.
- HEPLISAV-B and most of our earlier stage programs rely on oligonucleotide toll-like receptor ("TLR") agonists. In the event of serious adverse event data relating to TLR agonists, we may be required to reduce the scope of, or discontinue, our operations, or reevaluate the viability of strategic alternatives.
- As we plan for broader commercialization of HEPLISAV-B and for expanded capacity to manufacture our CpG 1018 adjuvant, our financial commitments to increase supply capacity might outpace actual demand for our products. Also, if we are unable to maintain our production operations in Düsseldorf, Germany, and our existing suppliers for CpG 1018 adjuvant, we would have to establish alternate qualified manufacturing capabilities, which could result in significant additional operating costs and delays in developing and commercializing HEPLISAV-B and any approved or potential vaccine utilizing CpG 1018. There can be no assurance that we, our existing suppliers, or other third parties will be able to produce CpG 1018 at a cost, quantity and quality sufficient to support our existing or any future collaborations.
- We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture HEPLISAV-B. We rely on a limited number of suppliers to produce the oligonucleotides we require for development and commercialization. Additionally, we and our collaborators have limited experience in manufacturing our products and product candidates in commercial quantities. With respect to HEPLISAV-B, we use a pre-filled syringe presentation of the vaccine and our ability to meet future demand will depend on our or our contract manufacturer's ability to provide sufficient supply in this presentation.
- As we continue to grow as a commercial organization and enter into supply agreements with customers and collaborators, those supply agreements will have obligations to deliver product for which we are reliant upon third parties to manufacture on our behalf.
- HEPLISAV-B is subject to regulatory obligations and continued regulatory review, and if we receive regulatory approval for our other product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review for such products.
- A key part of our business strategy for products in development is to establish collaborative relationships to help fund or manage development and commercialization of our product candidates and research programs. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to continue to develop and commercialize those products and programs, if at all. These relationships may not succeed on expected timelines, or at all.
- We rely on CROs and clinical sites and investigators for our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.
- As we focus on commercialization of HEPLISAV-B, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.
- 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.
- 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2022 (unaudited)	December 31, 2021 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 249,091	$ 436,189
Marketable securities available-for-sale	269,078	109,761
Accounts receivables, net	172,270	116,216
Other receivables	1,972	15,600
Inventories, net	73,979	61,335
Prepaid manufacturing	54,477	159,655
Prepaid expenses and other current assets	134,538	73,764
Total current assets	955,405	972,520
Property and equipment, net	36,286	35,020
Operating lease right-of-use assets	25,785	25,964
Goodwill	1,958	2,125
Restricted cash	202	219
Other assets	3,363	3,398
Total assets	$ 1,022,999	$ 1,039,246
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,959	$ 2,600
Accrued research and development	3,678	4,688
CEPI accrual (Note 6)	107,370	128,848
Accrued liabilities	34,146	49,796
Warrant liability	-	18,016
Deferred revenue	191,998	349,864
Other current liabilities	3,047	2,590
Total current liabilities	345,198	556,402
Convertible Notes, net of debt discount of $4,470 and $5,010 at June 30, 2022 and December 31, 2021, respectively	221,030	220,490
Long-term portion of lease liabilities	33,677	34,316
Other long-term liabilities	295	5,664
Total liabilities	600,200	816,872
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock: $0.001 par value; 278,000 shares authorized at June 30, 2022 and December 31, 2021; 126,439 shares and 122,945 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	126	123
Additional paid-in capital	1,484,970	1,441,868
Accumulated other comprehensive loss	(6,560)	(2,266)
Accumulated deficit	(1,055,737)	(1,217,351)
Total stockholders' equity	422,799	222,374
Total liabilities and stockholders' equity	$ 1,022,999	$ 1,039,246

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 255,320	$ 52,677	$ 367,647	$ 135,562
Other revenue	1,144	90	2,809	540
Total revenues	256,464	52,767	370,456	136,102
Operating expenses:				
Cost of sales - product	83,369	14,845	123,331	39,470
Research and development	9,689	7,167	20,784	14,925
Selling, general and administrative	36,179	21,583	68,351	44,006
Gain on sale of assets (Note 5)	(1,000)	-	(1,000)	-
Total operating expenses	128,237	43,595	211,466	98,401
Income from operations	128,227	9,172	158,990	37,701
Other income (expense):				
Interest income	765	48	1,026	95
Interest expense	(1,683)	(3,109)	(3,363)	(7,821)
Sublease income	2,025	1,670	3,634	3,692
Loss on debt extinguishment	-	(5,232)	-	(5,232)
Change in fair value of warrant liability (Note 10)	-	2,097	1,801	(23,455)
Other	40	(173)	145	384
Net income before income taxes	129,374	4,473	162,233	5,364
Provision for income taxes	(619)	-	(619)	-
Net income	$ 128,755	$ 4,473	$ 161,614	$ 5,364
Net income per share attributable to common stockholders:				
Basic	$ 1.02	$ 0.04	$ 1.29	$ 0.04
Diluted	$ 0.87	$ 0.02	$ 1.08	$ 0.04
Weighted-average shares used in computing net income per share attributable to common stockholders:				
Basic	126,347	114,629	125,456	113,339
Diluted	149,905	118,830	149,821	114,978

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income	$ 128,755	$ 4,473	$ 161,614	$ 5,364
Other comprehensive income (loss), net of tax:				
Change in unrealized gain (loss) on marketable securities available-for-sale	(629)	38	(1,901)	29
Foreign currency translation adjustments	(1,768)	375	(2,393)	(1,015)
Total other comprehensive income (loss)	(2,397)	413	(4,294)	(986)
Total comprehensive income	$ 126,358	$ 4,886	$ 157,320	$ 4,378

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 June 30, 2022	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at March 31, 2022	126,297	$ 126	-	$ -	$ 1,476,013	$ (4,163)	$ (1,184,492)	$ 287,484
Issuance of common stock upon exercise of stock options and/or release of restricted stock awards, net	142	-	-	-	1,028	-	-	1,028
Stock compensation expense	-	-	-	-	7,929	-	-	7,929
Total other comprehensive loss	-	-	-	-	-	(2,397)	-	(2,397)
Net income	-	-	-	-	-	-	128,755	128,755
Balances at June 30, 2022	126,439	$ 126	$ -	$ -	$ 1,484,970	$ (6,560)	$ (1,055,737)	$ 422,799
Six Months Ended June 30, 2022								
Balances at December 31, 2021	122,945	$ 123	-	$ -	$ 1,441,868	$ (2,266)	$ (1,217,351)	$ 222,374
Issuance of common stock upon exercise of warrants	1,879	2	-	-	24,668	-	-	24,670
Issuance of common stock upon exercise of stock options and/or release of restricted stock awards, net	1,533	1	-	-	2,149	-	-	2,150
Issuance of common stock under Employee Stock Purchase Plan	82	-	-	-	710	-	-	710
Stock compensation expense	-	-	-	-	15,575	-	-	15,575
Total other comprehensive loss	-	-	-	-	-	(4,294)	-	(4,294)
Net income	-	-	-	-	-	-	161,614	161,614
Balances at June 30, 2022	126,439	$ 126	$ -	$ -	$ 1,484,970	$ (6,560)	$ (1,055,737)	$ 422,799

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months Ended June 30, 2021	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss) Income**	**Deficit**	**Equity**
Balances at March 31, 2021	114,563	$ 114	4	$ -	$ 1,393,947	$ (1,126)	$ (1,293,173)	$ 99,762
Issuance of common stock upon exercise of stock options and restricted stock awards, net	193	-	-	-	948	-	-	948
Purchase of capped call options related to issuance of Convertible Notes (Note 7)	-	-	-	-	(27,240)	-	-	(27,240)
Stock compensation expense	-	-	-	-	5,024	-	-	5,024
Total other comprehensive income	-	-	-	-	-	413	-	413
Net income	-	-	-	-	-	-	4,473	4,473
Balances at June 30, 2021	114,756	$ 114	$ 4	$ -	$ 1,372,679	$ (713)	$ (1,288,700)	$ 83,380
Six Months Ended June 30, 2021								
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	833	-	-	-	1,335	-	-	1,335
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 11)	2,879	3	-	-	28,153	-	-	28,156
Purchase of capped call options related to issuance of Convertible Notes (see Note 7)	-	-	-	-	(27,240)	-	-	(27,240)
Stock compensation expense	-	-	-	-	9,747	-	-	9,747
Total other comprehensive loss	-	-	-	-	-	(986)	-	(986)
Net income	-	-	-	-	-	-	5,364	5,364
Balances at June 30, 2021	114,756	$ 114	$ 4	$ -	$ 1,372,679	$ (713)	$ (1,288,700)	$ 83,380

See accompanying notes.

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

	Six Months Ended June 30,	
	2022	**2021**
Operating activities		
Net income	161,614	5,364
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	2,085	2,202
Amortization of right-of-use assets and loss on disposal of property and equipment	1,644	1,326
(Accretion of discounts) amortization of premium on marketable securities	(498)	369
Loss on debt extinguishment	-	5,232
Change in fair value of warrant liability	(1,801)	23,455
Stock compensation expense	15,575	9,747
Non-cash interest expense	540	2,806
Gain on sale of assets (Note 5)	(1,000)	-
Changes in operating assets and liabilities:		
Accounts and other receivables, net	(42,426)	(83,239)
Inventories, net	(12,644)	(22,762)
Prepaid manufacturing	105,178	(6,875)
Prepaid expenses and other current assets	(60,774)	(247)
Other assets	35	(265)
Accounts payable	2,319	7,209
CEPI accrual (Note 6)	(21,478)	-
Lease liabilities	(1,678)	(1,554)
Deferred revenue	(157,866)	91,345
Long-term deferred revenue	-	106,950
Accrued liabilities and other liabilities	(22,617)	7,757
Net cash (used in) provided by operating activities	(33,792)	148,820
Investing activities		
Purchases of marketable securities	(313,660)	(164,928)
Proceeds from maturities and redemptions of marketable securities	152,950	81,355
Purchases of property and equipment, net	(4,271)	(2,812)
Proceeds from sale of assets	1,000	-
Net cash used in investing activities	(163,981)	(86,385)
Financing activities		
Proceeds from issuance of common stock, net	-	28,156
Proceeds from issuance of Convertible Notes, net	-	219,822
Purchases of capped call options	-	(27,240)
Repayment of long-term debt	-	(190,194)
Proceeds from warrants exercises	8,455	3,376
Proceeds from exercise of stock options and release of restricted stock awards, net	2,150	1,335
Proceeds from Employee Stock Purchase Plan	710	383
Net cash provided by financing activities	11,315	35,638
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(657)	(546)
Net (decrease) increase in cash, cash equivalents and restricted cash	(187,115)	97,527
Cash, cash equivalents and restricted cash at beginning of period	436,408	32,310
Cash, cash equivalents and restricted cash at end of period	249,293	129,837
Supplemental disclosure of cash flow information		
Cash paid during the period for income taxes	509	-
Cash paid during the period for interest	2,819	2,053
Non-cash investing and financing activities:		
Purchases of property and equipment, not yet paid	1,214	2,131
Right-of-use assets obtained in exchange of lease liabilities	1,767	-

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 innovative vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and the European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. We also manufacture and sell CpG 1018®, the adjuvant used in HEPLISAV-B, and have established a portfolio of global commercial supply agreements in the development of COVID-19 vaccines across a variety of vaccine platforms. Additionally, we are advancing a multi-program clinical pipeline leveraging CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs including phase 1 clinical trials in Tdap and shingles, and a phase 2 clinical trial in plague in collaboration with and fully funded by the U.S. Department of Defense ("DoD").

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 as of December 31, 2021 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 the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, 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, Dynavax India LLP in India and a branch of Dynavax registered in Italy. 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.

