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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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	Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the 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 October 31, 2023, the registrant had outstanding 129,260,850 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 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 adjuvant to meet potential future demand in connection with new 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, impact of COVID-19 on our business or operations, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, liquidity and cash needs (including our ability to collect on accounts receivables), 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2023 (unaudited)	December 31, 2022 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 154,511	$ 202,004
Marketable securities available-for-sale	565,905	422,391
Accounts receivables, net of allowance for doubtful accounts of $12,313 and $0 at September 30, 2023 and December 31, 2022, respectively	46,347	145,130
Other receivables	519	2,385
Inventories	49,412	59,446
Prepaid expenses and other current assets	18,972	85,629
Total current assets	835,666	916,985
Property and equipment, net	36,183	37,596
Operating lease right-of-use assets	24,949	25,745
Goodwill	1,981	2,006
Other assets	74,154	3,518
Total assets	$ 972,933	$ 985,850
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,120	$ 3,211
Accrued research and development	3,290	4,775
CEPI accrual (Note 6)	-	107,738
Accrued liabilities	43,462	30,719
Other current liabilities	4,392	3,631
Total current liabilities	54,264	150,074
Convertible Notes, net of debt discount of $3,085 and $3,922 at September 30, 2023 and December 31, 2022, respectively (Note 7)	222,415	221,578
Long-term portion of lease liabilities	30,680	32,801
CEPI accrual long-term (Note 6)	60,337	-
Other long-term liabilities	321	384
Total liabilities	368,017	404,837
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at September 30, 2023 and December 31, 2022; zero shares outstanding at September 30, 2023 and December 31, 2022, respectively	-	-
Common stock: $0.001 par value; 278,000 shares authorized at September 30, 2023 and December 31, 2022; 129,195 shares and 127,604 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	129	128
Additional paid-in capital	1,541,549	1,510,518
Accumulated other comprehensive loss	(5,959)	(5,438)
Accumulated deficit	(930,803)	(924,195)
Total stockholders' equity	604,916	581,013
Total liabilities and stockholders' equity	$ 972,933	$ 985,850

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 62,318	$ 163,815	$ 162,209	$ 531,462
Other revenue	7,196	3,920	14,479	6,729
Total revenues	69,514	167,735	176,688	538,191
Operating expenses:				
Cost of sales - product	13,229	61,334	41,478	184,665
Research and development	14,116	12,962	40,767	33,746
Selling, general and administrative	38,053	32,042	111,667	100,393
Gain on sale of assets (Note 5)	(1,000)	-	(1,000)	(1,000)
Bad debt expense	-	-	12,313	-
Total operating expenses	64,398	106,338	205,225	317,804
Income (loss) from operations	5,116	61,397	(28,537)	220,387
Other income (expense):				
Interest income	8,462	2,562	22,437	3,588
Interest expense	(1,691)	(1,685)	(5,065)	(5,048)
Sublease income	1,993	2,026	5,584	5,660
Change in fair value of warrant liability (Note 10)	-	-	-	1,801
Other	266	(208)	218	(63)
Net income (loss) before income taxes	14,146	64,092	(5,363)	226,325
Benefit from (provision for) income taxes	147	(283)	(1,245)	(902)
Net income (loss)	$ 14,293	$ 63,809	$ (6,608)	$ 225,423
Net income (loss) per share attributable to common stockholders:				
Basic	$ 0.11	$ 0.50	$ (0.05)	$ 1.79
Diluted	$ 0.10	$ 0.43	$ (0.05)	$ 1.51
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	128,988	127,062	128,515	125,997
Diluted	154,196	151,538	128,515	150,433

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income (loss)	$ 14,293	$ 63,809	$ (6,608)	$ 225,423
Other comprehensive income (loss), net of tax:				
Change in unrealized loss on marketable securities available-for-sale	426	(395)	(105)	(2,296)
Cumulative foreign currency translation adjustments	(1,013)	(2,307)	(416)	(4,700)
Total other comprehensive loss	(587)	(2,702)	(521)	(6,996)
Total comprehensive income (loss)	$ 13,706	$ 61,107	$ (7,129)	$ 218,427

See accompanying notes.

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

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months Ended September 30, 2023	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss)**	**Deficit**	**Equity**
Balances at June 30, 2023	128,779	$ 129	-	$ -	$ 1,527,544	$ (5,372)	$ (945,096)	$ 577,205
Issuance of common stock upon exercise of stock options	312	-	-	-	2,722	-	-	2,722
Issuance of common stock upon release of restricted stock awards, net of statutory tax withholdings	24	-	-	-	(162)	-	-	(162)
Issuance of common stock under Employee Stock Purchase Plan	80	-	-	-	758	-	-	758
Stock compensation expense	-	-	-	-	10,687	-	-	10,687
Total other comprehensive loss	-	-	-	-	-	(587)	-	(587)
Net income	-	-	-	-	-	-	14,293	14,293
Balances at September 30, 2023	129,195	$ 129	-	$ -	$ 1,541,549	$ (5,959)	$ (930,803)	$ 604,916
Nine Months Ended September 30, 2023								
Balances at December 31, 2022	127,604	$ 128	-	$ -	$ 1,510,518	$ (5,438)	$ (924,195)	$ 581,013
Issuance of common stock upon exercise of stock options	556	-	-	-	4,339	-	-	4,339
Issuance of common stock upon release of restricted stock awards, net of statutory tax withholdings	874	1	-	-	(6,126)	-	-	(6,125)
Issuance of common stock under Employee Stock Purchase Plan	161	-	-	-	1,535	-	-	1,535
Stock compensation expense	-	-	-	-	31,283	-	-	31,283
Total other comprehensive income	-	-	-	-	-	(521)	-	(521)
Net loss	-	-	-	-	-	-	(6,608)	(6,608)
Balances at September 30, 2023	129,195	$ 129	-	$ -	$ 1,541,549	$ (5,959)	$ (930,803)	$ 604,916

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
Three Months Ended September 30, 2022	**Shares**	**Par Amount**	**Shares**	**Par Amount**	**Capital**	**(Loss)**	**Deficit**	**Equity**
Balances at June 30, 2022	126,439	$ 126	-	$ -	$ 1,484,970	$ (6,560)	$ (1,055,737)	$ 422,799
Issuance of common stock upon exercise of stock options	884	1	-	-	7,336	-	-	7,337
Issuance of common stock upon release of restricted stock awards	186	-	-	-	-	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	72	-	-	-	720	-	-	720
Stock compensation expense	-	-	-	-	8,613	-	-	8,613
Total other comprehensive loss	-	-	-	-	-	(2,702)	-	(2,702)
Net income	-	-	-	-	-	-	63,809	63,809
Balances at September 30, 2022	127,581	$ 127	-	$ -	$ 1,501,639	$ (9,262)	$ (991,928)	$ 500,576
Nine Months Ended September 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	1,171	1	-	-	9,486	-	-	9,487
Issuance of common stock upon release of restricted stock awards	1,432	1	-	-	(1)	-	-	-
Issuance of common stock under Employee Stock Purchase Plan	154	-	-	-	1,430	-	-	1,430
Stock compensation expense	-	-	-	-	24,188	-	-	24,188
Total other comprehensive loss	-	-	-	-	-	(6,996)	-	(6,996)
Net income	-	-	-	-	-	-	225,423	225,423
Balances at September 30, 2022	127,581	$ 127	-	$ -	$ 1,501,639	$ (9,262)	$ (991,928)	$ 500,576

See accompanying notes.

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

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net (loss) income	$ (6,608)	$ 225,423
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,228	2,975
Amortization of right-of-use assets and loss on disposal of property and equipment	2,090	2,244
Accretion of discounts on marketable securities	(11,313)	(1,969)
Change in fair value of warrant liability (Note 10)	-	(1,801)
Stock-based compensation expense	31,283	24,188
Bad debt expense (Note 6)	12,313	-
Non-cash interest expense	2,246	2,222
Inventory write-off	-	14,485
Gain on sale of assets (Note 5)	(1,000)	(1,000)
Changes in operating assets and liabilities:		
Accounts and other receivables, net	40,935	698
Inventories	9,435	(55,759)
Prepaid manufacturing	-	146,928
Prepaid expenses and other current assets	(4,650)	(26,240)
Other assets	730	61
Accounts payable	(612)	301
CEPI accrual (Note 6)	-	(21,110)
Lease liabilities	(2,635)	(2,366)
Deferred revenue	-	(262,469)
Accrued liabilities and other liabilities	11,355	(19,043)
Net cash provided by operating activities	86,797	27,768
Investing activities		
Purchases of marketable securities	(484,040)	(514,676)
Proceeds from maturities of marketable securities	351,735	236,200
Purchases of property and equipment, net	(2,381)	(5,552)
Proceeds from sale of assets	1,000	1,000
Net cash used in investing activities	(133,686)	(283,028)
Financing activities		
Proceeds from warrants exercises	-	8,455
Proceeds from exercise of stock options and/or release of restricted stock awards, net	4,339	9,487
Proceeds from Employee Stock Purchase Plan	1,535	1,430
Payments for taxes related to net share settlement of RSUs	(6,264)	-
Net cash (used in) provided by financing activities	(390)	19,372
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(155)	(1,755)
Net decrease in cash and cash equivalents, and restricted cash	(47,434)	(237,643)
Cash and cash equivalents, and restricted cash at beginning of period	202,211	436,408
Cash and cash equivalents, and restricted cash at end of period	$ 154,777	$ 198,765
Supplemental disclosure of cash flow information		
Cash paid during the period for income taxes	$ 1,413	$ 788
Cash paid during the period for interest	$ 2,819	$ 2,819
Reclassification of contract asset from other current assets to other assets	$ 71,307	$ -
Reclassification of CEPI accrual to CEPI accrual long-term	$ (60,337)	$ -
Advance Payments forgiven per CEPI-Bio E Assignment Agreement (Note 6)	$ (47,401)	$ -
Non-cash investing and financing activities:		
Purchases of property and equipment, not yet paid	$ 704	$ 973
Right-of-use assets obtained in exchange of operating lease liabilities	$ 1,332	$ 2,475

See accompanying notes.

1. Organization

Dynavax Technologies Corporation (“we,” “our,” “us,” “Dynavax” or the “Company”) is a commercial stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. Our first marketed product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] is approved in the United States, the European Union and Great Britain for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 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 utilizing CpG 1018 adjuvant. As of September 30, 2023, we have satisfied all delivery obligations under these global commercial supply agreements.

We are also 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 for Tdap and shingles, and a Phase 2 clinical trial and studies for plague in collaboration with and fully funded by the U.S. Department of Defense ("DoD"). Additionally, we are working to advance product candidates utilizing our CpG 1018 adjuvant through discovery efforts and through preclinical and clinical collaborations with third-party research organizations.

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, 2022 has been derived from audited financial statements at that date, but excludes some 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, 2022, 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, located in India, and a branch of Dynavax registered in Italy. All significant intercompany accounts and transactions among these entities have been eliminated from the unaudited condensed consolidated financial statements. We operate in one business segment: discovery, development and commercialization of novel vaccines.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that may affect the amounts reported in the unaudited 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 unaudited 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 unaudited condensed consolidated financial statements include those related to revenue recognition; accounts receivable; useful lives of long-lived assets; valuation procedures for right-of-use assets and operating lease liabilities; valuation of inventory; 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. Changes in estimates are reflected in reported results in the period in which they become known.

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*, which was codified in Accounting Standards Codification ("ASC") 326, *Financial Instruments — Credit Losses* ("ASC 326"). The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. Because we were a smaller reporting company based on the most recent determination as of November 15, 2019, ASC 326 became effective for us for fiscal years beginning after December 15, 2022. As such, we adopted ASC 326 effective January 1, 2023, utilizing the modified retrospective transition method. Upon adoption, we updated our impairment model to utilize a forward-looking current expected credit losses ("CECL") model in place of the incurred loss methodology for financial instruments measured at amortized cost, primarily including our accounts receivable and contract asset. In relation to available-for-sale ("AFS") debt securities, the guidance eliminates the concept of "other-than-temporary" impairment, and instead focuses on determining whether any impairment is a result of a credit loss or other factors. The adoption of ASC 326 did not have a material impact on our unaudited condensed consolidated financial statements as of the adoption date.

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 each of the three and nine months ended September 30, 2023.

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) measured at fair value on a recurring basis (in thousands):

	Level 1	Level 2	Level 3	Total
September 30, 2023				
Assets				
Money market funds	$ 131,837	$ -	$ -	$ 131,837
U.S. treasuries	-	51,589	-	51,589
U.S. government agency securities	-	189,312	-	189,312
Corporate debt securities	-	325,756	-	325,756
Total assets	$ 131,837	$ 566,657	$ -	$ 698,494

	Level 1	Level 2	Level 3	Total
December 31, 2022				
Assets				
Money market funds	$ 172,418	$ -	$ -	$ 172,418
U.S. treasuries	-	42,308	-	42,308
U.S. government agency securities	-	88,032	-	88,032
Corporate debt securities	-	292,051	-	292,051
Total assets	$ 172,418	$ 422,391	$ -	$ 594,809

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.

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

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

	September 30, 2023	December 31, 2022	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 154,511	$ 202,004	$ 198,576	$ 436,189
Restricted cash (1)	266	207	189	219
Total cash and cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows	$ 154,777	$ 202,211	$ 198,765	$ 436,408

(1) Restricted cash is included in "Other assets" in the Condensed Consolidated Balance Sheets.

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2023				
Cash and cash equivalents:				
Cash	$ 21,922	$ -	$ -	$ 21,922
Money market funds	131,837	-	-	131,837
Corporate debt securities	752	-	-	752
Total cash and cash equivalents	154,511	-	-	154,511
Marketable securities available-for-sale:				
U.S. treasuries	51,734	-	(145)	51,589
U.S. government agency securities	190,323	-	(1,011)	189,312
Corporate debt securities	325,360	6	(362)	325,004
Total marketable securities available-for-sale	567,417	6	(1,518)	565,905
Total cash and cash equivalents, and marketable securities	$ 721,928	$ 6	$ (1,518)	$ 720,416
December 31, 2022				
Cash and cash equivalents:				
Cash	$ 29,586	$ -	$ -	$ 29,586
Money market funds	172,418	-	-	172,418
Total cash and cash equivalents	202,004	-	-	202,004
Marketable securities available-for-sale:				
U.S. treasuries	42,502	-	(194)	42,308
U.S. government agency securities	88,429	-	(397)	88,032
Corporate debt securities	292,865	12	(826)	292,051
Total marketable securities available-for-sale	423,796	12	(1,417)	422,391
Total cash and cash equivalents, and marketable securities	$ 625,800	$ 12	$ (1,417)	$ 624,395

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

	September 30, 2023	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 494,498	$ 493,376
Mature after one year through two years	72,919	72,529
	$ 567,417	$ 565,905

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. Unrealized losses are included in accumulated other comprehensive loss in stockholders' equity. Commencing with our adoption of ASC 326 on January 1, 2023, we determine whether a decline in the fair value of our AFS debt securities below their amortized cost basis (i.e., an impairment) is due to credit-related factors or noncredit-related factors. Any impairment that is not credit related is recognized in other comprehensive income (loss), net of applicable taxes. Credit-related impairments (if any) are recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Both the allowance and the adjustment to net income can be reversed if conditions change.

There were no realized gains or losses from the sale of marketable securities during each of the three and nine months ended September 30, 2023 and 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. During each of the three and nine months ended September 30, 2023, we did not record an allowance for credit losses, as management believes any such losses would be immaterial based on the investment-grade

credit rating for each of the investments as of September 30, 2023. As such, there have been no declines in fair value that have been identified as a credit-related impairment.

4. Inventories

The following table presents inventories (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 27,469	$ 25,517
Work-in-process	17,515	23,934
Finished goods	4,428	9,995
Total	$ 49,412	$ 59,446

5. Commitments and Contingencies

Leases

We lease our facilities in Emeryville, California and Düsseldorf, Germany. We lease and sublease certain manufacturing and office space with lease terms ranging from 3 to 12 years. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include options to renew or extend the lease for two successive five-year terms. These optional periods have not been considered in the determination of the right-of-use assets or lease liabilities associated with these leases as we did not consider the exercise of these options to be reasonably certain.

We also sublease one of our leased premises to a third party. Rent is subject to scheduled annual increases and the subtenant is responsible for certain operating expenses and taxes throughout the life of the sublease. The sublease term expires on March 31, 2031, unless earlier terminated, concurrent with the term of our lease. The subtenant has no option to extend the sublease term. Sublease income for the three and nine months ended September 30, 2023 was $2.0 million and $5.6 million, respectively. Sublease income for the three and nine months ended September 30, 2022 was $2.0 million and $5.7 million, respectively. Sublease income is included in other income (expense) in our condensed consolidated statements of operations. Rent received from the subtenant in excess of rent paid to the landlord shall be shared by paying the landlord 50% of the excess rent. The excess rent is considered a variable lease payment and the total estimated payments are being recognized as additional rent expense on a straight-line basis.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease expense	$ 1,392	$ 1,377	$ 4,172	$ 4,851

Cash paid for amounts included in the measurement of lease liabilities for each of the nine months ended September 30, 2023 and 2022 was $5.3 million and $5.1 million, respectively, and were 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):

	September 30, 2023	December 31, 2022
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 4,390	$ 3,631
Long-term portion of lease liabilities	30,680	32,801
Total operating lease liabilities	$ 35,070	$ 36,432

As of September 30, 2023, the maturities of our sublease income and operating lease liabilities were as follows (in thousands):

Years ending December 31,	Sublease Income	Operating Lease Liabilities
2023 (remaining)	$ 1,405	$ 1,873
2024	5,684	7,579
2025	5,854	6,954
2026	6,030	6,096
2027	6,211	6,026
Thereafter	21,500	21,171
Total	$ 46,684	49,699
Less:		
Present value adjustment		(14,629)
Total		$ 35,070

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

	September 30, 2023	December 31, 2022
Weighted average remaining lease term	6.8 years	7.6 years
Weighted average discount rate	10.1%	10.1%

Commitments

As of September 30, 2023 and December 31, 2022, our material non-cancelable purchase and other commitments for the supply of HEPLISAV-B totaled $39.8 million and $43.4 million, respectively.

On September 7, 2023 (the “Effective Date”), we entered into an agreement (the “Avecia Supply Agreement”) with Nitto Denko Avecia Inc. (“Avecia”) for the manufacture and supply of our CpG 1018 adjuvant using a specific production process. Under the Avecia Supply Agreement, Avecia has agreed to produce and supply to us quantities of CpG 1018 adjuvant ordered by us after the Effective Date. Subject to certain conditions in the Avecia Supply Agreement, we are obligated to purchase all of our annual volume requirements of CpG 1018 adjuvant from Avecia up to a specified production capacity. We may alternatively order CpG 1018 adjuvant produced using a different production process pursuant to the existing supply agreement between us and Avecia dated October 1, 2012 (the “2012 Agreement”). As of September 30, 2023, we have not placed any manufacturing orders under the Avecia Supply Agreement. As of September 30, 2023 and December 31, 2022, we have no non-cancelable purchase and other commitments for the supply of CpG 1018 adjuvant.

As of September 30, 2023, the aggregate principal amount of our convertible senior notes ("Convertible Notes") was $225.5 million, excluding debt discount of $3.1 million (see Note 7).

During 2004, we established a letter of credit with Deutsche Bank as security for our Düsseldorf lease in the amount of €0.2 million (Euros). The letter of credit remained outstanding through September 30, 2023 and was 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 September 30, 2023.

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, May 2022 and September 2023, we received $1.0 million from TriSalus because it met pre-commercialization milestones. We recorded the proceeds as gain on sale of assets in our condensed consolidated statements of operations. We paid Holdings $0.5 million in each of September 2021, May 2022 and October 2023. We included the payments in selling, general and administrative expenses in our condensed consolidated statements of operations. A liability of $0.5 million has been recorded under this agreement as of September 30, 2023 in relation to our payment to Holdings in October 2023.

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 (together with subsequent amendments, 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"). In May 2021, we entered into the first amendment to the CEPI Agreement. 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"). 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.

On April 27, 2023, we entered into a waiver and second amendment to the CEPI Agreement by and between us and CEPI (the "CEPI-Bio E Assignment Agreement"). Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of the outstanding Advance Payments for CpG 1018 Materials allocated to and ordered by Bio E under the CEPI Agreement and has assumed our previous rights to $47.4 million of Bio E accounts receivable.

Through September 30, 2023, we received Advance Payments totaling approximately $175.0 million pursuant to the CEPI Agreement, of which $67.3 million have been repaid and $47.4 million have been forgiven (as discussed above). As of September 30, 2023, remaining Advance Payments totaling $60.3 million in CEPI accrual long-term were reflected in our condensed consolidated balance sheets, representing the outstanding balance of the Advance Payments relating to the Clover Supply Agreement (as defined and discussed below). As of December 31, 2022, we recorded Advance Payments of $107.7 million included in CEPI accrual. There were no deferred revenue balances related to the CEPI Agreement as of September 30, 2023 and December 31, 2022.

Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited

In June 2021, we entered into an agreement with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (collectively, "Clover"), for the commercial supply of CpG 1018 adjuvant, for use with Clover's COVID-19 vaccine candidate, SCB-2019 (together with subsequent amendments, the "Clover Supply Agreement"). Under the Clover Supply Agreement, Clover committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Clover's commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant ("Clover Product"). The Clover Supply Agreement also provides terms for Clover to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In 2022 and 2023, we signed four amendments to the Clover Supply Agreement. The terms and conditions of the Clover Supply Agreement were operative through December 2022, and as of September 30, 2023, we had satisfied all delivery obligations thereunder.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay us 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. When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement, we recognize product revenue and a corresponding contract asset as our right to consideration is contingent on something other than the passage of time, as outlined above.

The contract asset of $71.3 million relating to Clover was included in other current assets as of December 31, 2022. The contract asset was subsequently reclassified to other assets (long term) and remains classified in other assets (long term) as of September 30,

2023. The contract asset was reclassified to other assets (long term) to reflect the timing of expected long term demand for CpG 1018 adjuvant for Clover Product.

Corresponding Advance Payments of $60.3 million relating to Clover are recorded in CEPI accrual long-term in our condensed consolidated balance sheets as of September 30, 2023. These Advance Payments may be repaid using cash collected from Clover or forgiven in accordance with the CEPI Agreement. We had no accounts receivable balance from Clover as of September 30, 2023 and December 31, 2022. We did not recognize CpG 1018 adjuvant net product revenue from Clover for each of the three and nine months ended September 30, 2023. We recognized CpG 1018 adjuvant product revenue, net of $87.5 million and $201.1 million, respectively, for each of the three and nine months ended September 30, 2022.

Biological E. Limited

In July 2021, we entered into an agreement (together with subsequent amendments, 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 committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine ("Bio E Product") with specified delivery dates in 2021 and the first quarter of 2022. The Bio E Supply Agreement also provides terms for Bio E to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In June 2022 and in October 2022, we entered into amendments to the Bio E Supply Agreement (the "Bio E Amendment No. 1" and the "Bio E Amendment No. 2," together the "Bio E Amendments"). The Bio E Amendments primarily established: (i) a new payment schedule for certain outstanding invoices related to the CEPI product to be the earlier of December 31, 2022, or receipt of certain amounts from Bio E from the Government of India in connection with their advance purchase agreement for CORBEVAX, and (ii) further modified the scope of the Bio E Supply Agreement, by reducing certain quantities of CpG 1018 adjuvant to be delivered. The terms and conditions of the Bio E Supply Agreement were operative through December 2022, and as of September 30, 2023, we had satisfied all delivery obligations thereunder.

As of September 30, 2023, we had no accounts receivable balance from Bio E. During the first quarter of 2023, we recorded an allowance for doubtful accounts of $12.3 million, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3 (defined below), and Bio E's dependence on cash collections from the Government of India, which have been delayed and significantly reduced in connection with the overall reduction in demand for CORBEVAX from the Government of India.

On April 26, 2023, we entered into a third amendment to the Bio E Supply Agreement (the "Bio E Amendment No. 3"), and on April 27, 2023, we entered into the CEPI-Bio E Assignment Agreement. Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to a liability for Advance Payments of $47.4 million (the "Bio E CEPI Advance Payments") for CpG 1018 Materials allocated to Bio E, and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Pursuant to the Bio E Amendment No. 3, we collected $14.5 million from Bio E (including $13.5 million in April 2023 and $1.0 million in August 2023). Accordingly, as of September 30, 2023, the CEPI-Bio E Assignment Agreement resulted in: (i) no accounts receivable balance, and (ii) the derecognition of $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

We did not recognize CpG 1018 adjuvant net product revenue from Bio E for each of the three and nine months ended September 30, 2023. We recognized CpG 1018 adjuvant net product revenue of $27.6 million and $146.0 million for the three and nine months ended September 30, 2022, 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 adjuvant for approximately $22.0 million over two and a half years. Under the agreement, we are conducting a Phase 2 clinical trial combining our CpG 1018 adjuvant with the DoD's rF1V vaccine. In July 2023, we executed a contract modification with the DoD to support advancement into a nonhuman primate challenge study, with the agreement now totaling $33.7 million through 2025. For the three and nine months ended September 30, 2023, we recognized revenue of $7.2 million and $14.5 million, respectively, which is included in other revenue in our condensed consolidated statements of operations. For the three and nine months ended September 30, 2022, we recognized revenue of $3.9 million and $6.6 million, respectively.

7. Convertible Notes

In May 2021, we issued $225.5 million of 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 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, beginning on November 15, 2021. 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:

- 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;
- 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;
- 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
- 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.

On October 1, 2023, the conditional conversion feature of the Convertible Notes was triggered as the last reported sale price of our common stock was more than or equal to 130% of the conversion price for at least 20 trading days in the period of 30 consecutive trading days ending on September 30, 2023 (the last trading day of the immediately preceding fiscal quarter), and therefore the Convertible Notes are currently convertible, in whole or in part, at the option of the holders between October 1, 2023 through December 31, 2023. Whether the Convertible Notes will be convertible following such period will depend on the continued satisfaction of this condition or another conversion condition in the future. As of November 2, 2023, we had not received any conversion notices. Since we have the election of repaying the Convertible Notes in cash, shares of our common stock, or a combination of both, we continued to classify the Convertible Notes as long-term debt on the condensed consolidated balance sheets as of September 30, 2023.

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.

We accounted for the Convertible Notes as a single liability in accordance with ASU 2020-06 - *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). As of September 30, 2023, the Convertible Notes were recorded at the aggregate principal amount of $225.5 million less unamortized issuance costs of $3.1 million as a long-term liability on the condensed consolidated balance sheets. As of September 30, 2023, the fair value of the Convertible Notes was $344.8 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. The debt issuance costs are amortized to interest expense over the contractual term of the Convertible Notes at an effective interest rate of 3.1%.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stated coupon interest	$ 1,409	$ 1,409	$ 4,227	$ 4,228
Amortization of debt issuance cost	282	273	838	812
Total interest expense	$ 1,691	$ 1,682	$ 5,065	$ 5,040

Capped Calls

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with one of the initial purchasers of the Convertible Notes and other financial institutions, totaling $27.2 million (the "Capped Calls"). The Capped Calls cover, subject to customary adjustments, the number of shares of our common stock that initially underlie the Convertible Notes (or 21,542,871 shares of our common stock). The Capped Calls have an initial strike price and an initial cap price of $10.47 per share and $15.80 per share, respectively, subject to certain adjustments. Conditions that cause adjustments to the initial strike price of the Capped Calls mirror conditions that result in corresponding adjustments to the conversion price of the Convertible Notes. The Capped Calls are expected to offset the potential dilution to our common stock as a result of any conversion of the Convertible Notes, subject to a cap based on the cap price.