Use of Estimates

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

Summary of Significant Accounting Policies

Revenue Recognition

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

Product Revenue, Net – HEPLISAV-B

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

Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product upon delivery to the Customer. The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Because our standard credit terms are short term and we expect to receive payment in less than one-year, there is no significant financing component on the related receivables. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

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

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, pharmacies and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. We evaluate our estimates of variable considerations including, but not limited to, product returns, chargebacks and rebates, periodically or when there is an event or change in circumstances that may indicate that our estimates may change. For the three and six months ended June 30, 2022, we recorded an adjustment resulting in $0.7 million increase in HEPLISAV-B net product revenue. For the three and six months ended June 30, 2021, there were no material adjustments to these estimates recognized.

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 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 innovative adjuvant, CpG 1018, to our collaboration partners for use in their development and/or commercialization of COVID-19 vaccines. We have determined that our collaboration partners meet the definition of customers under ASC 606. Therefore, we accounted for our CpG 1018 adjuvant sales under ASC 606. Revenues from product sales are recognized when we have satisfied our performance obligation, which is the transfer of control of our product to the customer. Because the timing between the recognition of revenue for product sales and the receipt of payment is less than one year, there is no significant financing component on the related receivables. Since our performance obligation is part of a contract that has an original expected duration of one year or less, we elect not to disclose the information about our remaining performance obligations.

In the second quarter of 2022, we entered into a bill and hold arrangement. When we entered into this arrangement, we determined if the customer obtained control of the product by determining (a) the reason for the bill-and-hold arrangement; (b) whether the product was identified separately as belonging to the customer; (c) whether the product was ready for physical transfer to the customer; and (d) whether we were unable to utilize the product or direct it to another 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 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.

Other Revenue

Other revenue includes revenue from our agreement with the DoD, grant, collaboration and manufacturing service revenue. We have entered into grant agreements, 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.

Inventories, net

HEPLISAV-B Inventories, net

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("FIFO") basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete

inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the three and six months ended June 30, 2022 and 2021, 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.

CpG 1018 Inventories, net

Inventory is stated at the lower of cost or estimated net realizable value, on a FIFO basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the three and six months ended June 30, 2022 and 2021, there were no inventory reserves recognized.

Convertible Notes

We account for our 2.50% convertible senior notes due 2026 (“Convertible Notes”), see Note 7, as a long-term liability equal to the proceeds received from issuance, including the embedded conversion feature, net of the unamortized debt issuance and offering costs on the condensed consolidated balance sheets. We evaluate all conversion, repurchase and redemption features contained in a debt instrument to determine if there are any embedded features that require bifurcation as a derivative. The conversion feature is not required to be accounted for separately as an embedded derivative. We amortize debt issuance and offering costs over the contractual term of the Convertible Notes, using the effective interest method, as interest expense on the condensed consolidated statements of operations.

Capped Calls

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

Recent Accounting Pronouncements

Accounting Standards Update 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 condensed consolidated financial statements.

2. Fair Value Measurements

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

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

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. There were no transfers between Level 1, 2 and 3 during the three and six months ended June 30, 2022.

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
June 30, 2022				
Assets				
Money market funds	$ 211,632	$ -	$ -	$ 211,632
U.S. treasuries	-	62,891	-	62,891
U.S. government agency securities	-	1,748	-	1,748
Corporate debt securities	-	227,907	-	227,907
Total assets	$ 211,632	$ 292,546	$ -	$ 504,178

	Level 1	Level 2	Level 3	Total
December 31, 2021				
Assets				
Money market funds	$ 429,194	$ -	$ -	$ 429,194
U.S. treasuries	-	4,004	-	4,004
U.S. government agency securities	-	26,548	-	26,548
Corporate debt securities	-	79,209	-	79,209
Total assets	$ 429,194	$ 109,761	$ -	$ 538,955
Liabilities				
Warrant liability	$ -	$ -	$ 18,016	$ 18,016

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). As of June 30, 2022, all 1,882,600 of the outstanding warrants as of December 31, 2021 have been exercised or expired.

The following table provides a summary of changes in the fair value warrant liability for the six months ended June 30, 2022 (in thousands):

Balance at December 31, 2021	$ 18,016
Decrease in fair value of warrants exercised and/or expired	(1,801)
Warrants exercised and/or expired	(16,215)
Balance at June 30, 2022	$ -

Convertible Notes

As of June 30, 2022, the fair value of the Convertible Notes was $337.3 million. The fair value was estimated using a reputable third-party valuation model based on observable inputs and is considered Level 2 in the fair value hierarchy (see Note 7).

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):

	June 30, 2022	December 31, 2021	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 249,091	$ 436,189	$ 129,608	$ 32,073
Restricted cash	202	219	229	237
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 249,293	$ 436,408	$ 129,837	$ 32,310

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
June 30, 2022				
Cash and cash equivalents:				
Cash	$ 13,991	$ -	$ -	$ 13,991
Money market funds	211,632	-	-	211,632
Corporate debt securities	23,478	-	(10)	23,468
Total cash and cash equivalents	249,101	-	(10)	249,091
Marketable securities available-for-sale:				
U.S. treasuries	63,190	-	(299)	62,891
U.S. government agency securities	1,750	-	(2)	1,748
Corporate debt securities	206,028	-	(1,589)	204,439
Total marketable securities available-for-sale	270,968	-	(1,890)	269,078
Total cash, cash equivalents and marketable securities	$ 520,069	$ -	$ (1,900)	$ 518,169
December 31, 2021				
Cash and cash equivalents:				
Cash	$ 6,995	$ -	$ -	$ 6,995
Money market funds	429,194	-	-	429,194
Total cash and cash equivalents	436,189	-	-	436,189
Marketable securities available-for-sale:				
U.S. treasuries	4,005	-	(1)	4,004
U.S. government agency securities	26,555	-	(7)	26,548
Corporate debt securities	79,200	9	-	79,209
Total marketable securities available-for-sale	109,760	9	(8)	109,761
Total cash, cash equivalents and marketable securities	$ 545,949	$ 9	$ (8)	$ 545,950

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

	June 30, 2022	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 270,968	$ 269,078
Mature after one year through two years	-	-
	$ 270,968	$ 269,078

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

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

There were no realized gains or losses from the sale of marketable securities during the three and six months ended June 30, 2022 and 2021. Investments with unrealized losses longer than 12 months were insignificant as of June 30, 2022. We do not intend to sell, and are not required to sell, the investments that are in an unrealized loss position before recovery of their amortized cost basis. As such, 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):

	June 30, 2022	December 31, 2021
Raw materials	$ 32,789	$ 26,637
Work-in-process	18,189	14,748
Finished goods	23,001	19,950
Total	$ 73,979	$ 61,335

As of June 30, 2022 and December 31, 2021, included in finished goods inventory was $11.4 million and $18.6 million of HEPLISAV-B inventory, respectively. The remaining balance in finished goods inventory was CpG 1018 adjuvant for our collaboration partners.

We recorded prepaid manufacturing costs related to prepayments made to third-party manufacturers of CpG 1018 adjuvant, of $54.5 million and $159.7 million as of June 30, 2022 and December 31, 2021, respectively. We expect these costs to be converted into inventory within the next twelve months.

5. Commitments and Contingencies

Leases

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

In July 2019, we entered into a sublease for office space located at 2100 Powell Street, Suite 900, Emeryville, California (the "Powell Street Sublease") for our corporate headquarters. Under the terms of the Powell Street Sublease, we leased 23,976 square feet at the rate of $3.90 per square foot, paid on a monthly basis. We were also responsible for certain operating expenses and taxes throughout the life of the Powell Street Sublease. The Powell Street Sublease expired on June 30, 2022. There was no option to extend the sublease term.

In March 2022, we entered into a lease agreement (“Powell Street Lease”) for office space located at 2100 Powell Street, Suite 720, Emeryville, California to replace the Powell Street Sublease which expired on June 30, 2022. The Powell Street Lease commenced on June 1, 2022 ("Powell Street Commencement Date"). Under the Powell Street Lease, we are leasing 8,053 square feet at the rate of $4.65 per square foot, paid on a monthly basis. The first two monthly rent payments following the Powell Street Commencement Date will be abated. Rent is subject to scheduled annual increases, and we are responsible for certain operating expenses and taxes throughout the life of the Powell Street Lease. The Powell Street Lease will continue until July 31, 2025. There is no option to extend the lease term.

In September 2018, we entered into a lease (“Horton Street Master Lease”) for office and laboratory space located at 5959 Horton Street, Emeryville, California (“Horton Street Premises”). Under the terms of the Horton Street Master Lease, we are leasing 75,662 square feet at the rate of $4.75 per square foot, paid on a monthly basis, starting on April 1, 2019 (“Horton Street 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 June 30, 2022. The Horton Street Master Lease has an initial term of 12 years, following the Horton Street 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 June 30, 2022 condensed consolidated balance sheets primarily relate to the Horton Street Master Lease. Lease expense related to the Horton Street Master Lease is included in operating expense in our condensed consolidated statements of operations.

In connection with the organizational restructuring in May 2019, we did not occupy the Horton Street Premises and in July 2019, we entered into an agreement to sublease the Horton Street Premises to a third party (“Horton Street Sublease”). Under the terms of the Horton Street Sublease, we are subleasing the entire 75,662 rentable square feet at the rate of $5.50 per square foot, paid on a monthly basis. Rent is subject to scheduled annual increases and the subtenant (“Horton Street 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 Horton Street Subtenant has no option to extend the sublease term. Sublease income for the three and six months ended June 30, 2022 were $2.0 million and $3.6 million, respectively. For the three and six months ended June 30, 2021, we recognized sublease income of $1.7 million and $3.7 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 Horton Street Subtenant in excess of rent paid to the landlord shall be shared by paying the landlord 50% of the excess rent. The excess rent is considered a variable lease payment and the total estimated payments are being recognized as additional rent expense on a straight-line basis.

In September 2021, we entered into a commercial lease agreement in Düsseldorf, Germany (the "New Düsseldorf Lease") for the same space that we were previously leasing in Düsseldorf, Germany with the same landlord. The New Düsseldorf Lease became effective on January 1, 2022. The New Düsseldorf Lease has an initial term of 10 years, beginning on January 1, 2022, with an option to extend the lease for two successive five-year terms. The optional periods were not included in the lease term used in determining the right-of-use assets and liabilities as we did not consider it reasonably certain that we would exercise the options. Beginning on January 1, 2024, the base rent is subject to an annual increase at the same percentage of Consumer Price Index of Germany. We are also responsible for certain operating expenses and taxes throughout the life of the New Düsseldorf Lease.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease expense	$ 1,867	$ 1,570	$ 3,474	$ 3,130

Cash paid for amounts included in the measurement of lease liabilities for the six months ended June 30, 2022 and 2021 was $3.5 million and $3.4 million, respectively, and was included in change in lease liabilities in our condensed consolidated statements of cash flows.

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

	June 30, 2022	December 31, 2021
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 3,039	$ 2,577
Long-term portion of lease liabilities	33,677	34,316
Total operating lease liabilities	$ 36,716	$ 36,893

As of June 30, 2022, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2022 (remaining)	$ 2,709	$ 3,195
2023	5,518	6,512
2024	5,684	6,646
2025	5,854	6,123
2026	6,030	5,861
Thereafter	27,712	27,161
Total	$ 53,507	55,498
Less:		
Present value adjustment		(18,782)
Total		$ 36,716

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

	June 30, 2022	December 31, 2021
Weighted average remaining lease term	8.25 years	9.1 years
Weighted average discount rate	10.1%	10.1%

Commitments

As of June 30, 2022, our material non-cancelable purchase and other commitments, for the supply of HEPLISAV-B and CpG 1018, totaled $115.7 million.

As of June 30, 2022, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $4.5 million (see Note 7). The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased prior to such date.

During 2004, we established a letter of credit with Deutsche Bank as security for our Düsseldorf lease in the amount of €0.2 million (Euros). The letter of credit remained outstanding through June 30, 2022 and is collateralized by a certificate of deposit for €0.2 million, which has been included in restricted cash in the condensed consolidated balance sheets as of June 30, 2022.