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

8. Revenue Recognition

Disaggregation of Revenues

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

	Three Months Ended September 30, 2023			Three Months Ended September 30, 2022		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 62,318	$ -	$ 62,318	$ 37,508	$ -	$ 37,508
CpG 1018 adjuvant	-	-	-	-	126,307	126,307
Total product revenue, net	$ 62,318	$ -	$ 62,318	$ 37,508	$ 126,307	$ 163,815
Other revenue	7,196	-	7,196	3,877	43	3,920
Total revenues	$ 69,514	$ -	$ 69,514	$ 41,385	$ 126,350	$ 167,735

	Nine Months Ended September 30, 2023			Nine Months Ended September 30, 2022		
	U.S.	Non U.S.	Total	U.S.	Non U.S.	Total
Product revenue, net						
HEPLISAV-B	$ 162,209	$ -	$ 162,209	$ 90,057	$ 941	$ 90,998
CpG 1018 adjuvant	-	-	-	-	440,464	440,464
Total product revenue, net	$ 162,209	$ -	$ 162,209	$ 90,057	$ 441,405	$ 531,462
Other revenue	14,479	-	14,479	6,566	163	6,729
Total revenues	$ 176,688	$ -	$ 176,688	$ 96,623	$ 441,568	$ 538,191

Revenues from Major Customers and Collaboration Partners

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 Department of Defense, the Department of Veterans Affairs and retail pharmacies. All of our HEPLISAV-B sales in Germany are to one distributor.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Largest customer	27%	23%	25%	20%
Second largest customer	25%	19%	24%	18%
Third largest customer	18%	18%	17%	17%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Largest collaboration partner	0%	69%	0%	46%
Second largest collaboration partner	0%	22%	0%	33%
Third largest collaboration partner	0%	9%	0%	15%

Contract Balances

The following table summarizes balances and activities in HEPLISAV-B product revenue allowance and reserve categories for the nine months ended September 30, 2023 (in thousands):

	Balance at Beginning of Period	Provisions related to current period sales	Credit or payments made during the period	Adjustments related to prior periods	Balance at End of Period
Nine months ended September 30, 2023:					
Accounts receivable reserves (1)	$ 8,179	$ 42,949	$ (40,186)	$ (2,629)	$ 8,313
Revenue reserve accruals (2)	$ 10,552	$ 34,848	$ (27,528)	$ 2,297	$ 20,169

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

When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement to Clover and perform services under our agreement with the DoD, we recognize revenue and a corresponding contract asset as our right to consideration is conditioned on something other than the passage of time. See Note 6 for further discussion. The following table summarizes balances and activities in our contract asset account (in thousands):

	Balance at Beginning of Period	Additions	Subtractions	Reclassification (1)	Balance at End of Period
Nine months ended September 30, 2023:					
Contract asset, included in other current assets (2)	$ 71,965	$ 14,396	$ (13,175)	$ (71,307)	$ 1,879
Contract asset, included in other assets (long term)	$ -	$ -	$ -	$ 71,307	$ 71,307

(1) The Clover contract asset was reclassified to long term assets to reflect the timing of expected long term demand for CpG 1018 adjuvant for Clover Product. See Note 6 for further discussion.
(2) The $1.9 million of contract asset is derived from our agreement with the DoD.

9. Net Income (Loss) Per Share

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

For the calculation of diluted net income 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 net income (loss) and diluted net income per share computations for our common stock are calculated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator				
Net income (loss)	$ 14,293	$ 63,809	$ (6,608)	$ 225,423
Less: undistributed earnings allocated to participating securities	-	-	-	(291)
Net income (loss) attributable to common stockholders, basic	14,293	63,809	(6,608)	225,132
Add: undistributed earnings allocated to participating securities	-	-	-	291
Less: removal of change in fair value of warrant liability	-	-	-	(1,801)
Add: interest expense on convertible notes	1,268	1,262	-	3,780
Net income (loss) attributable to common stockholders, diluted	$ 15,561	$ 65,071	$ (6,608)	$ 227,402
Denominator				
Weighted average common stock outstanding, basic	128,988	127,062	128,515	125,997
Effect of dilutive shares:				
Stock-based compensation plans	3,665	2,933	-	2,784
Dilutive warrants	-	-	-	109
Convertible Notes (as converted to common stock)	21,543	21,543	-	21,543
Weighted average common stock outstanding, diluted	154,196	151,538	128,515	150,433

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Outstanding securities not included in diluted net income (loss) per share calculation:				
Stock options and stock awards	5,605	5,214	15,304	7,417
Convertible Notes (as converted to common stock)	-	-	21,543	-
Total	5,605	5,214	36,847	7,417

10. Common Stock and Warrants

Common Stock

As of September 30, 2023, there were 129,194,842 shares of our common stock outstanding.

We entered into an at-the-market Sales Agreement with Cowen and Company, LLC (“Cowen”) on August 6, 2020 and an amendment to such agreement on August 3, 2023 (the sales agreement as amended, the “2020 ATM Agreement”). Under the 2020 ATM Agreement, 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 $120.0 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 September 30, 2023, we had approximately $120.0 million remaining under the 2020 ATM Agreement.

Warrants

During the nine months ended September 30, 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. During the nine months ended September 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 January 2021, we adopted the Dynavax Technologies Corporation 2021 Inducement Award Plan ("2021 Inducement Plan"), pursuant to which we reserved 1,500,000 shares of common stock for issuance under the plan to be used exclusively for grants of awards to individuals who were not previously our employees or directors. In June 2021, we amended the 2021 Inducement Plan ("Amended 2021 Inducement Plan") to increase the number of shares of common stock reserved under the 2021 Inducement Plan to 3,250,000. The Amended 2021 Inducement Plan was terminated effective as of April 3, 2022 and, therefore, there are no shares of our common stock available for grant.

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 September 30, 2023, 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 seven years unless earlier terminated by the Board of Directors. As of September 30, 2023, there were 9,659,145 shares of common stock reserved for issuance under the Amended 2018 EIP.

Under our Amended 2018 EIP, we may grant stock options, RSUs, performance-based awards, and other awards that are settled in shares of our common stock. Our equity awards generally vest over a three-year period contingent upon continuous service and unless exercised, expire seven or ten years from the date of grant (or earlier upon termination of continuous service). Activity under our stock plans is set forth below:

Stock Options

The following table summarizes the activity of stock options for the nine months ended September 30, 2023:

	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, 2022	9,339	$ 10.70	4.61	$ 16,291
Options granted	1,968	11.14		
Options exercised	(556)	7.80		
Options cancelled:				
Options forfeited (unvested)	(83)	10.96		
Options expired (vested)	(260)	21.42		
Balance as of September 30, 2023	10,408	$ 10.66	4.38	$ 46,599
Vested and expected to vest as of September 30, 2023	10,211	$ 10.65	4.35	$ 45,949
Exercisable as of September 30, 2023	6,843	$ 10.17	3.64	$ 34,772

Restricted Stock Units

The following table summarizes the activity of RSUs for the nine months ended September 30, 2023:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2022	3,479	$ 11.00
Granted	2,497	11.16
Vested (1)	(1,456)	10.08
Forfeited	(218)	11.49
Non-vested as of September 30, 2023	4,302	$ 11.38

(1) Inclusive of approximately 582,838 RSUs for the nine months ended September 30, 2023, which were not converted into shares due to net share settlement in order to cover the required amount of employee withholding taxes. The value of the withheld shares was classified as a reduction to additional paid-in capital.

Market-based Performance Stock Units

We granted market-based performance restricted stock units ("PSUs") to certain executives. These PSUs vest upon a specified market condition. The summary of PSU activities for the nine months ended September 30, 2023 is as follows:

	Number of Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2022	193	$ 11.62
Granted	364	18.25
Non-vested as of September 30, 2023	557	$ 15.95

Performance-based Options

As of September 30, 2023, approximately 36,000 shares underlying performance-based options were outstanding.

Significant Assumptions in Estimating Fair Value

The fair value of each time-based 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 Units ("PSUs")	
	Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022
Weighted-average fair value per share	$ 8.61	$ -	$ 7.30	$ 7.97	$ 18.25	$ 11.62
Risk-free interest rate	4.2%	-	4.0%	2.01%	4.3%	1.7%
Expected life (in years)	4.5	-	4.5	4.5	2.9	2.9
Volatility	0.8	-	0.8	0.8	0.9	0.9

Stock-based Compensation

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods.

We have also granted performance-based equity awards to certain of our employees. For equity awards with performance-based vesting criteria, the fair value is amortized to expense when the achievement of the vesting criteria becomes probable. We recognized $0.7 million and $1.8 million of stock-based compensation expense for PSUs during the three and nine months ended September 30,

2023, respectively. We recognized $0.2 million and $0.6 million of stock-based compensation expense for PSUs during the three and nine months ended September 30, 2022, respectively.

The following table summarizes stock-based compensation expense recorded in each component of operating expenses in our condensed consolidated statements of operations, and amounts capitalized to our inventories (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 2,339	$ 1,532	$ 6,752	$ 4,271
Selling, general and administrative	7,320	6,019	21,353	17,043
Cost of sales - product	369	323	1,463	626
Inventories	659	739	1,715	2,248
Total	$ 10,687	$ 8,613	$ 31,283	$ 24,188

12. Income Taxes

We are subject to U.S. federal, state and foreign income taxes. For the three months ended September 30, 2023, we recorded an income tax benefit of approximately $(0.1) million. For the nine months ended September 30, 2023, we recorded a provision for income taxes of approximately $1.2 million. Our effective tax rate was approximately (1.0)% and (22.9)% for the three and nine months ended September 30, 2023, respectively. For the three and nine months ended September 30, 2022, we recorded a provision for income taxes of $0.3 million and $0.9 million, respectively. Our effective tax rate was approximately 0.4% for the nine months ended September 30, 2022. 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.

We have historically recorded our interim period provision for income taxes by applying our forecasted annual effective tax rate to year-to-date earnings and adjusting for discrete items. However, due to the level of forecasted provision for income taxes relative to the forecasted income used in computing the effective tax rate, the effective tax rate is highly sensitive to fluctuations in income and does not provide a reliable estimate for income taxes in the interim period. As such, we have computed our provision for income taxes for the three and nine months ended September 30, 2023 using an actual year-to-date tax calculation. We plan to revert back to applying our forecasted annual effective tax rate to year-to-date earnings and adjusting for discrete items once that method produces more reliable results.

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 September 30, 2023, 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, 2022.

Overview

We are a commercial stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. Our first marketed product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the United States, the European Union and Great Britain for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older. In May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. We also manufacture and sell CpG 1018 adjuvant, 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 utilizing CpG 1018 adjuvant. As of September 30, 2023, we have satisfied all delivery obligations under these global commercial supply agreements.

We are also 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 for Tdap and shingles, and a Phase 2 clinical trial and studies for plague in collaboration with and fully funded by the U.S. Department of Defense ("DoD"). Additionally, we are working to advance product candidates utilizing our CpG 1018 adjuvant through discovery efforts and through preclinical and clinical collaborations with third-party research organizations.

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., the European Union and Great Britain.

We have worldwide commercial rights to HEPLISAV-B and we market it in the United States, the European Union, and have marketing authorization in Great Britain. 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 for prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older. In May 2021, we entered into a commercialization agreement with Bavarian Nordic for the marketing and distribution of HEPLISAV-B in Germany, and in May 2022, we commenced commercial shipments of HEPLISAV-B in Germany. In March 2023, we received marketing authorization in Great Britain for HEPLISAV-B for the active immunization against hepatitis B virus infection caused by all known subtypes of hepatitis B virus in adults aged 18 years and older.

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 Department of Defense, the Department of Veterans Affairs and retail pharmacies. All of our HEPLISAV-B sales in Germany are to one distributor. For the three and nine months ended September 30, 2023, HEPLISAV-B product revenue, net was $62.3 million and $162.2 million, respectively.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

In January 2021, we entered into an agreement (together with subsequent amendments, 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 to the CEPI Agreement. The CEPI Agreement enables CEPI to direct the supply of

CpG 1018 adjuvant to CEPI partner(s). In exchange for reserving CpG 1018 adjuvant, CEPI has agreed to provide advance payments in the form of an interest-free, unsecured, forgivable loan (the "Advance Payments") of up to $176.4 million.

Through September 30, 2023, we have received Advance Payments totaling approximately $175.0 million pursuant to the CEPI Agreement, of which $67.3 million have been repaid and $47.4 million have been forgiven (as discussed below). As of September 30, 2023, remaining Advance Payments totaling $60.3 million were reflected in CEPI accrual long-term in our condensed consolidated balance sheets, representing the outstanding balance of the Advance Payments relating to the Clover Supply Agreement (as defined and discussed below). As of December 31, 2022, we recorded Advance Payments of $107.7 million included in CEPI accrual. There were no deferred revenue balances related to the CEPI Agreement as of September 30, 2023 and December 31, 2022.

On April 27, 2023, we entered into a waiver and second amendment to the CEPI Agreement by and between us and CEPI (the "CEPI-Bio E Assignment Agreement"). Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of the outstanding Advance Payments for CpG 1018 Materials allocated to and ordered by Bio E under the CEPI Agreement and has assumed our previous rights to $47.4 million of Bio E accounts receivable.

In June 2021, we entered into an agreement (together with subsequent amendments, the "Clover Supply Agreement") with Zhejiang Clover Biopharmaceuticals, Inc. and Clover Biopharmaceuticals (Hong Kong) Co., Limited (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 committed to purchase specified quantities of CpG 1018 adjuvant, at pre-negotiated prices pursuant to the CEPI Agreement, for use in Clover's commercialization of vaccines containing SCB-2019 and CpG 1018 adjuvant ("Clover Product"). The Clover Supply Agreement also provides terms for Clover to order additional quantities of CpG 1018 adjuvant beyond the quantities reserved by CEPI. In 2022 and 2023, we signed four amendments to the Clover Supply Agreement. The terms and conditions of the Clover Supply Agreement were operative through December 2022, and as of September 30, 2023, we had satisfied all delivery obligations thereunder.

For CpG 1018 adjuvant reserved for Clover under the CEPI Agreement, Clover is obligated to pay us 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. When we transfer control of CpG 1018 adjuvant that is reserved under the CEPI Agreement, we recognize product revenue and a corresponding contract asset as our right to consideration is contingent on something other than the passage of time, as outlined above.

Approximately $71.3 million relating to future amounts receivable representing a contract asset from Clover in connection with the CEPI Agreement are classified as other assets (long term) as of September 30, 2023. The classification as long term reflects the timing of expected utilization of CpG 1018 adjuvant for Clover Product expected to be sold under the CEPI Agreement. Corresponding Advance Payments of $60.3 million relating to Clover are recorded in CEPI accrual long-term in our condensed consolidated balance sheets as of September 30, 2023. These Advance Payments may be repaid using cash collected from Clover or forgiven in accordance with the CEPI Agreement. We had no accounts receivable balance from Clover as of September 30, 2023 and December 31, 2022. We did not recognize CpG 1018 adjuvant net product revenue from Clover for either of the three or nine months ended September 30, 2023. We recognized CpG 1018 adjuvant product revenue, net of $87.5 million and $201.1 million for the three and nine months ended September 30, 2022, respectively.

In July 2021, we entered into an agreement (together with subsequent amendments, 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 previously committed to purchase specified quantities of CpG 1018 adjuvant at pre-negotiated prices pursuant to the CEPI Agreement, for use in Bio E's commercialization of its CORBEVAX vaccine. 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 2022 and October 2022, we entered into two amendments to the Bio E Supply Agreement (the "Bio E Amendment No. 1" and the "Bio E Amendment No. 2," respectively, together the "Bio E Amendments"). The Bio E Amendments primarily established: (i) a new payment schedule for certain outstanding invoices related to the CEPI product to be the earlier of December 31, 2022, or receipt of certain amounts from Bio E from the Government of India in connection with their advance purchase agreement for CORBEVAX, and (ii) further modified the scope of the Bio E Supply Agreement, by reducing certain quantities of CpG 1018 adjuvant to be delivered. The terms and conditions of the Bio E Supply Agreement were operative through December 2022, and as of September 30, 2023, we had satisfied all delivery obligations thereunder.

As of September 30, 2023, we had no accounts receivable balance from Bio E. During the first quarter of 2023, we recorded an allowance for doubtful accounts of $12.3 million, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3 (defined below), and Bio E's dependence on cash collections from the Government of India, which have been delayed and significantly reduced in connection with the overall reduction in demand for CORBEVAX from the Government of India.

On April 26, 2023, we entered into a third amendment to the Bio E Supply Agreement (the “Bio E Amendment No. 3”), and on April 27, 2023, we entered into the CEPI-Bio E Assignment Agreement. Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to a liability for Advance Payments of $47.4 million (the “Bio E CEPI Advance Payments”) for CpG 1018 Materials allocated to Bio E, and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Pursuant to the Bio E Amendment No. 3, we collected $14.5 million from Bio E (including $13.5 million in April 2023 and $1.0 million in August 2023). Accordingly, as of September 30, 2023, the CEPI-Bio E Assignment Agreement resulted in: (i) no accounts receivable balance, and (ii) the derecognition of $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

We did not recognize CpG 1018 adjuvant net product revenue from Bio E for each of the three and nine months ended September 30, 2023. We recognized CpG 1018 adjuvant net product revenue of $27.6 million and $146.0 million for the three and nine months ended September 30, 2022, respectively.

Past performance is not a reliable indicator of future performance, however, and future revenue and associated profitability may therefore vary significantly. Specifically, as our CpG 1018 adjuvant customers have purchased a significant quantity of CpG 1018 adjuvant as part of their initial COVID-19 vaccine development inventory, we currently expect minimal to no CpG 1018 adjuvant revenue for the remainder of 2023 associated with these arrangements. See Note 6 - Collaborative Research Development and License Agreements, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1, “Financial Statements (unaudited)” of this Quarterly Report on Form 10-Q.

Other

In May 2021, we issued $225.5 million aggregate principal amount of 2.50% convertible senior notes due in 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 capped call transactions (the "Capped Calls").

The Convertible Notes are eligible for optional conversion during the fourth quarter of fiscal 2023. As of November 2, 2023, we had not received any conversion notices.

In connection with the issuance of the Convertible Notes, we entered into the Capped Calls with one of the initial purchasers and other financial institutions, totaling $27.2 million. 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.

Critical Accounting Estimates

We prepare our unaudited 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 nine months ended September 30, 2023, 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, 2022.

Results of Operations

Revenues

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

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

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2022 to 2023		Nine Months Ended September 30,		Increase (Decrease) from 2022 to 2023	
Revenues:	**2023**	**2022**	**$**	**%**	**2023**	**2022**	**$**	**%**
HEPLISAV-B	$ 62,318	$ 37,508	$ 24,810	66 %	$ 162,209	$ 90,998	$ 71,211	78 %
CpG 1018 adjuvant	-	126,307	(126,307)	(100)%	-	440,464	(440,464)	(100)%
Total product revenue, net	62,318	163,815	(101,497)	(62)%	162,209	531,462	(369,253)	(69)%
Other revenue	7,196	3,920	3,276	84 %	14,479	6,729	7,750	115 %
Total revenues	$ 69,514	$ 167,735	$ (98,221)	(59)%	$ 176,688	$ 538,191	$ (361,503)	(67)%

HEPLISAV-B product revenue increased by $24.8 million and $71.2 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, primarily due to higher volume driven by continued improvement in market share, particularly in the integrated delivery networks and retail segments, and growth in the U.S. hepatitis-B vaccine market related to the Advisory Committee on Immunization Practices ("ACIP") universal recommendation.

There was no CpG 1018 adjuvant product revenue for either of the three or nine months ended September 30, 2023, as we have completed all obligations and product delivery under our CpG 1018 adjuvant collaboration agreements as of December 31, 2022.

As our CpG 1018 adjuvant customers have purchased a significant quantity of CpG 1018 adjuvant as part of their initial COVID-19 vaccine development inventory, we currently expect minimal to no CpG 1018 adjuvant revenue for the remainder of 2023. Long-term demand for CpG 1018 vaccine adjuvant supporting COVID-19 vaccines will be highly dependent on each customer's ability to commercialize in respective territories and geographies where their respective COVID-19 vaccine is approved for use.

Other revenue primarily includes revenue from our agreement with the DoD. We recognized $7.2 million and $14.5 million of revenue from our agreement with the DoD for the three and nine months ended September 30, 2023, respectively. The increase was primarily driven by the advancement into a nonhuman primate challenge study initiated in August 2023.

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 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 September 30,		Increase (Decrease) from 2022 to 2023		Nine Months Ended September 30,		Increase (Decrease) from 2022 to 2023	
Cost of Sales - Product	**2023**	**2022**	**$**	**%**	**2023**	**2022**	**$**	**%**
HEPLISAV-B	$ 13,229	$ 11,511	$ 1,718	15 %	$ 41,478	$ 27,740	$ 13,738	50 %
CpG 1018 adjuvant	-	49,823	(49,823)	(100)%	-	156,925	(156,925)	(100)%
Total cost of sales - product	$ 13,229	$ 61,334	$ (48,105)	(78)%	$ 41,478	$ 184,665	$ (143,187)	(78)%

HEPLISAV-B cost of sales-product increased by $1.7 million and $13.7 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022. The increase was primarily due to higher sales volume driven by continued improvement in HEPLISAV-B market share, offset by lower per-unit manufacturing costs as the result of previous process improvements.

There was no CpG 1018 adjuvant cost of sales-product for each of the three and nine months ended September 30, 2023, as we have completed all obligations and product delivery under our CpG 1018 adjuvant collaboration agreements as of December 31, 2022.

Research and Development Expenses

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 expenses (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2022 to 2023		Nine Months Ended September 30,		Increase (Decrease) from 2022 to 2023	
Program Expenses:	**2023**	**2022**	**$**	**%**	**2023**	**2022**	**$**	**%**
HEPLISAV-B development	$ 403	$ 959	$ (556)	(58)%	$ 2,077	$ 3,064	$ (987)	(32)%
CpG 1018 adjuvant development	385	487	(102)	(21)%	1,260	2,182	(922)	(42)%
Tdap	1,575	2,902	(1,327)	(46)%	5,246	6,742	(1,496)	(22)%
Shingles	3,180	3,549	(369)	(10)%	11,330	9,337	1,993	21 %
Plague (1)	3,393	1,834	1,559	85 %	6,867	3,025	3,842	127 %
Other	2,234	1,187	1,047	88 %	5,485	3,693	1,792	49 %
Other research and development expenses:								
Facility costs	607	512	95	19 %	1,750	1,432	318	22 %
Non-cash stock-based compensation	2,339	1,532	807	53 %	6,752	4,271	2,481	58 %
Total research and development	$ 14,116	$ 12,962	$ 1,154	9 %	$ 40,767	$ 33,746	$ 7,021	21 %

(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 are conducting a Phase 2 clinical trial and studies 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.

Research and development expenses increased by $1.2 million and $7.0 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022.

- HEPLISAV-B development costs decreased due to lower clinical costs following the completion of the HEPLISAV-B dialysis study and lower other HEPLISAV-B related development costs. The first quarter of 2023 also included a $1.1 million expense related to an engineering run performed for product testing purposes.
- CpG 1018 adjuvant development costs decreased as supply agreements were fulfilled across various vaccine platforms utilizing CpG 1018 adjuvant in 2022.
- Tdap costs decreased as we completed the Phase 1 clinical trial in early 2023, offset by an increase in activities to support initiation of a human challenge study expected in 2024.
- Shingles program costs increased as we completed activities related to the Phase 1 clinical trial, including presentation of study results at a medical conference in June 2023, and due to trial start up activities, including manufacturing of clinical materials to support the expected initiation of a Phase 1/2 clinical trial in the first half of 2024.
- Plague program costs increased compared to the previous year following our initiation of part 2 of the Phase 2 clinical trial in early 2023 and advancement into a nonhuman primate challenge study in August 2023.
- Other program costs increased as we continue to invest in product candidates utilizing our CpG 1018 adjuvant through discovery efforts and through preclinical and clinical collaborations.
- Non-cash stock-based compensation expense increased due to the need for increased headcount to support the advancement of our clinical vaccine programs.

As we continue to progress our clinical-stage pipeline, we expect research and development expenses to continue to represent a substantial portion of our expenses and to continue to increase in future years.

Selling, General and Administrative Expenses

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2022 to 2023		Nine Months Ended September 30,		Increase (Decrease) from 2022 to 2023	
Selling, General and Administrative:	**2023**	**2022**	**$**	**%**	**2023**	**2022**	**$**	**%**
Compensation and related personnel costs	$ 15,170	$ 12,755	$ 2,415	19 %	$ 46,082	$ 38,865	$ 7,217	19 %
Outside services	12,753	9,738	3,015	31 %	35,435	33,555	1,880	6 %
Legal costs	894	438	456	104 %	2,495	1,590	905	57 %
Facility costs	1,916	3,092	(1,176)	(38)%	6,302	9,340	(3,038)	(33)%
Non-cash stock-based compensation	7,320	6,019	1,301	22 %	21,353	17,043	4,310	25 %
Total selling, general and administrative	$ 38,053	$ 32,042	$ 6,011	19 %	$ 111,667	$ 100,393	$ 11,274	11 %

Selling, general and administrative expenses increased by $6.0 million and $11.3 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022.

- Compensation and related personnel costs and non-cash stock-based compensation costs increased due to continued headcount and personnel investments in our general and administrative and field sales functions to support business growth and increased travel.
- Outside services increased due to more targeted commercial and marketing efforts to increase market share and maximize the opportunities presented by the ACIP's universal recommendation.
- Legal costs increased due to ongoing general legal activities supporting our continued growth and intellectual property activities supporting our clinical-stage pipeline.
- Facility costs decreased due to lower rent expense, as one of our leases expired in 2022, and lower depreciation expense related to furniture and fixtures fully depreciated in 2022.

We expect our selling, general and administrative expenses to increase in future periods to support the overall growth in our business.

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 $5.0 million upon closing of the transaction and $4.0 million in December 2020 as reimbursement for certain clinical trial expenses. In addition, we could receive up to an additional $250.0 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 each of September 2023 and May 2022, we received payment of $1.0 million from TriSalus because it met a pre-commercialization milestone. In each of the third quarter of 2023 and second quarter of 2022, we recognized a gain on sale of SD-101 assets of $1.0 million in our condensed consolidated statements of operations.

Bad Debt Expense

We recorded $12.3 million of bad debt expense during the nine months ended September 30, 2023 in connection with the allowance for doubtful accounts of $12.3 million recorded with respect to outstanding accounts receivable from Bio E and relating to CpG 1018 Materials delivered under the Bio E Supply Agreement and CEPI Agreement. The allowance for doubtful accounts was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to Bio E Amendment No. 3, and Bio E's dependence on cash collections from the Government of India, which have been delayed significantly by the Government of India.

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 of our 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.

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

	Three Months Ended September 30,		Increase (Decrease) from 2022 to 2023		Nine Months Ended September 30,		Increase (Decrease) from 2022 to 2023	
	2023	2022	$	%	2023	2022	$	%
Interest income	$ 8,462	$ 2,562	$ 5,900	230 %	$ 22,437	$ 3,588	$ 18,849	525 %
Interest expense	$ (1,691)	$ (1,685)	$ 6	0 %	$ (5,065)	$ (5,048)	$ 17	0 %
Sublease income	$ 1,993	$ 2,026	$ (33)	(2)%	$ 5,584	$ 5,660	$ (76)	(1)%
Change in fair value of warrant liability	$ -	$ -	$ -	-	$ -	$ 1,801	$ (1,801)	(100)%
Other	$ 266	$ (208)	$ 474	(228)%	$ 218	$ (63)	$ 281	(446)%

- Interest income increased due to higher yields and balances in our marketable securities portfolio.
- The change in the fair value of warrant liability resulted primarily from the warrants expiring in February 2022. There were no warrants outstanding as of September 30, 2023.
- 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

We are subject to U.S. federal, state and foreign income taxes. For the three months ended September 30, 2023, we recorded an income tax benefit of approximately $(0.1) million. For the nine months ended September 30, 2023, we recorded a provision for income taxes of approximately $1.2 million. Our effective tax rate was approximately (1.0)% and (22.9)% for the three and nine months ended September 30, 2023, respectively. For the three and nine months ended September 30, 2022, we recorded a provision for income taxes of $0.3 million and $0.9 million, respectively. Our effective tax rate was approximately 0.4% for the nine months ended September 30, 2022. 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 September 30, 2023 and the full valuation allowance we established on our federal, state, and certain foreign deferred tax assets.

Liquidity and Capital Resources

As of September 30, 2023, we had $720.4 million in cash and 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 and cash equivalents, and short-term marketable securities as of September 30, 2023, and anticipated revenues from HEPLISAV-B 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 September 30, 2023, we had no CEPI-related net accounts receivable relating to Bio E. CEPI-related accruals and contract assets relating to Clover totaled $60.3 million and $71.3 million as of September 30, 2023, respectively. As of September 30, 2023, the CEPI-related accrual relating to Clover may be repaid using cash to be collected from Clover or forgiven in accordance with the CEPI Agreement.

On April 26, 2023, we entered into the Bio E Amendment No. 3, and on April 27, 2023, we entered into the CEPI-Bio E Assignment Agreement. Pursuant to the CEPI-Bio E Assignment Agreement, CEPI has forgiven the entirety of remaining amounts outstanding relating to the Bio E CEPI Advance Payments for CpG 1018 Materials allocated to Bio E and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable. The CEPI-Bio E Assignment Agreement resulted in no accounts receivable balance from Bio E. Pursuant to the Bio E Amendment No. 3, we collected $13.5 million from Bio E in April 2023 and subsequently collected the remaining $1.0 million in August 2023. The Bio E Amendment No. 3 provides for additional future payment of either $5.5 million in the event that Bio E receives at least $125.0 million, or $12.3 million in the event that Bio E receives at least $250.0 million in future payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025. These additional amounts are not considered collectible until the achievement of these future milestones.

As of September 30, 2023, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $3.1 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. See Note 7 – Convertible Notes, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1, “Financial Statements (unaudited)” of this Quarterly Report on Form 10-Q.

We entered into an at-the-market Sales Agreement with Cowen and Company, LLC (“Cowen”) on August 6, 2020 and an amendment to such agreement on August 3, 2023 (the sales agreement as amended, the “2020 ATM Agreement”). Under the 2020 ATM Agreement, 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 $120.0 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 September 30, 2023, we had approximately $120.0 million remaining under the 2020 ATM Agreement.