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 our immune-oncology compound, SD-101. In July 2020, we sold assets related to SD-101 to Surefire Medical, Inc. d/b/a TriSalus Life Sciences (“TriSalus”). We paid $2.5 million to Holdings in August 2020. In each of September 2021 and May 2022, we received $1.0 million from TriSalus because it met a pre-commercialization milestone. We recorded the proceeds as gain on sale of assets in our condensed consolidated statements of operations in the third quarter of 2021 and second quarter of 2022. We paid Holdings $0.5 million in each of September 2021 and May 2022. We included the payments in selling, general and administrative expenses in our condensed consolidated statements of operations in the third quarter of 2021 and second quarter of 2022. No liability has been recorded under this agreement as of June 30, 2022.

Contingencies

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

6. Collaboration, Development and Supply Agreements

Coalition for Epidemic Preparedness Innovations

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

In exchange for reserving CpG 1018 Materials and agreeing to sell CpG 1018 Materials to CEPI partner(s) at pre-negotiated prices, CEPI agreed to provide payments in the form of an interest-free, unsecured, forgivable loan (the "Advance Payments") of up to $99.0 million. We are obligated to repay the Advance Payments, in proportion to quantity sold, if and to the extent we receive payments from sales of CpG 1018 Materials reserved under the CEPI Agreement. If the vaccine programs pursued by CEPI partner(s) are unsuccessful and no alternative use is found for CpG 1018 Materials reserved under the CEPI Agreement, the applicable Advance Payments will be forgiven at the end of the two-year term.

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

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

Through June 30, 2022, we have received Advance Payments totaling approximately $175.1 million pursuant to the CEPI Agreement, as amended. Advance payments totaling $107.4 million and $128.8 million were recorded as CEPI accrual in our condensed consolidated balance sheets as of June 30, 2022 and December 31, 2021, respectively. There was no deferred revenue balance related to the CEPI Agreement as of June 30, 2022. As of December 31, 2021, deferred revenue totaling $5.4 million were recorded as other long-term liabilities in our condensed consolidated balance sheets. There was no CEPI receivable balance recorded as of June 30, 2022. As of December 31, 2021, we recorded $14.6 million in CEPI receivable which is included in other receivables in our condensed consolidated balance sheets.

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

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Hong Kong Inc. (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with Clover's COVID-19 vaccine candidate, SCB-2019 (the "Clover Supply Agreement"). Under the Clover Supply Agreement, Clover has committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, as amended, for use in Clover's commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant ("Clover Product"). The Clover Supply Agreement also provides terms for Clover to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. The terms and conditions of the Clover Supply Agreement are through December 2022.

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

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

submitted by Clover, upon our acceptance of such purchase order, and the remainder of the purchase price upon the release of such CpG 1018 adjuvant.

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

As of June 30, 2022 and December 31, 2021, our contract asset balance of $71.3 million and $62.5 million, respectively was included in other current assets in our condensed consolidated balance sheets. As of June 30, 2022 and December 31, 2021, we recorded accounts receivable balance of $19.2 million and $2.1 million from Clover, respectively. As of June 30, 2022 and December 31, 2021, we recognized approximately $138.7 million and $191.1 million, respectively, in deferred revenue for a portion of Clover's binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement, as amended. There was no deferred revenue recognized for a portion of Clover's binding commitment to purchase CpG 1018 adjuvant that was reserved for Clover under the CEPI Agreement, as amended. For the three and six months ended June 30, 2022, we recognized CpG 1018 product revenue, net of $91.3 million and $113.6 million, respectively. There was no product revenue recognized under the Clover Supply Agreement for the three and six months ended June 30, 2021.

Biological E. Limited

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

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

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

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

As of June 30, 2022 and December 31, 2021, we recorded accounts receivable balance of $95.6 million and $96.1 million from Bio E, respectively. As of June 30, 2022 and December 31, 2021, we recognized approximately $47.7 million and $103.3 million, respectively, in deferred revenue for a portion of Bio E's binding commitment to purchase CpG 1018 adjuvant outside the CEPI Agreement, as amended. There was no deferred revenue recognized for a portion of Bio E's binding commitment to purchase CpG 1018 adjuvant that was reserved for Bio E under the CEPI Agreement, as amended. For the three and six months ended June 30, 2022, we recognized CpG 1018 adjuvant net product revenue of $51.0 million and $118.3 million, respectively from Bio E. There was no product revenue recognized under the Bio E Supply Agreement for the three and six months ended June 30, 2021.

PT Bio Farma (Persero)

In May 2022, we entered into a commercial supply agreement (the “Bio Farma Supply Agreement”) with PT Bio Farma (Persero) (“Bio Farma”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Bio Farma’s COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant (“Bio Farma Product”), for delivery in the second quarter and third quarter of 2022. The Bio Farma Supply Agreement also provides terms for Bio Farma to order additional quantities of CpG 1018 adjuvant for delivery throughout the life of the agreement. The terms and conditions of the Bio Farma Supply Agreement are through May 2023.

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

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

As of June 30, 2022, we recorded accounts receivable balance of $17.9 million from Bio Farma. As of June 30, 2022, we recognized approximately $5.5 million in deferred revenue for a portion of Bio Farma’s binding commitment to purchase CpG 1018 adjuvant. For the three and six months ended June 30, 2022, we recognized CpG 1018 adjuvant net product revenue from Bio Farma of $12.3 million and $14.3 million, respectively.

Medigen Vaccine Biologics

In February 2021, we entered into a Supply Agreement (“Medigen Supply Agreement”) with Medigen Vaccine Biologics (“Medigen”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen’s COVID-19 vaccine for delivery in the first and second quarters of 2021. In August 2021, we entered into a second supply agreement (“Medigen Supply Agreement No. 2”) to manufacture and supply additional specified quantities of CpG 1018 adjuvant for delivery in the third and fourth quarter of 2021. The terms and conditions of the Medigen Supply Agreement and the Medigen Supply Agreement No. 2 were through December 2021.

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

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

There was no accounts receivable balance from Medigen recorded as of June 30, 2022. As of December 31, 2021, we recorded accounts receivable balance of $2.4 million from Medigen. There was no product revenue recognized from Medigen for the three and six months ended June 30, 2022. For the three and six months ended June 30, 2021, we recognized CpG 1018 adjuvant net product revenue from Medigen of $10.6 million and $17.5 million, respectively.

Valneva SE

In April 2020, we entered into a collaboration agreement ("Valneva Collaboration Agreement") with Valneva Scotland Limited (“Valneva”) to provide CpG 1018 adjuvant for use in the development of Valneva’s COVID-19 vaccine candidate ("VLA2001"). The Valneva Collaboration Agreement was amended in July 2020, to provide additional quantities of CpG 1018 adjuvant. In September 2020, we entered into a supply agreement (“Valneva Supply Agreement”) with Valneva to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the commercialization of VLA2001.

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

In October 2021, we and Valneva entered into a letter agreement (the "Valneva Amendment") modifying certain deliverables of the Valneva Supply Agreement. Specifically, the Valneva Amendment modifies the original Valneva Supply Agreement as follows: (1) cancels certain purchase orders for CpG 1018 adjuvant previously issued under the original Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment; and (2) provides a future delivery schedule for commercial supply of CpG 1018 adjuvant through the end of 2022. As of the date of the Valneva Amendment, we had received non-refundable advance payments of approximately $55.4 million associated with the cancelled purchase orders. The terms and conditions of the Valneva Supply Agreement, as amended by the Valneva Amendment, were through our final delivery date in June 2022.

In accordance with revenue recognition guidance in ASC 606, the Valneva Amendment was determined to be a contract modification and will be accounted for prospectively as one agreement with consideration allocated to future performance obligations. We have identified one remaining performance obligation which is the delivery of CpG 1018 adjuvant through the end of 2022. The total amount of consideration allocated to the remaining performance obligation includes approximately $55.4 million of advance payments received as of the date of the Valneva Amendment plus additional future consideration to be received in connection with final delivery of product. We satisfied our remaining performance obligation to deliver CpG 1018 adjuvant under the Valneva Amendment in June 2022. Accordingly, we recognized the $55.4 million of advance payments as product revenue in the second quarter of 2022.

As of June 30, 2022 there was no deferred revenue balance related to Valneva. As of December 31 2021, deferred revenue related to Valneva was $55.4 million. As of June 30, 2022, we recorded accounts receivable balance of $12.6 million. As of December 31, 2021, there was no accounts receivable balance related to Valneva. For each of the three and six months ended June 30, 2022, we recognized CpG 1018 adjuvant net product revenue of $68.0 million from Valneva which was recognized under a bill and hold arrangement. For the three and six months ended June 30, 2021, we recognized CpG 1018 adjuvant net product revenue of $24.5 million and $89.4 million, respectively.

U.S. Department of Defense

In September 2021, we entered into an agreement with the DoD for the development of a recombinant plague vaccine adjuvanted with CpG 1018 for approximately $22.0 million over two and a half years. Under the agreement, we will conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. For the three and six months ended June 30, 2022, we recognized revenue of $1.1 million and $2.7 million, respectively which are included in other revenue in our condensed consolidated statements of operations. There was no revenue recognized under the DoD agreement for the three and six months ended June 30, 2021.

Serum Institute of India Pvt. Ltd.

In June 2017, we entered into an agreement to provide Serum Institute of India Pvt. Ltd. ("SIIPL") with technical support. In consideration, SIIPL agreed to pay us at an agreed upon hourly rate for services and reimburse certain out-of-pocket expenses. In addition, we have rights to commercialization of certain potential products manufactured at the SIIPL facility. For the three and six months ended June 30, 2022, we recognized revenue of $34,326 and $0.1 million, respectively, which are included in other revenue in our condensed consolidated statements of operations. For the three and six months ended June 30, 2021, we recognized revenue of $0.1 million and $0.3 million, respectively.

7. Convertible Notes

In May 2021, we issued $200.0 million aggregate principal amount of 2.50% convertible senior notes due 2026 in a private placement. The purchasers also partially exercised their option to purchase additional Convertible Notes and we issued an additional $25.5 million of the Convertible Notes in May 2021. Total proceeds from the issuance of the Convertible Notes, net of debt issuance and offering costs of $5.7 million, were $219.8 million. We used $190.2 million of the net proceeds to retire our previous loan agreement with CRG Servicing LLC and $27.2 million of the net proceeds to pay the costs of the Capped Calls described below.

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

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

1. During any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
2. During the five business day period after any ten consecutive trading day period (the "measurement period"), in which the "trading price" (as defined the indenture governing the Convertible Notes) per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;
3. If we call such Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
4. Upon the occurrence of specified corporate events as set forth in the indenture governing the Convertible Notes.

On or after February 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders of the Convertible Notes may convert all or any portion of their Convertible Notes regardless of the foregoing circumstances.

As of July 1, 2022, the conditions allowing holders of the Convertible Notes to convert were not met. As a result, the Convertible Notes are not convertible, in whole or in part, at the option of the holders during the three months ended September 30, 2022. Since we have the election of repaying the Convertible Notes in cash, shares of our common stock, or a combination of both, we continued to classify the Convertible Notes as long-term debt on the condensed consolidated balance sheets as of June 30, 2022.