Prior to January 1, 2021, we incurred net losses in each year since our inception. For the three and nine months ended September 30, 2023, we recorded a net income of $14.3 million and a net loss of $6.6 million, respectively. For the three and nine months ended September 30, 2022, we recorded a net income of $63.8 million and $225.4 million, respectively. We cannot be certain that sales of our products, and the revenue from our other activities will be sustainable. Further, we expect to continue to incur substantial expenses as we continue investing in commercialization of HEPLISAV-B, advancing our research and development pipeline, and investing in 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 interest 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 or at all. 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. 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.

During the nine months ended September 30, 2023, we generated $86.8 million of cash from our operations, which consisted of a net loss of $6.6 million, a $39.8 million net increase from non-cash items, which included stock-based compensation, depreciation and amortization, amortization of right-of-use assets, non-cash interest expense, accretion of discounts on marketable securities and bad debt expense, and approximately $54.6 million net cash increase from changes in operating assets and liabilities, which included a decrease of $40.9 million in accounts and other receivables, net. By comparison, during the nine months ended September 30, 2022, we generated $27.8 million of cash from our operations, which consisted of our net income of $225.4 million, a $42.3 million net increase from non-cash items, which included stock-based compensation, change in fair value of warrant liability, non-cash interest expense, depreciation and amortization, amortization of right-of-use assets, accretion of discount on marketable securities and inventory write-off, and approximately $239.0 million net cash decrease from changes in operating assets and liabilities, which included $262.5 million decrease in deferred revenue, $19.0 million decrease in accrued liabilities and other liabilities, $146.9 million decrease in prepaid manufacturing, which converted into CpG 1018 adjuvant inventory during 2022, $55.8 million increase in inventories, net and $21.1 million decrease in CEPI accrual. Overall, cash provided by our operations during the nine months ended September 30, 2023 increased by $59.0 million compared to the same period in September 30, 2022. Net cash provided by operating activities is also impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the nine months ended September 30, 2023, net cash used in investing activities was $133.7 million compared to $283.0 million of cash used in investing activities for the nine months ended September 30, 2022. Cash used in investing activities during the nine months ended September 30, 2023 included $132.3 million of net purchases of marketable securities compared to $278.5 million of net purchases of marketable securities for the nine months ended September 30, 2022.

During the nine months ended September 30, 2023, net cash used in financing activities was $0.4 million. During the nine months ended September 30, 2022, net cash provided by financing activities was $19.4 million. Cash used in financing activities for the nine months ended September 30, 2023 included $6.3 million for the payments of taxes related to net share settlement of RSUs, partially offset by proceeds received from the exercise of options and from share purchases under our employee stock purchase plan for $5.9 million combined. Cash provided by financing activities for the nine months ended September 30, 2022 included net proceeds of $8.5 million from warrants exercised and $10.9 million proceeds from options exercised and stock purchases under our employee stock purchase plan.

Contractual Obligations

As of September 30, 2023, our material non-cancelable purchase commitments for the supply of HEPLISAV-B totaled $39.8 million.

On September 7, 2023 (the “Effective Date”), we entered into an agreement (the “Avecia Supply Agreement”) with Nitto Denko Avecia Inc. (“Avecia”) for the manufacture and supply of our CpG 1018 adjuvant using a specific production process. Under the Avecia Supply Agreement, Avecia has agreed to produce and supply to us quantities of CpG 1018 adjuvant ordered by us after the Effective Date. Subject to certain conditions in the Avecia Supply Agreement, we are obligated to purchase all of our annual volume requirements of CpG 1018 adjuvant from Avecia up to a specified production capacity. We may alternatively order CpG 1018 adjuvant produced using a different production process pursuant to the existing supply agreement between us and Avecia dated October 1, 2012 (the “2012 Agreement”). As of September 30, 2023, we have not placed any manufacturing orders under the Avecia Supply Agreement. As of September 30, 2023 and December 31, 2022, we have no non-cancelable purchase and other commitments for the supply of CpG 1018 adjuvant.

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, 2022.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2023, 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, 2022.

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 our future efforts to obtain regulatory approval, advance our collaborations and our pipeline, 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, 2022 that was filed with the Securities and Exchange Commission on February 23, 2023.

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 carefully consider the risks and uncertainties described herein as part of your evaluation of an investment in our securities:

- HEPLISAV-B has been approved in the United States, the European Union and Great Britain and launched in the United States and Germany, 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 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 have incurred annual net losses in most years since our inception and anticipate that we could continue to incur significant losses if we do not successfully commercialize HEPLISAV-B, launch new products and/or significant sales of our CpG 1018 adjuvant do not resume. 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.
- 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 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.
- 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 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.
- 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.
- 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”), EU and comparable foreign 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.
- HEPLISAV-B and all of our clinical 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.
- 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.

- 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.
- 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.
- 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.
- As we plan for the broader commercialization of our HEPLISAV-B vaccine and for the requisite capacity to manufacture our CpG 1018 adjuvant, our financial commitments for manufacturing and supply capacity might outpace actual demand for our products.
- We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates outside of the U.S., the European Union and Great Britain, 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 rely on clinical research organizations ("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 a biopharmaceutical company, we engage CROs to conduct clinical studies, and failure by us or our CROs to conduct a clinical study in accordance with good clinical practices ("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.
- If third parties 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.
- Our stock price is subject to volatility, and your investment may suffer a decline in value.
- 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.
- Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Conversion of the Convertible Notes (defined below) may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.
- 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.

Risks Related to our Business and Capital Requirements

HEPLISAV-B has been approved in the United States, the European Union and Great Britain and launched in the United States and Germany, 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 United States and Germany. Successful commercialization of HEPLISAV-B in those countries or elsewhere will require significant resources and time, and there can be no certainty that we will succeed in these efforts. We have also received approval from the European Union and Great Britain for HEPLISAV-B. 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 through distribution, and the timing, trajectory, rate and sustainability for growth in sales is unpredictable, and we may not be successful in commercializing HEPLISAV-B in the long term. 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 are continually expanding our field sales force. It will take time for our expanded teams to generate significant sales momentum, if it does so at all. Although we have had some success growing and developing our field sales force following the launch of HEPLISAV-B, there is no guarantee that we will be able to generate sales at the same or improved rates going forward, if at all. In addition, retention of capable sales personnel may be more difficult for us compared to our competitors, as we focus on a single product offering. We must retain our sales force in order for HEPLISAV-B to maintain or expand its 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 dialysis patients, one of our targeted patient populations. We do not yet have approval to market the regimen for dialysis. 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 on dialysis, 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 able to enter new markets ourselves, 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 distribution in Germany, the product's 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 these new markets. 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.

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, who currently only markets 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 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.*

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 year ended December 31, 2022, we recognized $587.7 million of CpG 1018

adjuvant revenue. However, our CpG 1018 adjuvant supply agreements expired at the end of 2022, and we are not expecting these customers to place substantial new orders for CpG 1018 adjuvant during 2023. As a result, we currently expect minimal to no CpG 1018 adjuvant revenue for 2023, which will cause our future revenue and cash flow to decrease materially relative to prior periods. Similarly, if demand for HEPLISAV-B decreases from recent trends for any reason, that could also cause unexpected fluctuations in our quarterly and annual operating results.

The occurrence and timing of any transfer of control of product sold to customers can also be difficult to predict, and the recognition of revenue can vary widely depending on timing of product deliveries and satisfaction of other obligations. As an example, any revenue we do receive from sales of our CpG 1018 adjuvant has been and will continue to be difficult to predict, if it materializes at all. We generally require customers to place orders for CpG 1018 adjuvant with at least six months lead time and to make an advance payment toward the finished order. Where we receive such advance payments, we record such payments as deferred revenue until we have delivered the adjuvant and met all criteria to recognize revenue. In accordance with our stated revenue policy, we historically recorded 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. During the nine months ended September 30, 2023, we did not receive any advanced payments from any of our customers to purchase CpG 1018 adjuvant. Our COVID collaborators in many cases have purchase agreements with government agencies. If our collaborators do not receive payment from these agencies for any past or future adjuvant orders, our ability to collect our own receivables may be adversely affected. For example, as of September 30, 2023, we had recorded an allowance for doubtful accounts of $12.3 million in connection with our accounts receivable balance due from Bio E, which was determined by assessing changes in Bio E's credit risk, contemplation of ongoing negotiations relating to an amendment to the supply agreement with Bio E, and Bio E's dependence on cash collections from the Government of India, which have been delayed significantly by the Government of India.

We have in the past, and may in the future, adjust delivery dates, allow cancellations or give concessions on outstanding receivables in certain circumstances to better enable our customers to meet their obligations, which can impact the timing or amount of our revenue recognition, cash collections and transfer of control. For example, in August and October 2022, we entered into amendments to the Clover Supply Agreement, which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018 adjuvant deliverable under the agreement and/or reduce amounts receivable, which we originally intended to deliver in accordance with a purchase order previously issued by Clover, and apply prepayments Clover previously made to us as payment for portions of pending outstanding purchase orders. In January 2023, we entered into another amendment to the Clover Supply Agreement to modify the price per dose of CpG 1018 adjuvant paid by Clover for adjuvant used in finished vaccine doses sold through government procurement programs relating to the booster program promoted by the China National Health Commission. In addition, in April 2023, we entered into the Bio E Amendment No. 3 and the CEPI-Bio E Assignment Agreement, pursuant to which CEPI forgave amounts outstanding relating to the Bio E CEPI Advance Payments and assumed our previous rights to collect $47.4 million of Bio E accounts receivable. Among other things, the CEPI-Bio E Assignment Agreement resulted in no accounts receivable from Bio E, the derecognition of $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments, and certain additional future payments contingent on Bio E's receipt of payments from the Government of India associated with its CORBEVAX product on or before August 15, 2025.

Moreover, our revenue or operating expenses in one period may be disproportionately higher or lower relative to the others due to, among other factors, revenue fluctuations or increases in expenses as we invest in our pipeline. 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 have incurred annual net losses in most years since our inception and anticipate that we could continue to incur significant losses if we do not successfully commercialize HEPLISAV-B, launch new products and/or significant sales of our CpG 1018 adjuvant do not resume.*

We have generated limited revenue from the sale of products and, prior to January 1, 2021, had incurred losses in each year since we commenced operations in 1996. While we recognized net income of $14.3 million for the three months ended September 30, 2023, we recognized net loss of $6.6 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $930.8 million.

With our investment in the launch and commercialization of HEPLISAV-B in the United States and Germany, 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. Further, we expect to increase research and development costs as we invest in our pipeline. We are already 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 and studies for plague in collaboration with and fully funded by the U.S. Department of Defense (“DoD”). We expect research and development costs to increase further if we add additional programs to our pipeline.

While sales of CpG 1018 adjuvant generated significant revenue during the COVID-19 pandemic, we do not expect that such revenues will continue in the long term at the same scale, and we currently expect minimal to no CpG 1018 adjuvant revenue in 2023. 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.

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 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 United States, the European Union and Great Britain. Competition in European markets could affect our success or the success of our distributor in that market as well. 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, Bavarian Nordic A/S, Emergent BioSolutions, Inc., Novavax, Inc., Medicago Inc., Valneva, AstraZeneca plc, Moderna, Inc., Johnson & Johnson, VBI, Biontech SE and Curevo Vaccine. 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 properly manage our business, obtain financing as needed, enter into collaborative arrangements, advance or sell our product candidates or generate revenues.

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. We may continue to do the same for any additional products we might add in the future through natural internal expansion of our pipeline, or in transactions with an external third-party or parties. The FDA approved our pre-filled syringe 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 ourselves, 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. Qualifying a second source could take more than a year to accomplish. 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 manufacture of HEPLISAV-B and for sale to our collaborators and (ii) our pre-filled syringe presentation. In 2021, we qualified a second supplier to manufacture CpG 1018 adjuvant for our COVID business, but we have a limited operating relationship with them. 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 potentially 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.

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, collaboration partners, 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. Any failure to accomplish any of these activities could prevent us from successfully increasing or maintaining the same level of commercial growth as we have seen in the past.

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 future revenues, if any.*

Even if we obtain regulatory approval for our product candidates, such as our U.S., European Union and Great Britain 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 products;
- 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 products or product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenue could be significantly impaired.

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, as applicable, 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. To the extent we add new products in the future, these risks could be exacerbated by the added complexity of managing multiple product lines.

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. In circumstances where our collaborators do not purchase as much adjuvant as we anticipate or they delay placing orders or taking certain deliveries, there can be a negative impact on 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 September 30, 2023, all five of our collaborators have received emergency use authorization and one of them has received full approval from an applicable regulatory authority for a vaccine for COVID-19 containing our adjuvant. Even with approvals being received by our collaborators, whether for emergency use or full authorization, their ability to deliver, sell and collect on receivables is not guaranteed. This could, in turn, impact our own ability to collect receivables.

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 adjuvant. This could, in turn, adversely impact the demand for CpG 1018 adjuvant over the long term, which could 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 HEPLISAV-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, the willingness of third-party payors to reimburse for our products is uncertain. We will have to charge a price for HEPLISAV-B or any other products we commercialize 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.

The United Kingdom ("UK") and many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in European countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency (“MHRA”) is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (“SMC”), the National Institute for Health and Care Excellence (“NICE”), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products. For example, in March 2021, the UK introduced the Innovative Licensing and Access Pathways (“ILAP”) which brings together the MHRA, NICE, SMC and the All Wales Therapeutics and Toxicology Centre, to accelerate time to market for certain innovative products.

Legislators, policymakers and healthcare insurance funds in the EU and the United Kingdom may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that COVID-19 placed on national healthcare systems of European countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We are subject to ongoing FDA, EU and comparable foreign 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. Also, we received data from the autoimmune portion of our observational study, and the data indicated no association between HEPLISAV-B and any of the studied autoimmune diseases. We are also conducting a pregnancy registry study to provide information on outcomes following pregnancy exposure to HEPLISAV-B. This study requires significant effort and resources, and failure to timely conduct and/or complete the study 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, if authorized, or expose additional safety concerns that may result in product liability and withdrawal of a product or products 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 and the United Kingdom. For example, we are required to submit periodic safety update reports to the European Medicines Agency ("EMA") and the MHRA 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. In addition, in accordance with our EU marketing authorization for HEPLISAV-B, HEPLISAV-B is subject to additional monitoring, meaning that it is monitored more intensively than other medicinal products. We may have similar obligations for future products if and when approved. Non-compliance with European Union or United Kingdom 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, the European Union and Great Britain. 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, if authorized, 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.

HEPLISAV-B and all of our clinical 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.

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 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 Biologics License Application (“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 is 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.

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.

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"), Ethics Committee or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available vaccine or component 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. Failure of one or more product candidates to successfully advance through to approval and licensure could result in the loss off unrecoverable costs expended and impact our ability to generate future revenue from such products, either of which, or both of which, could have an adverse impact on our business.

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.