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

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

As a result of adopting ASU 2020-06, we accounted for the Convertible Notes as a single liability. As of June 30, 2022, the Convertible Notes were recorded at the aggregate principal amount of $225.5 million less unamortized issuance costs of $4.5 million as a long-term liability on the condensed consolidated balance sheets. As of June 30, 2022, the fair value of the Convertible Notes was $337.3 million. See Note 2. The debt issuance costs are amortized to interest expense over the contractual term of the Convertible Notes at an effective interest rate of 3.1%.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Stated coupon interest	$ 1,409	$ 736	$ 2,819	$ 736
Amortization of debt issuance cost	271	137	540	137
Total interest expense	$ 1,680	$ 873	$ 3,359	$ 873

Capped Calls

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers of the Convertible Notes and other financial institutions (the "Option Counterparties"), totaling $27.2 million (the “Capped Calls”). The Capped Calls cover, subject to customary adjustments, the number of shares of our common stock that initially underlie the Convertible Notes (or 21,542,871 shares of our common stock). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments under the terms of the Capped Calls. The Capped Call Transactions are freestanding and are considered separately exercisable from the Convertible Notes. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

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

8. Revenue Recognition

Disaggregation of Revenues

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

	Three Months Ended June 30, 2022			Three Months Ended June 30, 2021		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 31,739	$ 941	$ 32,680	$ 13,688	$ -	$ 13,688
CpG 1018	-	222,640	222,640	-	38,989	38,989
Total product revenue, net	$ 31,739	$ 223,581	$ 255,320	$ 13,688	$ 38,989	$ 52,677
Other revenue	1,083	61	1,144	-	90	90
Total revenues	$ 32,822	$ 223,642	$ 256,464	$ 13,688	$ 39,079	$ 52,767

	Six Months Ended June 30, 2022			Six Months Ended June 30, 2021		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 52,549	$ 941	$ 53,490	$ 21,991	$ -	$ 21,991
CpG 1018	-	314,157	314,157	-	113,571	113,571
Total product revenue, net	$ 52,549	$ 315,098	$ 367,647	$ 21,991	$ 113,571	$ 135,562
Other revenue	2,689	120	2,809	260	280	540
Total revenues	$ 55,238	$ 315,218	$ 370,456	$ 22,251	$ 113,851	$ 136,102

Revenues from Major Customers and Collaboration Partners

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Largest Customer	18%	28%	21%	28%
Second largest Customer	18%	21%	18%	23%
Third largest Customer	18%	16%	17%	17%

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Largest collaboration partner	41%	63%	38%	79%
Second largest collaboration partner	31%	27%	36%	15%
Third largest collaboration partner	23%	10%	22%	5%

Contract Balances

The following table summarizes balances and activities in HEPLISAV-B product revenue allowance and reserve categories for the six months ended June 30, 2022 (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
Six months ended June 30, 2022:				
Accounts receivable reserves(1)	$ 3,823	$ 15,201	$ (12,602)	$ 6,422
Revenue reserve accruals(2)	8,253	10,333	(9,945)	8,641

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

We recognize revenue and a corresponding contract asset when our right to consideration is conditioned on something other than the passage of time. The following table summarizes balances and activities in our contract asset account (in thousands):

	Balance at Beginning of Period	Additions (1)	Subtractions (2)	Balance at End of Period
Six months ended June 30, 2022:				
Contract asset	$ 62,525	$ 12,134	$ (3,151)	$ 71,508

(1) Additions are revenues recognized for CpG 1018 adjuvant transferred to Clover that is reserved under the CEPI Agreement, as amended.
(2) Subtractions are reclassifications from contract asset to accounts receivables.

Payments received or invoices issued before we satisfy our performance obligations are recorded as deferred revenue until we satisfy such performance obligations. Our deferred revenue activities are related to CpG 1018 adjuvant product sales. The following table summarizes balances and activities in our deferred revenue accounts for the six months ended June 30, 2022 (in thousands):

	Balance at Beginning of Period	Additions (1)	Subtractions (2)	Revenue recognized in the current period included in deferred revenue balance at the beginning of the period	Balance at End of Period
Six months ended June 30, 2022:					
Deferred revenue	$ 349,864	$ 12,068	$ (6,534)	$ (163,400)	$ 191,998
Long-term deferred revenue	5,385	6,582	(11,967)	-	-

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

9. Net Income Per Share

We compute net income per share of common stock using the two-class method required for participating securities. We consider 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 in determining net income attributable to common stockholders.

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator				
Net income	$ 128,755	$ 4,473	$ 161,614	$ 5,364
Less: undistributed earnings allocated to participating securities	-	(333)	(316)	(410)
Net income attributable to common stockholders, basic	128,755	4,140	161,298	4,954
Add: undistributed earnings allocated to participating securities	-	-	316	-
Less: removal of change in fair value of warrant liability	-	(2,097)	(1,801)	-
Add: interest expense on convertible notes	1,260	-	2,519	-
Net income attributable to common stockholders, diluted	$ 130,015	$ 2,043	$ 162,332	$ 4,954
Denominator				
Weighted average common stock outstanding, basic	126,347	114,629	125,456	113,339
Effect of dilutive shares:				
Stock-based compensation plans	2,015	1,630	2,659	1,639
Dilutive warrants	-	2,571	163	-
Convertible Notes (as converted to common stock)	21,543	-	21,543	-
Weighted average common stock outstanding, diluted	149,905	118,830	149,821	114,978

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Outstanding securities not included in diluted net income (loss) per share calculation:				
Stock options and stock awards	9,647	6,991	9,067	8,476
Series B Convertible Preferred Stock (as converted to common stock)	-	4,140	-	4,140
Warrants (as exercisable into common stock)	-	-	-	2,474
Convertible Notes (as converted to common stock)	-	11,363	-	5,713
Total	9,647	22,494	9,067	20,803

10. Common Stock, Preferred Stock and Warrants

Common Stock

As of June 30, 2022, there were 126,439,073 shares of our common stock outstanding.

In August 2019, we sold 18,525,000 shares of our common stock, par value $0.001 per share, 4,840 shares of our Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred Stock") and warrants to purchase up to an aggregate of 5,841,250 shares of our common stock in an underwritten public offering (the "Offering") for aggregate net proceeds of approximately $65.6 million. Investment funds associated with Bain Capital Life Sciences Investors, LLC ("Bain Capital Life Sciences") purchased approximately $35.0 million of common stock, Series B Preferred Stock and warrants in the Offering on the same terms as the other investors in the Offering. Following the Offering, Andrew A. F. Hack, M.D., Ph.D., a Managing Director of Bain Capital Life Sciences, was appointed to our board of directors.

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. As of June 30, 2022, we had $120.5 million remaining under the 2020 ATM Agreement.

Preferred Stock

As of June 30, 2022, all of the Series B Preferred Stock had been converted into common stock.

Warrants

During the three months ended March 31, 2022, all of the 1,882,600 outstanding warrants as of December 31, 2021 were exercised or expired resulting in cash proceeds totaling $8.5 million. For the three months ended June 30, 2022, there was no change in the estimated fair value of warrant liability recognized in other income (expense) in our condensed consolidated statements of operations. For the six months ended June 30, 2022, we recognized the decrease in the estimated fair value of warrant liability of $1.8 million as income in other income (expense) in our condensed consolidated statements of operations.

11. Equity Plans and Stock-Based Compensation

In May 2022, our stockholders approved the amendment and restatement of our 2018 Equity Incentive Plan (the "Amended 2018 EIP") to, among other things, increase the authorized number of shares of common stock by 15,000,000. The maximum number of shares of common stock that may be issued under the Amended 2018 EIP, will not exceed 32,600,000 shares of common stock. As of June 30, 2022, the Amended 2018 EIP and the Amended and Restated 2014 Employee Stock Purchase Plan are our active plans.

The Amended 2018 EIP is administered by our Board of Directors, or a designated committee of the Board of Directors, and awards granted under the Amended 2018 EIP have a term of 7 years unless earlier terminated by the Board of Directors. As of June 30, 2022, there were 15,465,070 shares of common stock reserved for issuance under the Amended 2018 EIP.

Activity under our stock plans is set forth below:

	Shares Underlying Outstanding Options (in thousands)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2021	10,399	$ 11.55	4.16	42,756
Options granted	2,053	12.54		
Options exercised	(287)	7.49		
Options cancelled:				
Options forfeited (unvested)	(73)	9.52		
Options expired (vested)	(566)	20.63		
Balance at June 30, 2022	11,526	11.40	4.37	31,382
Vested and expected to vest at June 30, 2022	11,146	$ 11.37	4.31	$ 30,946
Exercisable at June 30, 2022	6,542	$ 11.52	3.09	$ 21,654

Restricted stock unit activity under our stock-based compensation plans during the six months ended June 30, 2022 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, 2021	2,651	$ 8.30
Granted	2,021	12.42
Vested	(1,009)	8.21
Forfeited	(168)	10.40
Non-vested as of June 30, 2022	3,495	10.60

We granted performance-based restricted stock unit (“PSU”) to certain executives. These PSUs vest upon a specified market condition. The summary of PSU activities for the six months ended June 30, 2022 is as follows:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2021	237	$ 8.40
Granted	193	11.62
Vested	(237)	8.40
Non-vested as of June 30, 2022	193	$ 11.62

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

	Stock Options		Stock Options		Market-Based Performance Stock Unit (“PSUs”)
	Three Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30
	2022	2021	2022	2021	2022
Weighted-average fair value per share	$ 7.39	$ 6.20	$ 7.97	$ 6.57	$ 11.62
Risk-free interest rate	2.9%	0.9%	2.01%	0.6%	1.7%
Expected life (in years)	4.5	4.5	4.5	4.5	2.9
Volatility	0.8	0.9	0.8	1.0	0.9

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 1,463	$ 937	$ 2,739	$ 1,809
Selling, general and administrative	5,597	3,445	11,024	6,589
Cost of sales - product	143	155	303	324
Inventory	726	487	1,509	1,025
Total	$ 7,929	$ 5,024	$ 15,575	$ 9,747

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures.

12. Income Taxes

We are subject to U.S. federal, state and foreign income taxes. For each of the three and six months ended June 30, 2022, we recorded a provision for income taxes of approximately $0.6 million and our effective tax rate was approximately 0.4%. The primary difference between the effective tax rate and the federal statutory rate is due to the benefit of net operating losses utilized during the periods and the full valuation allowance we established on our federal, state, and certain foreign deferred tax assets.

The tax benefit of net operating losses, temporary differences and credit carryforwards is required to be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. A high degree of judgment is required to determine if, and the extent to which, valuation allowances should be recorded against deferred tax assets. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Based on all available evidence as of June 30, 2022, both positive and negative, and the weight of that evidence to the extent such evidence can be objectively verified, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more likely than not to be realized, and, accordingly, has provided a valuation allowance.

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 Part II, Item 7 "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, 2021.

Overview

We are a commercial stage biopharmaceutical company focused on developing and commercializing innovative vaccines. Our first marketed product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted) is approved in the United States and the European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. We also manufacture and sell CpG 1018, the adjuvant used in HEPLISAV-B, and have established a portfolio of global commercial supply agreements in the development of COVID-19 vaccines across a variety of vaccine platforms. Additionally, we are advancing a multi-program clinical pipeline leveraging CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical needs including phase 1 clinical trials in Tdap and shingles, and a phase 2 clinical trial in plague in collaboration with and fully funded by the U.S. Department of Defense ("DoD").

HEPLISAV-B® Vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted]

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. and the European Union.

We have worldwide commercial rights to HEPLISAV-B and we market it in the United States and the European Union. There are four other vaccines approved for the prevention of hepatitis B in the U.S.: Engerix-B and Twinrix® from GlaxoSmithKline plc, Recombivax-HB® from Merck & Co and PreHevbrio™ from VBI Vaccines Inc. In February 2021, we received Marketing Authorization approval of HEPLISAV-B from the European Commission ("EC") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany.

All of our HEPLISAV-B sales in the U.S. are to certain wholesalers and specialty distributors 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. All of our HEPLISAV-B sales in Germany are to one distributor. For the three and six months ended June 30, 2022, HEPLISAV-B product revenue, net was $32.7 million and $53.5 million, respectively.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

In January 2021, we entered into an agreement (the "CEPI Agreement") with Coalition for Epidemic Preparedness Innovations ("CEPI") for the manufacture and reservation of a specified quantity of CpG 1018 adjuvant. In May 2021, we entered into the first amendment (the "Amendment") to the CEPI Agreement. The CEPI Agreement, as amended, enables CEPI to direct the supply of CpG 1018 adjuvant to CEPI partner(s). In exchange for reserving CpG 1018 adjuvant, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan of up to $176.4 million. As of June 30, 2022, advance payments totaling $107.4 million were recorded as CEPI accrual in our condensed consolidated balance sheets.

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

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

In May 2022, we entered into a commercial supply agreement (the “Bio Farma Supply Agreement”) with PT Bio Farma (Persero) (“Bio Farma”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Bio Farma’s COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant, for delivery in the second quarter and third quarter of 2022. The Bio Farma Supply Agreement also provides terms for Bio Farma to order additional quantities of CpG 1018 adjuvant for delivery throughout the life of the agreement.

In 2021, we entered into supply agreements with Medigen Vaccine Biologics (“Medigen”) to manufacture and supply specified quantities of CpG 1018 adjuvant for use in the development and commercialization of Medigen’s COVID-19 vaccine, adjuvanted with our CpG 1018 adjuvant, MVC-COV1901, for delivery throughout the life of the agreements.

In the third quarter of 2020, we announced a commercial supply agreement (the “Valneva Supply Agreement”) with Valneva Scotland Limited (“Valneva”) to cover the supply of CpG 1018 adjuvant for its SARS-COV-2 vaccine candidate, VLA2001, in support of its supply agreement with the United Kingdom Government and subject to the terms of such agreement. In September 2021, Valneva received a termination notice from the United Kingdom Government in relation to such supply agreement.

In October 2021, we and Valneva entered into a letter agreement (the “Valneva Amendment”) modifying certain deliverables of the Valneva Supply Agreement. Specifically, the Valneva Amendment modifies the original Valneva Supply Agreement as follows: (1) cancels certain purchase orders for CpG 1018 adjuvant previously issued under the original Valneva Supply Agreement that had not been fulfilled as of the date of the Valneva Amendment; and (2) provides a future delivery schedule for commercial supply of CpG 1018 adjuvant through 2022. As of the date of the Valneva Amendment, we had received non-refundable advance payments of approximately $55.4 million associated with the cancelled purchase orders. We satisfied our remaining performance obligation to deliver CpG 1018 adjuvant under the Valneva Amendment in June 2022. Accordingly, we recognized $68.0 million of product revenue from Valneva in the second quarter of 2022 which included the $55.4 million of the non-refundable advance payments.

For the three and six months ended June 30, 2022, CpG 1018 product revenue, net, was $222.6 million and $314.2 million, respectively.

Other

In May 2021, we issued $225.5 million aggregate principal amount of 2.50% convertible senior notes due 2026 (the “Convertible Notes”) in a private placement. Total proceeds from the issuance of the Convertible Notes, net of debt issuance and offering costs of $5.7 million, were $219.8 million. We used $190.2 million of the net proceeds to repay, in full, our outstanding debt and other obligations under our previous loan agreement with CRG Servicing LLC ("Loan Agreement") and $27.2 million of the net proceeds to pay the costs of the Capped Calls (defined below).

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers and other financial institutions, totaling $27.2 million (the “Capped Calls”). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments under the terms of the Capped Calls. The Capped Calls are freestanding and are considered separately exercisable from the Convertible Notes. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

COVID-19 Update

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

To date, we and our distribution partners have been able to continue to supply HEPLISAV-B throughout the United States, and currently do not anticipate any interruptions in supply. Due to the ongoing COVID-19 global pandemic, most medical centers began restricting access to their facilities and focused on providing care to only the most severely affected patients, beginning in March 2020. As states began phasing out restrictions in the middle of 2020, medical centers began operating under limited capacity or with strict social distancing rules. There has been a significant reduction in the utilization of adult vaccines (other than COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B which has impacted sales of HEPLISAV-B. While adult hepatitis B vaccine utilization rates have continued to stay below pre-pandemic levels, we have been seeing a gradual recovery in such utilization above all-time lows, but still well below pre-pandemic levels. Notwithstanding reduced overall utilization of hepatitis B vaccines, HEPLISAV-B nonetheless continues to gain market share in the U.S. hepatitis B adult vaccine market.

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. To help protect the health and safety of our workforce, we implemented a mandatory work-from-home policy for employees who can perform their jobs offsite. More recently we have downsized our office space and are embracing a flexible work environment where many employees will be allowed, but not required, to be permanently remote as restrictions lift. In the conduct of our business activities, we are also taking actions to help protect the safety of patients and healthcare professionals. In the early stages of the pandemic, our field-based personnel reduced in-person customer interactions in healthcare settings and primarily used electronic communication, such as emails, phone calls and video conferences. Many health care and contracting professionals at hospitals and other medical institutions with whom our field-based personnel interact began conducting a greater proportion of their work from their homes and were facing additional demands on their time during the COVID-19 pandemic. While the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, impacted the effectiveness of our sales personnel, we have gradually moved back to in-person interactions in many cases. With the rise of new variants, and related precautions, however, our customers' procurement activities and those of our collaborators continue to be impacted which could negatively affect our overall product sales. It is possible that we may have to limit in-person engagement again in the future.

Our HEPLISAV-B post-marketing follow-up has been completed. In April 2021, we announced the results of the post-marketing study assessing the rates of occurrence of acute myocardial infarction ("AMI") in persons receiving HEPLISAV-B compared with Engerix-B. 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 made available in the fourth quarter of 2022. Our HEPLISAV-B dialysis study has also been completed. Final immunogenicity results included a seroprotection rate of 89.3% with high levels of anti-HBs antibodies. Safety data showed HEPLISAV-B was well tolerated and no safety concerns were observed.

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 actively pursued opportunities to collaborate with other organizations on the development of a COVID-19 vaccine, by leveraging CpG 1018 adjuvant, our toll-like receptor 9 (“TLR9”) agonist, which is also used in our HEPLISAV-B product. Since the first half of 2021, we announced multiple collaborations focused on COVID-19 and we continue to work to identify other programs where CpG 1018 adjuvant can be utilized to enhance the immune response to a coronavirus vaccine or other vaccines. To date, three of our collaborators have received emergency use authorizations for their COVID-19 vaccines, and we anticipate that another could be announced during 2022. We and our contract manufacturers have been developing and implementing 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 adjuvanted COVID-19 vaccines or other vaccines over the long term.

Critical Accounting Estimates

We prepare our condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles. In doing so, we are required to make estimates and assumptions. Our critical accounting estimates are those estimates that involve a significant level of uncertainty at the time the estimate was made, and changes in them have had or are reasonably likely to have a material effect on our financial condition or results of operations. Actual results could differ materially from our estimates. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis

We believe that there have been no significant changes in our critical accounting policies during the six months ended June 30, 2022, as compared with those disclosed in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Revenues

Revenues consist of amounts earned from product sales and other revenues. Product revenue, net, includes sales of HEPLISAV-B and CpG 1018 adjuvant.

Revenue from HEPLISAV-B product sales is recorded at the net sales price, which includes estimates of product returns, chargebacks, discounts, rebates and other fees. We sell our CpG 1018 adjuvant to our collaboration partners for use in their development and/or potential commercialization of COVID-19 vaccines. Overall, product revenue, net, reflects our best estimates of the amount of consideration to which we are entitled based on the terms of the contract.

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

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

	Three Months Ended June 30,		Increase (Decrease) from 2021 to 2022		Six Months Ended June 30,		Increase (Decrease) from 2021 to 2022	
Revenues:	**2022**	**2021**	**$**	**%**	**2022**	**2021**	**$**	**%**
HEPLISAV-B	$ 32,680	$ 13,688	$ 18,992	139 %	$ 53,490	$ 21,991	$ 31,499	143 %
CpG 1018	222,640	38,989	183,651	471 %	314,157	113,571	200,586	177 %
Total product revenue, net	255,320	52,677	202,643	385 %	367,647	135,562	232,085	171 %
Other revenue	1,144	90	1,054	1,171 %	2,809	540	2,269	420 %
Total revenues	$ 256,464	$ 52,767	$ 203,697	386 %	$ 370,456	$ 136,102	$ 234,354	172 %

HEPLISAV-B product revenue for the three and six months ended June 30, 2022 increased, compared to the same periods in 2021, primarily due to higher volume driven by continued improvement in market share and utilization of adult vaccines. In addition, we commenced commercial shipments of HEPLISAV-B in Germany in May 2022.

The increase in CpG 1018 adjuvant product revenue for the three and six months ended June 30, 2022, compared to the same periods in 2021, was due to an increase in sales volume as we entered into supply and collaboration agreements with major collaboration partners in the second quarter of 2021, third quarter of 2021 and second quarter of 2022 and we continued to manufacture and ship CpG 1018 adjuvant pursuant to such supply and collaboration agreements. In addition, we recognized $55.4 million of advance payments as product revenue in June 2022 as we satisfied our remaining performance obligation to deliver CpG 1018 adjuvant under the Valneva Amendment.

Other revenue includes revenue from our agreement with the DoD and collaboration revenue related to services performed under a collaboration agreement with Serum Institute of India Pvt. Ltd. The increase in other revenue for the three and six months ended June 30, 2022, compared to the same periods of 2021, was due to $1.1 million revenue and $2.7 million recognized from our agreement with the DoD, respectively.

Cost of Sales – Product

Cost of sales - product consists primarily of raw materials, certain fill, finish and overhead costs and any inventory adjustment charges for pre-filled syringes (“PFS”) of HEPLISAV-B and inventory costs to produce CpG 1018 adjuvant for our collaboration partners.

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

	Three Months Ended June 30,		Increase (Decrease) from 2021 to 2022		Six Months Ended June 30,		Increase (Decrease) from 2021 to 2022	
Cost of Sales - Product	**2022**	**2021**	**$**	**%**	**2022**	**2021**	**$**	**%**
HEPLISAV-B	$ 10,252	$ 4,624	$ 5,628	122 %	$ 16,229	$ 7,369	$ 8,860	120 %
CpG 1018	73,117	10,221	62,896	615 %	107,102	32,101	75,001	234 %
Total cost of sales - product	$ 83,369	$ 14,845	$ 68,524	462 %	$ 123,331	$ 39,470	$ 83,861	212 %

For the three and six months ended June 30, 2022, HEPLISAV-B cost of sales-product increased, compared to the same periods in 2021, primarily due to higher volume driven by continued improvement in market share and utilization of adult vaccines. In addition, we commenced commercial shipments of HEPLISAV-B in Germany in May 2022.

The increase in CpG 1018 cost of sales-product for the three and six months ended June 30, 2022, compared to the same periods in 2021, was due to an increase in sales volume as we entered into supply and collaboration agreements with major collaboration partners in the second quarter of 2021, third quarter of 2021 and second quarter of 2022 and we continued to manufacture and ship CpG 1018 adjuvant pursuant to such supply and collaboration agreements.

Research and Development Expense

Research and development expenses are tracked on a program-by-program basis and consist primarily of costs incurred for the continued research and development of HEPLISAV-B and CpG 1018 adjuvant, clinical product candidates and preclinical studies, which include but are not limited to, compensation and related personnel costs (which include benefits, recruitment and travel costs), expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical studies and costs associated with our preclinical activities, development activities and regulatory operations. We do not allocate stock-based compensation or facility expenses to specific programs because these costs are deployed across multiple programs.

The following is a summary of our research and development expense (in thousands, except for percentages). Certain prior period amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the total research and development expenses:

	Three Months Ended June 30,		Increase (Decrease) from 2021 to 2022		Six Months Ended June 30,		Increase (Decrease) from 2021 to 2022	
Program expenses:	**2022**	**2021**	**$**	**%**	**2022**	**2021**	**$**	**%**
HEPLISAV-B development	$ 866	$ 2,356	$ (1,490)	(63)%	$ 2,105	$ 5,490	$ (3,385)	(62)%
CpG 1018 adjuvant development	562	1,768	(1,206)	(68)%	1,695	3,156	(1,461)	(46)%
Tetanus, diphtheria, and acellular pertussis	2,275	1,156	1,119	97 %	3,840	2,315	1,525	66 %
Shingles	2,855	381	2,474	649 %	5,788	433	5,355	1,237 %
Plague (1)	439	-	439	NM	1,191	-	1,191	NM
Other (2)	677	99	578	584 %	2,506	856	1,650	193 %
Other research and development expenses:								
Facility costs	552	470	82	17 %	920	866	54	6 %
Non-cash stock-based compensation	1,463	937	526	56 %	2,739	1,809	930	51 %
Total research and development	$ 9,689	$ 7,167	$ 2,522	35 %	$ 20,784	$ 14,925	$ 5,859	39 %

(1) In September 2021, we entered into an agreement with the DoD for the development of a recombinant plague vaccine adjuvanted with CpG 1018. Under the agreement, we will conduct a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's

rF1V vaccine. We are being fully reimbursed by the DoD for the costs of this study which is recorded in other revenue in our condensed consolidated statements of operations.