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 September 30, 2023, we had $720.4 million in cash and cash equivalents, and marketable securities. Prior to January 1, 2021, we incurred net losses in each year since our inception. While we recorded net income of $14.3 million for the three months ended September 30, 2023, we recorded net loss of $6.6 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $930.8 million. We cannot be certain that sales of our products, and the revenue from our other activities will 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 may 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 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. 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.

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

As we manage our production capabilities for HEPLISAV-B and CpG 1018 adjuvant to support recent market share gains and other initiatives, we have been, and in the future will be, required to make significant financial commitments at our contract manufacturing organizations ("CMOs"), including minimum purchase commitments and prepayments of purchase orders to facilitate the procurement of raw materials and the incurrence of various manufacturing costs. Because of minimum or advance purchase commitments and uncertainty about the expected demand for HEPLISAV-B or CpG 1018 adjuvant, the financial commitments we make to our CMOs to support manufacturing may not be recovered in their entirety, or at all, if our customers do not ultimately purchase from us at expected volumes, or other concessions are made by us. As a result, we could end up making financial commitments that we never recover if demand for HEPLISAV-B or CpG 1018 adjuvant does not materialize in the volumes we are expecting or at all. This may require us to record certain charges or write-offs in one or more fiscal periods, which in turn could result in significant, unexpected fluctuations in our quarterly and annual operating results, and potentially have a material adverse effect on our results of operations, and financial condition.

In order to maintain the requisite capacity to manufacture our CpG 1018 adjuvant to support our COVID-19 collaborations and other potential vaccine collaborations and initiatives, we have been in the past, and in the future may be, required to make significant financial commitments to reserve manufacturing capacity at our CMOs. 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. Similarly, prepayments of purchase orders may not be recoverable if we do not ultimately require the entire volume subject to the applicable purchase order.

As a result of the foregoing, we could end up making financial commitments that we never recover if demand for our products do not materialize in the volumes we are expecting, or at all. This may require us to record certain charges or write-offs in one or more fiscal periods, which in turn could result in significant, unexpected fluctuations in our quarterly and annual operating results, and potentially have a material adverse effect on our results of operations, and financial condition. For example, in August and October 2022, we entered into amendments to the Clover Supply Agreement, which, among other things, modified the scope of the Clover Supply Agreement to reduce certain quantities of CpG 1018 adjuvant that we originally intended to deliver in accordance with a purchase order previously issued by Clover. As a result of the concessions made in the amendments to the Clover Supply Agreement, prior financial commitments made to certain CMOs to manufacture quantities of CpG 1018 adjuvant to fulfill the original Clover purchase order, and reduced demand for CpG 1018 adjuvant, we recorded write-offs of $13.9 million of CpG 1018 adjuvant raw materials inventory and $20.4 million of finished goods inventory during the year ended December 31, 2022. Relating to our Bio E Supply Agreement, we entered into an amendment and an assignment agreement in April 2023, pursuant to which (i) CEPI forgave the entirety of remaining amounts outstanding relating to the Bio E CEPI Advance Payments for CpG 1018 Materials allocated to Bio E and has assumed our previous rights to collect $47.4 million of Bio E accounts receivable, (ii) we collected $14.5 million from Bio E, resulting in no accounts receivable balance as of September 30, 2023, and (iii) we derecognized a $47.4 million CEPI accrual in connection with the Bio E CEPI Advance Payments. It is possible we may have similar write-offs in the future.

We may develop, seek regulatory approval for and market HEPLISAV-B or any other product candidates outside of the U.S., the European Union and Great Britain, 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., the European Union and Great Britain. Developing, seeking regulatory approval for and marketing our product candidates outside of the U.S., the European Union and Great Britain in new jurisdictions where we don't currently have approval

could impose substantial costs, impose burdens on our personnel, and divert 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, the European Union and Great Britain, 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 existing regulatory approval in the United States, the European Union and Great Britain. 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 products or product candidates, which would impair our ability to generate revenues.

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

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

As a biopharmaceutical company, we engage 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, IRBs and the Ethics Committees 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 or Ethics Committee 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 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.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.*

We have incurred significant net operating losses ("NOLs") during our history, and despite recent profitability, may not be able to achieve sustained profitability over the long term. Unused U.S. federal NOLs for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation enacted in 2017, as modified by legislation enacted in 2020, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the aforementioned U.S. tax law provisions.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as one or more stockholders or groups of stockholders who own at least 5% of our stock increasing their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period, the corporation’s ability to use its pre-change NOL carryforwards to offset its post-change income or taxes may be limited. We have experienced ownership changes as a result of shifts in our stock ownership in the past, and in the future it is possible that we may be deemed to have experienced additional ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Tax law changes could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Tax Cuts and Jobs Act of 2017, the 2020 Coronavirus Aid, Relief, and Economic Security Act, and the 2022 Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of the foregoing tax legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under past or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data we may collect about trial participants in connection with clinical trials, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018 (“CCPA”) requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 (“CPRA”), which became operative January 1, 2023, will expand the CCPA’s requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts and may increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union’s General Data Protection Regulation (“EU GDPR”), the United Kingdom’s General Data Protection Regulation (“UK GDPR”), Brazil’s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or “LGPD”)

(Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.

In the ordinary course of business, we may transfer personal data from the EEA and other jurisdictions to the United States or other countries. We may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some regulators in the EEA have ordered certain companies to suspend or permanently cease certain transfers of data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

On October 7, 2022, President Biden signed an Executive Order on "Enhancing Safeguards for United States Signals Intelligence Activities," which implements into United States law the agreement in principle announced in March 2022 on a new EU-U.S. Data Privacy Framework. However, if this new transatlantic data transfer framework is not adopted and we are unable to continue to rely on standard contractual clauses or alternative mechanisms of data transfers from the EEA to the United States, this may materially and adversely affect our business, financial condition, and results of operations.

Additional privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may be subject to contractual obligations and policies related to data privacy and security. We may also be bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU GDPR and UK GDPR, require our customers to impose specific contractual restrictions on their service providers.

Data privacy and security laws are quickly changing, and compliance (and any perceived non-compliance) is costly. Although we endeavor to comply with all applicable data privacy and security obligations, these obligations are quickly changing in an increasingly stringent fashion, creating some uncertainty as to how to comply. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations, including our clinical trials; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our 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, 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 knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- 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 our 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.

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

We have applied for, and in some cases have received, grants that, if and when received, may involve pricing or other restrictions.

We have applied for, and in some cases have received, grants from various charitable, philanthropic and other organizations that, if and when received, may come with certain pricing requirements, global access requirements, reporting requirements or other covenants that require us to make the funded product available worldwide and on a nondiscriminatory basis. For example, we received such an initial grant from the Bill and Melinda Gates Foundation in 2020 to help fund the potential scale-up of production of our CpG 1018 adjuvant that may be required in the event the CpG 1018 adjuvant is included in any approved and commercially available vaccine, whether a COVID-19 vaccine or otherwise. Covenants in these types of grants 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.

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. In addition, the ACA has been subject to various health reform measures. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how any such challenges and additional healthcare reform measures by the Biden administration 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 until 2032 unless additional Congressional action is taken. 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, 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, the U.S. Department of Health and Human Services ("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, the IRA, among other things, (i) directs HHS to negotiate the price of certain drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug pricing negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

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.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and

reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that COVID-19 placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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, and other equivalent foreign systems, some of which could further limit coverage and reimbursement of products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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

In September 2021, we entered into an agreement with the DoD relating to the conduct of a clinical trial and studies 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 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 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 with 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 and scope 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 administrative 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 collaborators 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 may decrease, and we may be unable to realize any commercial benefit from the development of our vaccine candidates.

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., and worldwide, 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. Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing us and our collaborators' ability to protect our products.

Our HEPLISAV-B vaccine 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 vaccine and the use of CpG 1018 adjuvant in vaccines, and trade secret protection and confidentiality and other agreements to protect our interests in proprietary know-how related to HEPLISAV-B vaccine and CpG 1018 adjuvant. 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 adjuvant 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 adjuvant 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 and be in a position to diligently control patent prosecution, or enforce our rights. If we are unable to adequately obtain patent protection or enforce our other proprietary rights relating to CpG 1018 adjuvant, we may be unable to realize any 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 CpG 1018 adjuvant. We also 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 or our collaborators 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 or our collaborators 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. 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 adjuvant. 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;
- 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 may be subject to claims that our employees or consultants have used or disclosed trade secrets or other proprietary information of their former employers or clients, thus putting our intellectual property at risk;
- our reliance on trade secret protection and confidentiality and other agreements may not be sufficient to protect our interests and proprietary know-how related to our products and processes; and
- it may be found that we or our collaborators have not complied with various procedural, document submission, fee payment and other requirements imposed by patent offices, and our patent protection could be reduced or eliminated.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that may not be directed to what is considered to be patentable subject matter, 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.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees or consultants may have been previously employed in other biopharmaceutical companies, including our competitors or potential competitors. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or engagements. Although no claims against us are currently pending, we may be subject to claims that these employees or consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. Our standard practice is to require each of our collaborators, commercial partners, employees, consultants and advisors to enter into an agreement before beginning their employment, consulting or advisory relationship with us that in general provides that the individuals must keep confidential and not disclose to other parties any of our confidential information developed or learned by the individuals during the course of their relationship with us except in limited circumstances. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions, which could result in substantial costs which could severely harm our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications are due to be paid to the United States Patent and Trademark Office and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdictions, and in such an event, our competitors might be able to enter the market.

Risks Related to our Common Stock

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

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

- impact of COVID-19 on our HEPLISAV-B 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, to the extent needed;
- 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.

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. Changes in the broader macroeconomic condition, including historically high inflation, changes in interest rates, impact of COVID-19 or any future pandemic or endemic and instances of geopolitical instability, such as that resulting from the conflict between Russia and Ukraine, can and have caused changes in market prices, notwithstanding a lack of fundamental change in the underlying business models or prospects of 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 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 $120.0 million. As of September 30, 2023, we had approximately $120.0 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 therefore or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture governing the Convertible Notes or to pay any cash payable on future conversions of the Convertible Notes as required by the indenture governing the Convertible Notes would constitute a default under the indenture governing the Convertible Notes. A default under the indenture governing the Convertible Notes or the occurrence of a fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes could constitute an event of default under any agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

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

As of October 1, 2023, the holders of Convertible Notes are entitled to convert their Convertible Notes at any time during the fourth quarter of fiscal 2023 at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

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

The conversion of some or all of the Convertible Notes to shares of common stock may dilute the ownership interests of our stockholders. As of October 1, 2023, the holders of Convertible Notes are entitled to convert their Convertible Notes at any time during the fourth quarter of fiscal 2023 at their option. 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 Calls 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, or other future products we may attempt to commercialize, 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 and achieving profitability.

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

Our business operations are subject to interruption by natural disasters and other catastrophic events beyond our control, including, but not limited to, earthquakes, hurricanes, fires, droughts, tornadoes, electrical blackouts, public health crises and pandemics, war, terrorism, bank failures 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 COVID-19, 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. Furthermore, during the peak of the COVID-19 pandemic there was a significantly reduced utilization of all adult vaccines (other than COVID-19 vaccines), including a reduced utilization of HEPLISAV-B.

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

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

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

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support business processes as well as internal and external communications. In addition, our dependence on information technology systems has intensified because many of our critical business activities are now being conducted remotely in our remote-first work environment. 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 customers, suppliers, or third-party service providers which operate critical business systems to process sensitive information in a variety of contexts 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), online and offline fraud, 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. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

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). If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

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, (d) significant interruptions in our operations, or (e) 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 EU GDPR and UK 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.

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 equivalent foreign authorities and international authorities warned 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.

Adverse developments affecting the financial services industry may have adverse consequences on our business, financial condition and stock price.*

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

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	Indenture between Company and U.S. Bank National Association, as trustee, dated May 13, 2021	4.1	8-K	May 13, 2021	001-34207	
4.4	Form of Global Note, representing Dynavax Technologies Corporation's 2.50% Convertible Senior Notes due 2026	4.2	8-K	May 13, 2021	001-34207	
10.1^	Supply Agreement, effective as of September 7, 2023, by and between Company and Nitto Denko Avecia Inc.					X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

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

^ 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 Company has determined that the information is both not material and is the type that the Company treats as private or confidential.

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

SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: November 2, 2023

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

Date: November 2, 2023

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

Date: November 2, 2023

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

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

Exhibit 10.1

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT is effective as of September 7, 2023 (the "***Effective Date***") and is made by and between **Dynavax Technologies Corporation**, having an office at 2100 Powell Street, Suite 720, Emeryville, CA 94608 ("***CUSTOMER***") and **Nitto Denko Avecia Inc.** ("***AVECIA***"), having an office at 125 Fortune Boulevard, Milford, MA 01757. CUSTOMER and AVECIA are sometimes referred to herein individually as a "***Party***" and collectively as "***Parties***".

Recital

WHEREAS, AVECIA has supplied to CUSTOMER a certain product identified by CUSTOMER as CpG 1018 pursuant to that certain Master Services Agreement by and between the Parties dated February 24, 2016, as amended (the "***MSA***"), and Scopes of Work thereto, as amended ("***SOWs***"), and that certain Supply Agreement between the Parties dated October 1, 2012, as amended (the "***2012 Supply Agreement***");

WHEREAS, it is the intention of the Parties that: (a) AVECIA produce the quantities of Product (defined below) in liquid bulk formulation that are subject to outstanding orders submitted pursuant to the MSA and related SOWs prior to the Effective Date (the "***MSA Outstanding Quantities***") using the Manufacturing Process (defined below), and supply the MSA Outstanding Quantities to CUSTOMER, in accordance with the MSA, related SOWs and Sections 7.2-7.6 and 11.8 of this Agreement; (b) this Supply Agreement will be the operative and governing document with respect to the supply of all quantities of Product, other than the MSA Outstanding Quantities, ordered by CUSTOMER for production using the Manufacturing Process during the term of this Agreement; and (c) the 2012 Supply Agreement will continue to be the operative and governing document with respect to the supply of Product produced using the [*] "Current Process" (as such term is defined in the 2012 Supply Agreement).

NOW, INTENDING TO BE LEGALLY BOUND, IT IS HEREBY AGREED as follows:

1. DEFINITIONS

The terms in this Agreement with initial letters capitalized or all letters capitalized, as applicable, whether used in the singular or plural, shall have the meaning set forth or cross referenced in this Section 1 below (and derivative forms of such terms shall be interpreted accordingly):

1.1***"2012 Supply Agreement"*** has the meaning set forth in the Recitals.

1.2***"Affiliate"*** means any person, corporation or other entity which Controls, is Controlled by or is under common Control with, a Party to this Agreement.