(2) For the six months ended June 30, 2022 other includes approximately $1.0 million in final close-out costs associated with the divestment of our immuno-oncology portfolio in 2019.

NM = Not meaningful

Research and development expenses increased by $2.5 million and $5.9 million for the three and six months ended June 30, 2022, respectively compared to the same periods in 2021. The increase was primarily due to $4.6 million and $9.7 million for the three and six months ended June 30, 2022, respectively of continued investments in our product candidates with CpG 1018 adjuvant through pre-clinical and clinical collaborations and additional discovery efforts. We expect these costs to continue to increase for the remaining period of 2022 in line with the progression of our clinical trials through the year. These are offset by a $2.7 million and $4.8 million decreases for the three and six months ended June 30, 2022, respectively in HEPLISAV-B and CpG 1018 adjuvant development costs. HEPLISAV-B development costs for the three and six months ended June 30, 2022 decreased, compared to the same periods of 2021, primarily due to winding down of dialysis study. In addition, HEPLISAV-B development costs for six months ended June 30, 2021 included activities associated with increasing production yields at our Düsseldorf manufacturing facility. CpG 1018 adjuvant development costs for the three and six months ended June 30, 2021 included CpG 1018 adjuvant production scale-up costs.

Non-cash stock-based compensation for the three and six months ended June 30, 2022 increased, compared to the same periods in 2021, primarily due to higher headcount to support investment in our clinical vaccine programs.

Selling, General and Administrative Expense

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

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

	Three Months Ended June 30,		Increase (Decrease) from 2021 to 2022		Six Months Ended June 30,		Increase (Decrease) from 2021 to 2022	
Selling, General and Administrative:	**2022**	**2021**	**$**	**%**	**2022**	**2021**	**$**	**%**
Compensation and related personnel costs	$ 12,929	$ 9,172	$ 3,757	41 %	$ 26,110	$ 18,376	$ 7,734	42 %
Outside services	13,751	5,699	8,052	141 %	23,817	12,287	11,530	94 %
Legal costs	444	508	(64)	(13)%	1,152	994	158	16 %
Facility costs	3,458	2,759	699	25 %	6,248	5,760	488	8 %
Non-cash stock-based compensation	5,597	3,445	2,152	62 %	11,024	6,589	4,435	67 %
Total selling, general and administrative	$ 36,179	$ 21,583	$ 14,596	68 %	$ 68,351	$ 44,006	$ 24,345	55 %

For the three and six months ended June 30, 2022, compensation and related personnel costs increased, as compared to the same period in 2021, due to the expansion of our field sales force in July 2021, increase in business travel as COVID-19 travel restrictions were easing and increase in recruiting expenses.

For the three and six months ended June 30, 2022, outside services increased, as compared to the same periods in 2021 primarily due to an overall increase in commercial and marketing efforts related to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (“ACIP”) universal recommendation and social media campaigns.

The increase in non-cash stock-based compensation for the three and six months ended June 30, 2022, compared to the same periods in 2021, was primarily due to higher headcount in connection with the expansion of our field sales force in July 2021.

Gain on Sale of Assets

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

In May 2022, we received payment of $1 million from TriSalus for their meeting a pre-commercialization milestone. In the three and six months ended June 30, 2022, we recognized a gain on sale of SD-101 assets of $1 million in our condensed consolidated statements of operations.

Other Income (Expense)

Interest income is reported net of amortization of premiums and discounts on marketable securities and includes realized gains on investments. Interest expense includes the stated interest and accretion of discount and end of term fee related to our terminated long-term debt agreement and Convertible Notes. Sublease income is recognized in connection with our sublease of office and laboratory space. 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 June 30,		Increase (Decrease) from 2021 to 2022		Six Months Ended June 30,		Increase (Decrease) from 2021 to 2022	
	2022	2021	$	%	2022	2021	$	%
Interest income	$ 765	$ 48	$ 717	1,494 %	$ 1,026	$ 95	$ 931	980 %
Interest expense	$ (1,683)	$ (3,109)	$ (1,426)	(46)%	$ (3,363)	$ (7,821)	$ (4,458)	(57)%
Sublease income	$ 2,025	$ 1,670	$ 355	21 %	$ 3,634	$ 3,692	$ (58)	(2)%
Loss on debt extinguishment	$ -	$ (5,232)	$ (5,232)	NM	$ -	$ (5,232)	$ (5,232)	NM
Change in fair value of warrant liability	$ -	$ 2,097	$ (2,097)	NM	$ 1,801	$ (23,455)	$ 25,256	108 %
Other	$ 40	$ (173)	$ (213)	(123)%	$ 145	$ 384	$ (239)	(62)%

Interest income for the three and six months ended June 30, 2022 increased, as compared to the same periods in 2021, primarily due to higher yields on our marketable securities portfolio. Interest expense for the three and six months ended June 30, 2022 decreased, as compared to the same periods in 2021, due to the repayment of our long-term debt in May 2021, replaced by the issuance of Convertible Notes in May 2021 at a lower effective interest rate. Sublease income for the three months ended June 30, 2021 was reduced by a common area credit for 2020 that we received from the landlord. The change in the fair value of warrant liability is primarily due to the decrease in our stock price from January 1, 2022 through the expiration date of the warrants on February 12, 2022. There were no warrants outstanding as of June 30, 2022. 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.

Income Taxes

For each of the three and six months ended June 30, 2022, we recorded a provision for income taxes of approximately $0.6 million and our effective tax rate was approximately 0.4%. We recorded no income tax provision and our effective tax rate was 0% for the three and six months ended June 30, 2021. The primary difference between the effective tax rate and the federal statutory rate is due to the benefit of net operating losses utilized during the period ended June 30, 2022 and the full valuation allowance we established on our federal, state, and certain foreign deferred tax assets.

Liquidity and Capital Resources

As of June 30, 2022, we had $518.2 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, borrowings, government grants and revenues from product sales and collaboration agreements to fund our operations. Our funds are currently invested in money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We currently anticipate that our cash, cash equivalents and short-term marketable securities as of June 30, 2022, and anticipated revenues from HEPLISAV-B and CpG 1018 adjuvant, will be sufficient to fund our operations for at least the next 12 months from the date of this filing and in the longer term.

Advanced payments received from CEPI to reserve a specified quantity of CpG 1018 adjuvant are initially accounted for as long-term deferred revenue. When we deliver CpG 1018 adjuvant to CEPI partner(s) or when we receive payment from CEPI partner(s), we reclassify the advanced payments from long-term deferred revenue to accrued liabilities. As of June 30, 2022, advance payments totaling $107.4 million were recorded as CEPI accrual in our condensed consolidated balance sheets.

As of June 30, 2022, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $4.5 million. The Convertible Notes bear interest at a rate of 2.50% per year, payable semiannually in arrears on May 15 and November 15 of each year. The Convertible Notes mature on May 15, 2026, unless converted, redeemed or repurchased in accordance with their terms prior to such date.

2022 versus 2021

During the six months ended June 30, 2022, we used $33.8 million of cash from our operations primarily due to our net income of $161.6 million, of which $17.5 million consisted of non-cash items which included stock-based compensation, depreciation and amortization, change in fair value of warrant liability, amortization of right-of-use assets, non-cash interest expense, and accretion and amortization on marketable securities. By comparison, during the six months ended June 30, 2021, we generated $148.8 million of cash from our operations primarily due to our net income of $5.4 million, of which $37.9 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. For the six months ended June 30, 2022 and 2021, we recognized revenue totaling $163.4 million and $37.1 million, respectively, that were included in deferred revenue balances at December 31, 2021 and 2020, respectively. Net cash used in operating activities is also impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the six months ended June 30, 2022 and 2021, net cash used in investing activities was $164.0 million and $86.4 million, respectively. Cash used in investing activities during the first six months of 2022 and 2021 included $160.7 million and $83.6 million of net purchases of marketable securities, respectively.

During the six months ended June 30, 2022 and 2021, net cash provided by financing activities was $11.3 million and $35.6 million, respectively. Cash provided by financing activities for the six months ended June 30, 2022 included net proceeds of $8.5 million from warrants exercised and $2.9 million proceeds from options exercised and employee stock purchase plan. Cash provided by financing activities for the first six months of 2021 included net proceeds of $219.8 million from the issuance of our Convertible Notes, $28.2 million from our 2020 At The Market Sales Agreement with Cowen and Company, LLC (“2020 ATM Agreement”), $3.4 million from warrants exercised offset by $190.2 million repayment of our long-term debt and $27.2 million purchases of capped call options.

As of June 30, 2022, we had $120.5 million available pursuant to the 2020 ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and six months ended June 30, 2022, we recorded net income of $128.8 million and $161.6 million, respectively. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable. Further, we expect to continue to incur substantial expenses as we continue to invest in commercialization of HEPLISAV-B, development of our CpG 1018 adjuvant and clinical trials and other development. If we cannot generate a sufficient amount of revenue from product sales, we will need to finance our operations through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

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

Contractual Obligations

As of June 30, 2022, our material non-cancelable purchase commitments, for the supply of HEPLISAV-B and CpG 1018 adjuvant totaled $115.7 million.

There were no other material changes to the contractual obligations previously disclosed in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2021.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2022, 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, 2021.

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, as amended (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 direct and indirect impact of the ongoing COVID-19 pandemic on our business, our future efforts to obtain regulatory approval, advance our collaborations, manufacture and commercialize approved products, or expectations about our anticipated expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including those in the risk factors that follow. We have marked with an asterisk (*) those risks described below that reflect material changes from, or additions to, the risks described under Part 1, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2021 that was filed with the Securities and Exchange Commission on February 28, 2022.

Risks Related to our Business and Capital Requirements

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

We have established sales, marketing and distribution capabilities and commercialized HEPLISAV-B in the U.S and Germany. Successful commercialization of HEPLISAV-B there or elsewhere will require significant resources and time and, while our personnel are experienced with respect to marketing of healthcare products, because HEPLISAV-B is our first marketed product, the potential uptake of the product in distribution and the timing for growth in sales, if any, is unpredictable and we may not be successful in commercializing HEPLISAV-B in the long term. Additionally, while we have received European approval for HEPLISAV-B and we commenced commercial shipments of HEPLISAV-B in Germany in May 2022, we have never launched a product in the European Union before and there can be no certainty that we will succeed in our European launch efforts. In particular, successful commercialization of HEPLISAV-B will require that we continue to negotiate and enter into contracts with wholesalers, distributors, group purchasing organizations, and other parties, and that we maintain those contractual relationships. There is a risk that we may fail to complete or maintain some or all of these important contracts on favorable terms or at all, or that in a potentially evolving reimbursement environment, our efforts may fail to overcome established competition at favorable pricing or at all.

We converted our contracted U.S. field sales team into full-time 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 2021 we significantly expanded our field sales force. It will take time for this expanded team to generate significant sales momentum, if it does so at all. In addition, retention of capable sales personnel may be more difficult as we 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 we will need to invest significant resources in order to successfully market, sell and distribute HEPLISAV-B for use with diabetes patients, one of our targeted patient populations for which we do not yet have approval to market. Although the Centers for Disease Control and Prevention ("CDC") and the CDC's Advisory Committee on Immunization Practices ("ACIP") recommend that all adults aged 19-59, including patients with diabetes, receive hepatitis B vaccinations, we are unable to predict how many of those patients may actually receive HEPLISAV-B.

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

- whether we are able to recruit and retain adequate numbers of effective sales and marketing personnel;
- whether we are able to access key health care providers to discuss HEPLISAV-B;

- whether we can compete successfully as a relatively new entrant in established distribution channels for vaccine products; and
- whether we will maintain sufficient financial resources to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure.

If we are not successful, we may be required to collaborate or partner HEPLISAV-B with a third-party pharmaceutical or biotechnology company with existing products. To the extent we collaborate or partner, as we have done for HEPLISAV-B in Germany, 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 actions 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. To help protect the health and safety of our workforce, we implemented a mandatory work-from-home policy for employees who can perform their jobs offsite. More recently we have downsized our office space and are embracing a flexible work environment where many employees will be allowed, but not required, to be permanently remote as restrictions lift. In the conduct of our business activities, we are also taking actions to protect the safety of patients and healthcare professionals. In the early stage of the pandemic, our field-based personnel reduced in-person customer interactions in healthcare settings and primarily used electronic communication, such as emails, phone calls and video conferences. We may be required to do again so in the future. Many healthcare and contracting professionals at hospitals and other medical institutions with whom our field-based personnel interact began conducting a greater proportion of their working schedule from home and were facing additional demands on their time during the COVID-19 pandemic. While the different quality of electronic interactions as compared with in-person interactions, as well as the reduced quantity of interactions during the COVID-19 pandemic, impacted the effectiveness of our sale personnel, we have gradually moved back to in-person interactions in many cases. With the rise of new variants and related precautions, however, our customers' procurement activities and those of our collaborators continue to be impacted which could negatively affect our overall product sales. It is possible that we may have to limit in-person engagement again the in future.

In addition, due to the ongoing COVID-19 global pandemic, most medical centers initially 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 these restrictions, medical centers began operating under limited capacity and strict social distancing rules. The overall impact has generally resulted in a significant reduction in the utilization of adult vaccines (other than COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B which has impacted sales of HEPLISAV-B. While adult hepatitis B vaccine utilization rates have continued to stay below pre-pandemic levels, we have been seeing a gradual recovery in such utilization above all-time lows, but still well below pre-pandemic levels.

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

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

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

Our business has been, and may continue to be, adversely affected by the effects of the ongoing COVID-19 pandemic and its variants. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease. 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, including a mandatory work-from-home policy for employees who can perform their jobs offsite.

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. 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 curtailed their day-to-day activities to some extent and at times have ceased allowing or significantly reduced access to their facilities for non-COVID-19 related business. Thus, our field sales and medical science employees are working a greater proportion of their working schedule from home and are facing additional demands on their time during the COVID-19 pandemic. 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.

There has been a significant reduction in the utilization of adult vaccines (other than COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B which has impacted sales of HEPLISAV-B. While adult hepatitis B vaccine utilization rates have continued to stay below pre-pandemic levels, we have been seeing a gradual recovery in such utilization above all-time lows, but still well below pre-pandemic levels. 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.

If the effect of any quarantines, shelter-in-place, executive and similar government orders related to COVID-19 increase, they could impact personnel at our manufacturing facility in Germany and third-party manufacturing facilities in the United States or abroad. This could adversely affect our ability to maintain and distribute a consistent supply of HEPLISAV-B or CpG 1018 adjuvant sufficient to meet demand.

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

The COVID-19 pandemic continues to rapidly evolve, and new variants of the virus continue to emerge. While some vaccines have been approved, it is not clear whether, which, or to what extent these vaccines will protect against current or future variants of the virus. The extent to which the COVID-19 pandemic impacts our business, our future sales of HEPLISAV-B, sales of CpG 1018 adjuvant and our total 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 and severity of the outbreak including current and future variants, 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 U.S. 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 our HEPLISAV-B vaccine and our CpG 1018 adjuvant, we may encounter difficulties in managing our commercial growth and expanding our operations successfully.

As our commercial operations expand, we expect that we will also need to manage additional relationships with various third parties, including sole source suppliers, distributors, wholesalers and hospital customers. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to successfully commercialize our HEPLISAV-B vaccine and CpG 1018 adjuvant, 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, retain and integrate additional management, administrative and sales and marketing personnel, or secure sufficient or timely supply from third party service and product providers, and our failure to accomplish any of these activities could prevent us from successfully growing or our company or maintaining the same level of commercial growth.

As we plan for broader commercialization of our HEPLISAV-B vaccine 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 adjuvant, to support market share gains or potential vaccine collaborations in 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 or customers 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 or any other product 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 adjuvant, the contracts we enter into with our customers will generally carry delivery obligations that require us to deliver product in certain quantities and meet certain quality thresholds, among other things, all within specified timeframes. If, for any reason, whether due to reliance on third-party manufacturers or otherwise, we are unable to deliver timely, compliant products to our customers in quantities that meet our contractual obligations, we could be subject to lost revenue, contractual penalties, suits for damages, harm to our reputation or other problems that could materially and adversely affect our business.

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

A substantial portion of our revenue for the foreseeable future may depend on sales of CpG 1018 adjuvant, which are difficult to predict. For example, as of June 30, 2022, we received advanced payments from certain of our customers to purchase specified quantities of CpG 1018 adjuvant which were recorded as deferred revenue until we deliver the adjuvant and meet all criteria to recognize revenue. In accordance with our stated revenue policy, we expect to record revenue for these contracts upon meeting all of the criteria for revenue recognition under Accounting Standards Codification 606, which includes, among other criteria, the transfer of control for CpG 1018 adjuvant to our customer. Our COVID collaborators in many cases have purchase agreements with government agencies,. In the event that our collaborators do not receive payment from these agencies, it may negatively impact our ability to collect our own receivables. We have in the past, and may in the future, adjust delivery dates or allow cancellations in certain circumstances to better enable our customers to meet their obligations, which can impact the timing of revenue recognition, cash collections and transfer of control. The occurrence and timing of such transfer of control can be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. We expect that our visibility into future revenue relating to sales of CpG 1018 adjuvant, including volumes, prices and timing, will continue to be limited and could result in significant, unexpected fluctuations in our quarterly and annual operating results.

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. For example, during the six months ended June 30, 2022, sales of CpG 1018 accounted for 85% of our overall revenue, and two CpG 1018 customers accounted for 63% of our revenue. If orders from our top customers or the number of CpG 1018 collaborations are reduced or discontinued, or orders or payments are delayed, our revenue and/or cash flow in future periods may materially decrease or deviate from stated expectations. As our CpG 1018 customers rely on government orders and

payments for their approved vaccines, delays in government funding or budget approval processes can exacerbate these issues. Fluctuations in our operating results may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. Similarly, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others. Accordingly, comparing our operating results on a period-to-period basis may not be meaningful, and investors should not rely on any particular past results as an indication of our future performance. If such fluctuations occur or if our operating results deviate from our expectations or the expectations of investors or securities analysts, our stock price may be adversely affected.

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

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing HEPLISAV-B surface antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. The FDA approved our pre-filled presentation of HEPLISAV-B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV-B going forward. We have limited experience in manufacturing and supplying this presentation and rely on a contract manufacturer to do so. Our contract manufacturer is the only approved provider that we have, and there can be no assurance that we or they can successfully manufacture sufficient quantities of pre-filled syringes in compliance with good manufacturing practice ("GMP") in order to meet market demand, whether because of our supplier's own operations, operations of its sub-suppliers, issues with downstream supply chains or otherwise. If our contract manufacturer is unable to source components needed to complete fill and finish of our pre-filled syringes, we may be required to identify a second source which would have associated costs and regulatory requirements. If we are unable to do all this, on a timely basis or at all, our HEPLISAV-B sales could be materially and adversely impacted.

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

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

We have entered into collaborative relationships to develop vaccines utilizing our CpG 1018 adjuvant, including collaborations to develop vaccines for COVID-19. These collaborations may not be successful. If the combination of patents, trade secrets and other proprietary rights that we rely on to protect our intellectual property rights in CpG 1018 adjuvant or otherwise are inadequate, we may be unable to realize recurring commercial benefit from the development of any vaccines 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, partnerships and supply arrangements. Current relationships and efforts are focused on adjuvanted vaccines for COVID-19, plague, Tdap, seasonal influenza, universal influenza and shingles. There are risks and uncertainties inherent in vaccine research and development, including the timing of completing vaccine development, the results of clinical trials, whether a vaccine will be approved for use, the extent of competition, government actions and whether a vaccine can be successfully manufactured and commercialized. As a result, these internal or 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. Our collaborators may not purchase as much adjuvant as we anticipate, and they may delay placing orders or delay taking certain deliveries under certain circumstances which can affect our revenue recognition. If a collaborator fails to conduct collaborative activities successfully, the development and commercialization of a vaccine could be delayed, and may not occur at all. For example, as of June 30, 2022, only three of our collaborators have received emergency use authorization from an

applicable regulatory authority for any vaccine for COVID-19 containing our adjuvant and none had received a full approval. We have historically relied on a single supplier to produce our CpG 1018 adjuvant, and only recently have qualified an alternate supplier to produce the adjuvant with whom we have a limited operating relationship. If we were unable to maintain our existing suppliers for the adjuvant, we would have to establish and maintain an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing any potential adjuvanted vaccines produced by us or 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 suppliers, or at all, and even if we are successful in adding an additional supplier, there is no guarantee such supplier will be able to manufacture compliant supplemental quantities sufficient to support commercial demand, to the extent it materializes, and in the timeframes required.

Our adjuvant has no composition of matter patent protection. We have filed patent applications claiming compositions and methods of use of CpG 1018 adjuvant for COVID-19 and other vaccines, some of which are co-owned with various collaborators. Such patent applications may or may not be allowed, granted or issued. 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, protect or enforce our proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize recurring commercial benefit from the development of a vaccine containing CpG 1018 adjuvant, and we may not have the ability to prevent others from developing or commercializing a vaccine containing the adjuvant. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

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

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price, as well as the availability of coverage and adequate reimbursement, from third-party payors, in particular for HEPLISAV-B, where existing products are already marketed. In the U.S., pricing for hepatitis B vaccines is currently stable and reimbursement is favorable as we believe private and public payors recognize the value of prophylaxis in this setting given the high costs of potential morbidity and mortality, and we have achieved coverage with most third-party payors. However, there is a risk that some payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include HEPLISAV-B. Reimbursement or pricing in jurisdictions outside the U.S. may be less favorable. 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. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability, and such unavailability could harm our future prospects and reduce our stock price.

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

In order to help fund potential scale-up of production of CpG 1018 adjuvant that may be required in the event that our CpG 1018 adjuvant is included in any approved and commercially-available novel vaccine, whether a COVID-19 vaccine or otherwise, we have applied for, and in some cases have received grants from various charitable and philanthropic organizations. We may seek such

grants in the future. These grants and others, if and when received, may come with certain pricing requirements, global access requirements or reporting or other covenants to ensure that any funded product is made available by us worldwide and on a nondiscriminatory basis. Such covenants may limit the price we can charge for any funded product and may involve a license to use technology we own that is included in the funded products if we do not comply. Such price limitations or licenses, if invoked, could serve to limit the prices we charge, or our control over the manufacturing and distribution of grant-funded products. Failure to agree to such requirements, may result in us not receiving some or all of the grant.

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

Our HEPLISAV-B regulatory approval in the United States is subject to certain post-marketing obligations and commitments to the FDA. For example, we were required to conduct an observational comparative study of HEPLISAV-B to Engerix-B to assess occurrence of acute myocardial infarction ("AMI"). This post-marketing study was initiated in August 2018 and concluded in November 2020. While the results of the study, announced in April 2021, provided that there was no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B, we may be required to conduct further studies on HEPLISAV-B or our other product candidates in the future. We are also awaiting data from the autoimmune portion of our observational study and we expect that data to be made available in the fourth quarter of 2022. We are also committed to conducting an observational surveillance study to evaluate the incidence of new onset immune-mediated diseases, herpes zoster and anaphylaxis, and we are required to establish a pregnancy registry to provide information on outcomes following pregnancy exposure to HEPLISAV-B. These studies will require significant effort and resources, and failure to timely conduct and/or complete these studies to the satisfaction of the FDA could result in withdrawal of our biologics license application approval, which would have a material adverse effect on our business, results of operations, financial condition and prospects. As we advance our pipeline, similar studies may be required for other candidates. The results of post-marketing studies may also result in additional warnings or precautions for the HEPLISAV-B label or labels of any future products, or expose additional safety concerns that may result in product liability and withdrawal of a product or prodcuts 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 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 HEPLISAV-B. We may have similar obligations for future products if and when approved. 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"), International Conference on Harmonization guidelines, and good laboratory practices ("GLP"). If we are not able to meet and maintain regulatory compliance for HEPLISAV-B or any future product, we may lose marketing approval and be required to withdraw our product. Withdrawal of our product would have a material adverse effect on our business.