1.3***"Agreement"*** means this Supply Agreement with all Exhibits, Schedules, and Appendices, as may be amended.

1.4***"Annual Volume Requirements"*** means all requirements of CUSTOMER and its Affiliates and CUSTOMER Product Licensees for Product in the Territory for any calendar year during the Term.

1.5***"Applicable Laws"*** means the applicable provisions of any and all national, supranational, regional, state, and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, Regulatory Authority, or governmental agency or authority having jurisdiction over the performance of AVECIA's obligations under this Agreement.

1.6***"Applicable Price"*** shall have the meaning set forth in Section 4.1.

1.7***"AVECIA"*** shall have the meaning set forth in the preamble to this Agreement.

1.8***"AVECIA-Owned Project IP"*** shall have the meaning set forth in Section 15.2.

1.9***"Batch"*** means a batch of Product using the Manufacturing Process [*] that is intended to be of uniform character and quality and is produced by synthesis [*], as defined by the applicable Master Batch Record.

1.10***"Batch Records"*** means, with respect to any Batch of Product, a final, executed production and control record prepared in accordance with 21 CFR 211.188.

1.11[***]

1.12***"Capacity Allocation"*** means [*] of Product manufactured during any calendar year; provided, however, that, if CUSTOMER during any calendar year during the Term purchases Product in a quantity which is [*], the Parties, in good faith and if appropriate, will agree on [*].

1.13***"Certificate of Analysis"*** or ***"CoA"*** means a document identified as such, that (a) is provided by AVECIA and signed by an employee designated by AVECIA as having responsibility for the issuance of such certificate certifying that a particular Batch of Product to be Delivered hereunder conforms to the Specifications and that the testing methods applied to such Batch of Product provide accurate results and (b) sets forth the analytical test results obtained from testing of a representative sample of such Batch against the

Specifications. The CoA shall include, but not be limited to, Product name, lot number, Specifications, test results for the specific Batch, a reference to the test method, date of manufacture, date of release and date for retesting.

1.14***"Certificate of Compliance"*** or ***"CoC"*** means a document identified as such, that is provided by AVECIA and signed by an employee designated by AVECIA as having responsibility for the issuance of such certificate, certifying that a particular Batch of Product was manufactured in accordance with GMP, the applicable Manufacturing Process for such Product, and Applicable Laws.

1.15***"CFR"*** means the United States Code of Federal Regulations.

1.16***"Confidential Information"*** means any technical, business, financial and other information of a confidential nature disclosed (whether disclosed in writing, orally, by way of sample or by any other means and whether directly or indirectly) by or on behalf of either Party (the "***Disclosing Party***") or any of its Representatives to the other Party (the "***Receiving Party***") or any of its Representatives. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, [*] shall be deemed CUSTOMER's Confidential Information, with respect to which CUSTOMER shall be deemed the Disclosing Party and AVECIA shall be deemed the Receiving Party. For the avoidance of doubt and subject to the exceptions as to what information constitutes Confidential Information of a Party set forth in Section 14 herein, [*] are CUSTOMER's Confidential Information.

1.17***"Control"*** (and, with a correlative meaning, ***"Controlled by"***) means having the power to vote more than fifty percent (50%) of the voting shares or other voting interests of another entity or the right to vote for or appoint a majority of the board of directors or other governing body of another entity, or otherwise having the direct or indirect power to direct or cause the direction of the management and policies of another entity.

1.18***"CUSTOMER"*** shall have the meaning set forth in the preamble to this Agreement.

1.19***"CUSTOMER Demand Forecast"*** shall have the meaning set forth in Section 5.1.

1.20***"CUSTOMER Materials"*** shall have the meaning set forth in Section 8.2.

1.21"***CUSTOMER Product Licensee***" means any Third Party that is granted, directly or indirectly, a license or similar right to market or sell the Product or any product containing, or to be administered in combination with, the Product.

1.22"***CUSTOMER's Purchase Obligations***" shall have the meaning set forth in Section 3.1.

1.23***"CUSTOMER-Owned Project IP"*** shall have the meaning set forth in Section 15.2.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

1.24***"CUSTOMER Records"*** shall have the meaning set forth in Section 11.5.

1.25***"Defective Product"*** means any Product supplied hereunder (or, in the case of the MSA Outstanding Quantities, pursuant to the MSA and related SOWs) that fails to conform to the Product Requirements.

1.26***"Delivery"*** (and its derivatives) shall have the meaning set forth in Section 6.2.

1.27***"Documentation"*** means the documents to be provided by AVECIA to CUSTOMER with each shipment of Product, including the Certificate of Analysis and Certificate of Compliance for each Batch of Product included in such shipment.

1.28***"Effective Date"*** shall have the meaning set forth in the preamble to this Agreement.

1.29***"Extended Term"*** shall have the meaning set forth in Section 2.1.

1.30***"Facility"*** means AVECIA's GMP manufacturing facility located in Milford, MA.

1.31***"FDA"*** means the U.S. Food and Drug Administration, or any successor entity thereto.

1.32***"Firm Take or Pay Obligation"*** shall have the meaning set forth in Section 5.1.1.

1.33***"GMP"*** means applicable current good manufacturing practices and standards for the production of pharmaceutical products, as set forth in (a) 21 CFR Parts 210, 211 and 610, (b) Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, (c) EudraLex Volume 4 of the Rules Governing Medicinal Products in the European Union, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, (d) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and (e) all relevant regulations or guidance for WHO Prequalification; in each case (clauses (a)–(e) above), as amended, supplemented or superseded from time to time; and with the agreement of AVECIA, other comparable laws and regulations of any competent regulatory authority applicable to Product and its manufacture.

1.34***"Independent Intellectual Property"*** shall have the meaning set forth in Section 15.1.

1.35***"Initial Term"*** shall have the meaning set forth in Section 2.1.

1.36***"Intellectual Property"*** means (a) patents, patent applications, all provisional, divisional, continuations, renewals, continuations-in-part, re-examinations, patents of additions, supplementary protection certificates, extensions, letters of patent, registration or confirmation patents and reissues with respect to any patents described in the foregoing clauses, and (b) any Know-How, data, technology, works of authorship, copyrights,

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

industrial property and technical information, and all intellectual property and other rights in and to any of the foregoing.

1.37 ***"Know-How"*** means proprietary information, inventions, discoveries, designs, developments, techniques, materials, processes, manufactures, compositions of matter or methods of use and trade secrets, whether or not patentable or copyrightable.

1.38 ***"Latent Defect"*** means a defect that exists at the time of Delivery of Product pursuant to this Agreement (or, in the case of the MSA Outstanding Quantities, pursuant to the MSA and related SOWs) and causes such Product to be Defective Product, which defect is not discoverable upon receipt by CUSTOMER but is discovered at a later time.

1.39 ***"Manufacturing Process"*** means [*] manufacturing process being used as of the Effective Date for the production of Product as set forth in the Batch Records.

1.40 ***"MSA"*** shall have the meaning set forth in the Recital to this Agreement.

1.41 ***"MSA Outstanding Quantities"*** shall have the meaning set forth in the Recital to this Agreement.

1.42 ***"Order Invoice"*** shall have the meaning set forth in Section 7.1.

1.43 ***"Party"*** shall have the meaning set forth in the preamble to this Agreement.

1.44 ***"Permits"*** shall have the meaning set forth in Section 9.1.

1.45 ***"[*]"*** and ***"[*] Adjustment"*** shall have the meanings set forth in Section 4.3.

1.46 ***"Product"*** shall mean CUSTOMER's proprietary CpG oligodeoxynucleotide referred to by CUSTOMER as CpG 1018.

1.47 ***"Product Requirements"*** means the requirements relating to the process development, process validation, manufacturing, quality control and quality assurance services to be performed hereunder (or, in the case of the MSA Outstanding Quantities, under the MSA and related SOWs) as required by (a) Applicable Laws, including GMP, (b) the Specifications, (c) this Agreement and (d) the Quality Agreement.

1.48 ***"Quality Agreement"*** means the Quality Agreement dated March 16, 2021 between the Parties, as it may be amended from time to time.

1.49 ***"Quarterly Volume Requirements"*** means all requirements of CUSTOMER and its Affiliates and CUSTOMER Product Licensees for Product in the Territory for any calendar quarter during the Term.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

1.50***"Records"*** shall have the meaning set forth in Section 11.5

1.51***"Regulatory Authority"*** means the FDA or any other competent government agency, regulatory authority or other administrative body, including the EMA and WHO, responsible for regulating or otherwise exercising authority with respect to the development, manufacture, sale, promotion, marketing, distribution, use, import, export, pricing or reimbursement of medicinal products in the Territory.

1.52***"Representative"*** means, with respect to each Party, each of such Party's Affiliates, and each of the directors, officers, managers, employees, agents or other authorized representatives of such Party and its Affiliates.

1.53***"Retention Samples"*** shall have the meaning set forth in Section 6.3.

1.54***"SOWs"*** shall have the meaning set forth in the Recital to this Agreement.

1.55***"Specifications"*** means the specifications set forth on Product Specification Document PS-000213 approved by the Parties, as such may be modified in writing from time to time by CUSTOMER with the approval of AVECIA, such approval not to be unreasonably withheld, delayed or conditioned.

1.56***"Term"*** shall have the meaning set forth in Section 2.1.

1.57***"Territory"*** means worldwide.

1.58***"Third Party"*** means any person or entity other than a Party or any of its Affiliates.

1.59***"Third Party Infringement Claim"*** shall have the meaning set forth in Section 15.5.

1.60***"Transfer Taxes"*** shall have the meaning set forth in Section 4.4.

2. TERM

2.1This Agreement is effective as of the Effective Date and shall remain in effect for a period of eight (8) years from the Effective Date (such period, the "***Initial Term***"). The Initial Term shall be automatically extended for additional successive terms of [*] years each (the "***Extended Term***"), unless either Party provides written notice to the other Party (a) at least [*] months, in the case of notice by CUSTOMER to AVECIA, or (b) at least [*] months, in the case of notice by AVECIA to CUSTOMER, prior to the expiration of the Initial Term or Extended Term (as applicable), stating that it is terminating this Agreement at the end of such Initial Term or Extended Term (the Initial Term and any and all Extended Terms, the "***Term***").

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3. PURCHASE OF VOLUME REQUIREMENTS; CAPACITY ALLOCATION; FAILURE TO SUPPLY; AFFILIATES AND CUSTOMER PRODUCT LICENSEES.

3.1Subject to the terms and conditions of this Agreement, CUSTOMER shall purchase from AVECIA, and AVECIA shall manufacture and supply to CUSTOMER, all of its Annual Volume Requirements up to the Capacity Allocation (the "***CUSTOMER's Purchase Obligations***"). [*]. To effectuate such intention, CUSTOMER and AVECIA shall meet as appropriate, but at least [*], to address CUSTOMER's non-binding good faith estimate of such Volume Requirements to be supplied by AVECIA during the next succeeding [*] month period or such longer period, as appropriate, to enable AVECIA to better understand the likelihood of CUSTOMER's Annual Volume Requirements exceeding the Capacity Allocation during any calendar year during the Term.

3.2AVECIA shall have and maintain throughout the Term the ability and capacity to manufacture at the Facility quantities of Product equal to the Capacity Allocation in each calendar year and [*] of the Capacity Allocation of Product in each calendar quarter). To the extent that any CUSTOMER Demand Forecast forecasts Annual Volume Requirements in excess of the Capacity Allocation for a calendar year, AVECIA shall [*], which [*] within [*] days of AVECIA's receipt of such CUSTOMER Demand Forecast. If AVECIA [*], CUSTOMER may [*], and [*] during the applicable calendar year. In the event that CUSTOMER's Quarterly Volume Requirements for a calendar quarter are in excess of [*] of the Capacity Allocation of Product (a "**Quarterly Excess of Product**"), AVECIA will manufacture and supply CUSTOMER with such Quarterly Excess of Product [*], subject to the Capacity Allocation and the provisions of the second sentence of this Section 3.2. CUSTOMER shall [*] to the extent [*] and, to the extent requested by CUSTOMER, AVECIA will [*].

3.3If AVECIA is unable to supply at least [*] of the [*] of Product for [*] and such shortfall in supply is not made up by AVECIA [*], CUSTOMER, upon written notice to AVECIA, will [*].

3.4AVECIA shall accept purchase orders for Product hereunder solely from CUSTOMER and shall not accept any purchase order for Product, or supply or offer to supply, or sell or offer to sell, Product to any CUSTOMER Product Licensee without the express prior written consent of CUSTOMER on a case-by-case basis, which may be withheld in CUSTOMER's absolute discretion. CUSTOMER shall [*] submit, and shall [*], all purchase orders for Product [*] hereunder.

3.5AVECIA agrees on behalf of itself and its Affiliates that, during the Term, [*] in each case without [*]. In addition, AVECIA agrees on behalf of itself and its Affiliates that, both during and after the Term, [*].

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3.6For avoidance of doubt (a) all quantities of Product ordered by CUSTOMER after the Effective Date for production using the Manufacturing Process shall be ordered pursuant to, and governed exclusively by the terms and conditions of, this Agreement; and (b) all quantities of Product ordered by CUSTOMER after the Effective Date for production using the [*] "**Current Process**" (as such term is defined in the 2012 Supply Agreement) shall be ordered pursuant to, and governed exclusively by the terms and conditions of, the 2012 Supply Agreement.

4. PRICE

4.1The price to be paid to AVECIA for quantities of Product ordered by CUSTOMER in accordance with all applicable terms and conditions of this Agreement, including all Product Requirements, shall be as set forth in Section 4.2 (the "***Applicable Price***"), subject to adjustment of such Applicable Price as set forth in this Section 4.3.

4.2Except as otherwise expressly set forth below in this Section 4.2, the Applicable Price of Product will be based on the following table:

[*]	**[*]** **[*]**
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]
[*]	$[*]

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[*]	$[*]
[*]	$[*]
[*]	$[*]

** All orders of Product of [*] shall be ordered by CUSTOMER [*], provided that CUSTOMER shall [*].

The Applicable Price for Product purchased in a calendar year shall be initially based on [*] in any such calendar year as set forth in the CUSTOMER Demand Forecast [*], subject to adjustment as provided in Section 7.1.2.

4.3The Applicable Price will be inflated or deflated annually (beginning as of May 1, 2024, and each anniversary date thereafter during the Term) in line with [*]. The adjustment shall be equal to the change in the [*] between the [*] and the [*] (the "***[*] Adjustment***"). For example, [*]. The appropriate adjustment in Applicable Price shall be effectuated [*], with the applicable adjustment in the Applicable Price of any Product purchased in such calendar prior to such [*] being available. Any such adjustment to the Applicable Price shall apply to all purchases of Product by CUSTOMER beginning as of [*].