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

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

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

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;

- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of sufficient reimbursement by third-party payors.

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

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

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing vaccines and adjuvants. For example, HEPLISAV-B competes in the U.S. with established hepatitis B vaccines marketed by Merck, GlaxoSmithKline plc (“GSK”) and VBI Vaccines Inc. ("VBI"), and, when commercialized outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies who market abroad. 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.

We are also in competition with companies developing vaccines and vaccine adjuvants, generally including, among others, GSK, Pfizer, Inc., Sanofi S.A., Merck, Novartis International AG, Agenus, Inc., Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson and VBI. We will likely compete with several of these companies in the hepatitis space, Tdap space, shingles space and other spaces occupied by any other product candidates we ultimately choose to advance through our pipeline in the future.

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

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

We have generated limited revenue from the sale of products and, prior to January 1, 2021, have incurred losses in each year since we commenced operations in 1996. Our net income for the three and six months ended June 30, 2022 was $128.8 million and $161.6 million, respectively compared to net income of $4.5 million and $5.4 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $1.1 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S. and Europe, we have in the past, and could in the future, incur operating losses. 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. We expect to increase research and development costs as we invest in our pipeline. While new sales of CpG 1018 adjuvant have generated significant 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. and abroad may further affect costs or losses related to commercialization. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine products or other products we may choose to offer in the future, we are unable to predict the extent of any future losses or when, if ever, we will become profitable on an annual recurring basis, or, that if we are able to reach consistent profitability that it will be sustainable for any period of time.

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

As of June 30, 2022, we had $518.2 million in cash, cash equivalents and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and six months ended June 30, 2022, we recorded net income of $128.8 million and $161.6 million, respectively. As of June 30, 2022, we had an accumulated deficit of $1.1 billion. We cannot be certain that sales of our products, and the revenue from our other activities are sustainable and past results are not a reliable indicator of future performance. Further, we expect to continue to incur substantial expenses as we continue to invest in the commercialization and development of HEPLISAV-B and our CpG 1018 adjuvant, clinical trials for our pipeline candidates, 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 or otherwise. Adequate financing may not be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we may need to significantly reduce our operations while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives and the value of our stock.

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 any requests that they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

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

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

We may seek to introduce HEPLISAV-B, or any other product candidates we may develop, to various additional markets in or outside of the U.S. and Europe. Developing, seeking regulatory approval for and marketing our product candidates outside of the U.S. and Europe in new jurisdictions where we don't currently have approval 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;
- foreign tax compliance and 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, even if we undertake these efforts.

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 have uncertain outcomes.

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

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

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

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

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

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

guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

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

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

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other candidates, therapies or 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.

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. Even if we complete all such activities without issue, final results may not actually support approval of a particular product candidate.

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

Most of our programs, including HEPLISAV-B, incorporate TLR9 agonist CpG oligonucleotides. If any of our product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy, or significantly reevaluate strategic alternatives. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates

or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- federal false claims laws, including the False Claims Act, and Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;

- the Federal Food, Drug and Cosmetic Act and governing regulations which, among other things, prohibit off-label promotion of prescription drugs;
- the federal Physician Payments Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education and Reconciliation Act of 2010 (collectively, "ACA") which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by such physicians and their immediate family members;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created, among other things, new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements 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 California Consumer Privacy Act of 2018 ("CCPA") will be interpreted, but as currently written, it will likely impact our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data. As we expand our operations, the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

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

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 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 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare reform measures will impact the ACA and our business.

Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2039 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through June 30, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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 concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services ("HHS") finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other reform 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.

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

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

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

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

Risks Related to our Intellectual Property

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 or other dispute 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 have been, and in the future may become, involved in various administrative proceedings related to our intellectual property which can cause 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 intellectual property or technologies 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, operations or financial condition.

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, if any at all. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

For example, our HEPLISAV-B and CpG 1018 adjuvant have no composition of matter patent protection in the United States or elsewhere. We must therefore rely primarily on the protection afforded by method of use patent claims relating to HEPLISAV-B and the use of CpG 1018 in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to HEPLISAV-B and CpG 1018. We have three issued U.S. patents relating to certain uses of HEPLISAV-B that are projected to expire in 2032. We have filed patent applications claiming compositions and methods of use of CpG 1018 for COVID-19 and other vaccines, but we cannot provide any assurances that we will receive an issued patent for any of these patent applications or that, if issued, any of these patents will provide adequate protection for any intended use of CpG 1018 in vaccines. In addition, we are or may be subject to co-ownership of the underlying intellectual property with our collaborators and, therefore, may not be the sole owner. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018, we may be unable to realize any recurring commercial benefit from the development of a vaccine containing CpG 1018, and we may not have the ability to prevent others from developing or commercializing a vaccine containing CpG 1018.

The biopharmaceutical patent environment outside the U.S. is also uncertain. We may be particularly affected by this uncertainty since several of our product candidates or our collaborators' vaccine candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection, if any at all. For example, while many countries such as the U.S. permit method of use patents or patent claims relating to the use of drug products, in some countries the law relating to patentability of such use claims is evolving, or may prohibit certain activities, 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 patent claims, or that significantly limit the types of uses, claims or subject matter 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 may have exclusively licensed, now or in the future;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent;
- other parties may design around technologies we have licensed, patented or developed; and
- pending patent applications or issued patents may be challenged by third parties in litigation or other proceedings, such as inter partes reviews, pre- and post-grant oppositions, reexaminations, derivation proceedings and post-grant review, in the U.S or abroad.

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 or other proprietary know-how 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 or continue to commercialize our products, enter into or maintain collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

We have in the past, and may in the future, rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to obtain or maintain them could severely harm our business.

Our current or future research and development efforts may depend in part upon our license arrangements for certain intellectual property owned by or co-owned with third parties. Our dependence on these licenses could subject 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 could 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 such agreements could allow 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 or at all. In addition, license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses or any rights to the underlying intellectual property. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our products or 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 or product candidates. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to develop or commercialize certain of our products or 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 intellectual property (including patents), which may not be possible or could require substantial funds and time.

Risks Related to our Common Stock

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

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

- impact of the COVID-19 pandemic on our HEPLISAV-B vaccine, CpG 1018 adjuvant, or other product revenue;
- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and BLA filing and communications, from the FDA or other regulatory agencies;
- our ability to receive timely regulatory approval for our product candidates;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our products or product candidates or establish manufacturing capacity on our own;
- our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;
- changes in government regulations, general economic conditions or industry announcements;
- changes in the structure of healthcare payment systems;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- the volume of trading in our common stock;
- investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance; and
- industry conditions and general financial, economic and political instability, as well as developments with respect to the COVID-19 global pandemic, including but not limited to regulatory initiatives, such as the imposition of compulsory licenses related to COVID-19 vaccines, that may result in a general weakening of intellectual property protections.

The stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies, including recently in connection with the ongoing COVID-19 pandemic, broader macroeconomic conditional and/or geopolitical instability such as that resulting from the conflict between Russia and Ukraine, 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, interest rate increases and/or other tapering policies from the government, and other adverse effects or developments relating to the ongoing COVID-19 pandemic or general economic environment 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 have often been brought against a company following a decline in the market price of its securities. We have in the past been, and we may in the future be, the target of such litigation. Securities and shareholder derivative litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

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

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

Under our universal shelf registration statement, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our sales agreement with Cowen & Company, LLC, under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million. As of June 30, 2022, we had $120.5 million of our common stock remaining available for future issuance under our sales agreement with Cowen & Company, LLC. The sale or issuance of our securities, including those issuable upon exercise of the outstanding warrants or conversion of the preferred stock, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

Risks Related to Our Outstanding Convertible Notes

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

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

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

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

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

From January 1 through June 30, 2022, the conditions allowing holders to convert all or any portion of their Convertible Notes were not met. In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert their Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion

obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

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

From January 1, through June 30, 2022, the conditions allowing holders to convert all or any portion of their Convertible Notes have not been met. In the event the conditional conversion feature of the Convertible Notes is triggered, the conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. Upon conversion of the Convertible Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could be used to satisfy short positions, or anticipated conversion of the Convertible Notes into shares of our common stock could depress the price of our common stock.

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

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

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

In connection with the issuance of the Convertible Notes, we have entered into capped call transactions with the option counterparties totaling $27.2 million (the "Capped Calls"). The Capped Calls cover, subject to customary adjustments under the terms of the Capped Calls, the number of shares of common stock that initially underlie the Capped Calls. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

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

We are subject to counterparty risk with respect to the capped call transactions.*

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the option counterparties will not be secured by any collateral.

If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the capped call transactions with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

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 (such as the ongoing COVID-19 pandemic) 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, have and could again in the future cause restrictions on supply chains, restrict 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. For example, the COVID-19 pandemic has generally resulted in significantly reduced utilization of all adult vaccines (other than the COVID-19 vaccines) since the end of the first quarter of 2020, including a reduction in the utilization of HEPLISAV-B.

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, along with those of our suppliers or customers, are potentially vulnerable to a variety of evolving threats and data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such threats could include, but not be limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable flaws or bugs that could result in a breach of or disruption to our information technology systems (including our products or the third-party information technology systems that support us and our goods).

The potential liability and associated consequences we could suffer as a result of any such cyber events could be catastrophic and result in irreparable harm including (a) the loss of trade secrets or other intellectual property, or (b) the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others, (c) extortion and other monetary damages due to malware or business email compromise, or (d) other significant damages. 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 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 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Document	Incorporated by Reference				Filed Herewith
		Exhibit Number	Filing	Filing Date	File No.	
3.1	Sixth Amended and Restated Certificate of Incorporation	3.1	S-1/A	February 5, 2004	333-109965	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 4, 2010	001-34207	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.1	8-K	January 5, 2011	001-34207	
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation	3.6	8-K	May 30, 2013	001-34207	
3.5	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	November 10, 2014	001-34207	
3.6	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	June 2, 2017	001-34207	
3.7	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	July 31, 2017	001-34207	
3.8	Certificate of Amendment of the Sixth Amended and Restated Certificate of Incorporation	3.1	8-K	May 29, 2020	001-34207	
3.9	Amended and Restated Bylaws	3.8	10-Q	November 6, 2018	001-34207	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, and 3.9					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
4.3	Form of Warrant to Purchase Common Stock	4.1	8-K	August 8, 2019	001-34207	
4.4	Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021	4.1	8-K	May 13, 2021	001-34207	
4.5	Form of Global Note, representing Dynavax Technologies Corporation's 2.5% Convertible Senior Notes due 2026	4.2	8-K	May 13, 2021	001-34207	
10.1+	Amended and Restated Dynavax Technologies Corporation 2018 Equity Incentive Plan	Appendix A	DEF 14A	April 14, 2022	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

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

+ Indicates management contract, compensatory plan or arrangement.

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

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

SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: August 4, 2022

By: /s/ RYAN SPENCER

Ryan Spencer

Chief Executive Officer

(Principal Executive Officer)

Date: August 4, 2022

By: /s/ KELLY MACDONALD

Kelly MacDonald

Chief Financial Officer

(Principal Financial Officer)

Date: August 4, 2022

By: /s/ JUSTIN BURGESS

Justin Burgess

Controller, Chief Accounting Officer

(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: August 4, 2022

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: August 4, 2022

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 June 30, 2022 (the "Periodic Report"), to which this Certificate is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 4th day of August, 2022.

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 June 30, 2022 (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 her hand hereto as of the 4th day of August, 2022.

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.