4.4The prices chargeable to CUSTOMER, its Affiliate(s) and CUSTOMER Product Licensee(s) exclude any applicable sales, use, consumption, value added or excise taxes duties, tariffs and other similar assessments which may be imposed by any governmental authority on the sale to CUSTOMER (other than with respect to any income, corporate or similar taxation on AVECIA) ("***Transfer Taxes***"); provided, however, that the Parties shall cooperate and take any lawful and reasonable steps necessary to reduce or eliminate any Transfer Taxes.

5. FORECASTS AND ORDERS; DELAY

5.1Subject to the provisions of Section 3.1 regarding Capacity Allocation, [*] after the [*] during the Term, beginning with the [*], CUSTOMER shall provide to AVECIA a written forecast of CUSTOMER's Delivery requirements for Product ([*]) during the [*] beginning as of the [*] (each, a "***CUSTOMER Demand Forecast***"). (For example, the CUSTOMER Demand Forecast to be issued [*] shall be for the period that [*]. Within [*] of AVECIA's receipt of a CUSTOMER Demand Forecast, AVECIA shall confirm to CUSTOMER in writing [*] for up to [*] of the Capacity Allocation of Product [*]. In addition, if the quantity of Product set forth [*] in a CUSTOMER Demand Forecast exceeds [*] of the Capacity Allocation of Product, [*], and [*], commits to meet, [*] of the Capacity Allocation of Product set forth for [*] of such CUSTOMER Demand Forecast. Without [*], if AVECIA believes [*] for [*] a CUSTOMER Demand Forecast, AVECIA shall so notify CUSTOMER in writing within [*] of AVECIA's receipt thereof.

5.1.1 The forecasted quantities with respect to [*] of the CUSTOMER Demand Forecasts provided by CUSTOMER to AVECIA shall constitute (a) [*] period or (ii) [*], and (b) a firm commitment of AVECIA to Deliver at least [*] of such forecasted quantities during [*] period. Notwithstanding the foregoing, if the forecasted quantity for [*] of a CUSTOMER Demand Forecast exceeds [*] of the Capacity Allocation, and AVECIA notifies CUSTOMER in writing [*] of AVECIA's receipt of such CUSTOMER Demand Forecast that [*] of the Capacity Allocation, then the applicable portion of such excess quantity indicated in AVECIA's notice shall [*]. The forecasted quantities with respect to [*] of such CUSTOMER Demand Forecasts shall be [*].

5.1.2 For clarity, CUSTOMER is [*] under this Agreement, except to the extent that [*].

5.1.3 If CUSTOMER fails [*] to submit a CUSTOMER Demand Forecast within the time set forth in this Section 5.1, [*] shall be [*]. If the failure to submit such CUSTOMER Demand Forecast [*], the [*] shall [*] for [*] until the [*].

5.1.4 In the event that AVECIA [*], AVECIA shall promptly inform CUSTOMER, and the Parties, in good faith, will agree on [*] of AVECIA so informing CUSTOMER, [*] and, [*].

5.1.5 Except as otherwise agreed by the Parties in writing, CUSTOMER shall submit a purchase order for [*] at least [*] for such Product set forth in the CUSTOMER Demand Forecast. [*] following AVECIA's receipt of any purchase order, AVECIA shall notify CUSTOMER of [*]; provided that AVECIA shall (i) accept any purchase order [*] pursuant to Section 5.1 and (ii) [*] pursuant to Section 5.1. If AVECIA [*], CUSTOMER shall [*], which [*].

5.1.6 All purchase orders are subject to the terms of this Agreement, and any provision of a purchase order that conflicts with the terms of this Agreement shall not have any force and effect. No modification or amendment to this Agreement shall be affected by, or result from, the receipt, acceptance, signing or acknowledgment by either Party of any purchase order, quotation, invoice, shipping documents or other business form.

6. RELEASE; DELIVERY; STORAGE; TITLE

6.1In accordance with the Quality Agreement, AVECIA shall test and release or cause to be tested and released by Third Party testing facilities specified in the Quality Agreement and audited by AVECIA, Product manufactured pursuant to this Agreement. AVECIA shall deliver to CUSTOMER the Documentation for Product in accordance with the Quality Agreement. AVECIA shall inform CUSTOMER of the discovery of any failure of Product

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to conform to the Product Requirements as a result of such testing or otherwise during or after manufacture thereof. AVECIA shall not Deliver to CUSTOMER any Product that AVECIA knows does not conform to the Product Requirements without CUSTOMER's prior written consent.

6.2Product will be delivered [*] (INCOTERMS 2020) [*] ("***Delivery***"). Title and risk of loss in Product shall pass to CUSTOMER, its Affiliate or expressly authorized CUSTOMER Product Licensee, as the case may be, [*].

6.3AVECIA shall properly store and retain appropriate samples (identified by batch number) of Product that its supplies under this Agreement in conditions and for times consistent with Product Requirements and to permit appropriate or required internal recordkeeping, stability testing, regulatory checks, and references (collectively, the ***"Retention Samples"***). AVECIA will notify CUSTOMER before disposing of any Retention Samples, and CUSTOMER will have the option of having such Retention Samples delivered to CUSTOMER or its designee. Upon CUSTOMER's request, AVECIA will provide CUSTOMER reasonable access to such Retention Samples without additional charge.

6.4Each Product Delivered hereunder will be [*]in accordance with the applicable Product Requirements or as otherwise agreed by the Parties in writing. [*]. CUSTOMER understands and agrees that [*].

7. INVOICING; ACCEPTANCE AND PAYMENT

7.1With respect to the supply of Product, upon AVECIA's receipt of CUSTOMER's order for Product, AVECIA shall issue to CUSTOMER an invoice or invoices (each an "***Order Invoice***") equal to [*] of the Applicable Price then in effect, as determined in accordance with Section 4.2, for the quantity of Product so ordered, with such amount being then due and payable by CUSTOMER on the terms as set forth herein. AVECIA shall issue to CUSTOMER an Order Invoice or Invoices for the remaining [*] of the Applicable Price for such quantity of Product so ordered with or promptly after Delivery of such Product in full accordance with the terms of this Agreement, with such amount being then due and payable by CUSTOMER on the terms as set forth herein.

Regardless of [*] or, [*], AVECIA shall issue all invoices for such Product [*]. For the avoidance of doubt, CUSTOMER shall [*] or, except as expressly provided in Section 5.1 [*].

7.1.1 Each of the foregoing invoices shall be provided by email (with confirmation of receipt) and, [*] shall be due and payable within [*] of CUSTOMER's receipt thereof.

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7.1.2 On or before [*], AVECIA will send to CUSTOMER a report that shows in reasonable detail (i) the total quantity of Product purchased hereunder in the immediately preceding calendar year or [*] (such total, the "***Total Quantity***"), (ii) the actual price paid by CUSTOMER for such Total Quantity based upon the Order Invoices corresponding to the Total Quantity (the "***Total Amount Paid***" for such Total Quantity), and (iii) the total price that should have been paid for the Total Quantity as determined in accordance with Section 4.2 (the "***Total Amount Payable***" for such Total Quantity). For purposes of the foregoing, the Total Amount Payable shall be calculated using the Applicable Price determined based on [*] the Total Quantity [*] in accordance with this Agreement that [*] – *i.e.*, CUSTOMER shall [*] notwithstanding [*]. [*].

7.2Commencing upon CUSTOMER's receipt of Delivery of any such Product and the applicable Certificate of Analysis, CUSTOMER shall have [*] days to determine if (i) the quantity of Product so Delivered is less than the quantity required to be Delivered to CUSTOMER or (ii) the corresponding Product fails to conform to the Product Requirements in any ways that are reasonably detectable through the performance of standard testing and inspections protocols.

7.3If CUSTOMER fails to notify AVECIA within the time period specified in Section 7.2 that such Product does not conform to the Product Requirements, then CUSTOMER shall be deemed to have accepted such Product; *provided, however,* that [*].

7.4If CUSTOMER believes that (i) the quantity of Product so Delivered is less than the quantity required to be Delivered to CUSTOMER under this Agreement (or, in the case of the MSA Outstanding Quantities, pursuant to the MSA and related SOWs), or (ii) Product so Delivered does not conform to the Product Requirements, CUSTOMER (a) shall give written notice to AVECIA either documenting such shortage or specifying the manner in which such Product does not conform to the Product Requirements within the applicable period specified in Section 7.2 or Section 7.3 (as applicable) and (b) [*]. In the event AVECIA accepts such determination, AVECIA shall [*] within [*].

7.5If a dispute arises between the Parties as to any failure of Product to meet the Product Requirements which cannot be resolved by the Parties within thirty (30) days of CUSTOMER notifying AVECIA thereof pursuant to Section 7.4, either CUSTOMER or AVECIA shall be entitled to require that the matter in dispute be referred to an independent laboratory nominated by agreement of the Parties. Such referral shall be solely for the purpose of establishing whether or not there is any failure of the relevant Product delivered by AVECIA to CUSTOMER to meet the Product Requirements. The decision of such independent laboratory shall be binding upon the Parties and the Party against which the decision is made shall be responsible for the costs of the independent laboratory. If the

decision of such independent laboratory shows that AVECIA failed to supply Product in accordance with the Product Requirements, then AVECIA shall [*].

7.6Each Party will promptly notify the other Party of any relevant new or changed specifications or requirements for Product or the manufacture thereof required by a Regulatory Authority of which such Party becomes aware. [*].

8. MANUFACTURING; QUALITY AGREEMENT; CHANGE IN SPECIFICATIONS

8.1AVECIA shall manufacture and supply Product in accordance with the applicable Manufacturing Process and the Product Requirements.

8.2Unless otherwise set forth in the Quality Agreement or mutually agreed by the Parties in writing, AVECIA shall be responsible for [*] for the manufacture and supply of Product in accordance with this Agreement and shall use commercially reasonable efforts to [*] as reasonably necessary to manufacture Product in the required quantities in a timely fashion to meet mutually-agreed Delivery dates. As of the Effective Date, the Parties acknowledge that CUSTOMER [*] AVECIA in the manufacture of Product. Should the Parties agree in writing after the Effective Date that CUSTOMER [*], CUSTOMER shall provide to AVECIA such information regarding the [*], as reasonably requested by AVECIA or as is reasonably necessary to enable AVECIA safely [*]. AVECIA agrees (a) [*] without the express prior written consent of CUSTOMER, (b) [*] as provided herein, (c) [*], and (d) to [*] CUSTOMER [*]. [*].

8.3The Quality Agreement is hereby incorporated in this Agreement by reference. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any other matter, [*] the provisions of this Agreement shall govern.

8.4The Specifications may be changed only by written agreement of the Parties in accordance with the Quality Agreement. The Party seeking to change the Specifications shall [*]; provided, however, that [*].

9. REPRESENTATIONS AND WARRANTIES

9.1AVECIA represents and warrants to CUSTOMER as follows: (i) all Product supplied hereunder will have been manufactured in accordance with, and will conform to, the Product Requirements; (ii) all personnel used by AVECIA to manufacture Product and provide services hereunder will have the appropriate skills, training and experience; (iii) AVECIA has obtained and will maintain, and will remain in material compliance with, during the Term of this Agreement, all permits, licenses and other authorizations which are required under

Applicable Laws for the manufacture of Product in accordance with this Agreement; (iv) neither AVECIA nor any person or entity performing services on behalf of AVECIA under this Agreement has been debarred under Section 306 of the United States Federal Food, Drug and Cosmetic Act or convicted of a crime for which a person can be debarred under Section 306 of the United States Federal Food, Drug and Cosmetic Act, or any analogous laws in any other country; (v) [*]; (vi) title to all Products supplied to CUSTOMER hereunder will pass to CUSTOMER as provided in this Agreement free and clear of any lien or encumbrance; and (vii) [*]. This representation shall [*].

9.2CUSTOMER represents and warrants to AVECIA that, [*]. This representation shall [*].

9.3Each Party represents and warrants to the other Party as of the Effective Date that: (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation and has the corporate or other power and authority to enter into this Agreement and to perform its obligations hereunder; (ii) it is duly authorized to execute and deliver this Agreement, to perform its obligations hereunder and to grant all licenses and other rights it purports to grant hereunder; and (iii) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound.

9.4EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

10. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

10.1AVECIA shall indemnify, defend and hold harmless CUSTOMER and its Affiliates, and their respective employees, officers, directors and agents ("***CUSTOMER Indemnitees***") from all losses, liabilities, damages, costs and expenses, including reasonable attorneys' fees and costs ("***Losses***") to which any CUSTOMER Indemnitee may become subject as a result of any claim, demand, action or other proceeding by a Third Party (a "***Claim***") to the extent arising from (i) any breach of the covenants, representations, warranties or other agreements of AVECIA hereunder, (ii) the negligence or willful misconduct of any AVECIA Indemnitee (defined below), or (iii) [*]; in each case other than to the extent arising from (a) any breach of the covenants, representations, warranties or other agreements of CUSTOMER hereunder or (b) the negligence or willful misconduct of any CUSTOMER Indemnitee.

10.2CUSTOMER shall indemnify, defend and hold harmless AVECIA and its Affiliates, and their respective employees, officers, directors and agents (collectively, "***AVECIA Indemnitees***") from all Losses to which any AVECIA Indemnitee may become subject as a

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result of any Claim to the extent arising from (i) any breach of the covenants, representations, warranties or other agreements of CUSTOMER hereunder, (ii) the negligence or willful misconduct of any CUSTOMER Indemnitee, (iii) [*], or (iv) the use or sale of Product by CUSTOMER; in each case other than to the extent arising from (a) any breach of the covenants, representations, warranties or other agreements of AVECIA hereunder or (b) the negligence or willful misconduct of any AVECIA Indemnitee.

10.3Each Party's agreement to indemnify, defend and hold harmless the other is conditioned on the indemnified Party (i) providing written notice to the indemnifying Party of any Claim arising out of the indemnified activities within thirty (30) days after the indemnified Party has knowledge of such Claim, provided that the failure to so notify the indemnifying Party will not relieve the indemnifying Party of its obligations hereunder except to the extent such failure shall have actually materially prejudiced the indemnifying Party's ability to defend such Claim; (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Claim; (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, and defense of any such Claim; (iv) undertaking reasonable steps to mitigate any loss, damage or expense with respect to the applicable Claim; and (v) not settling such Claim without the indemnifying Party's prior written consent.

10.4Except for [*], AVECIA's maximum aggregate liability under this Agreement shall in no event exceed [*]; *provided, however,* that the foregoing shall [*]. Except in the case of [*], in no event shall either Party be liable to the other for any lost profits, lost savings or any other special, incidental, punitive or consequential damages arising out of or in connection with this Agreement, whether the claim is in contract, negligence, strict liability or otherwise, regardless of any notice of the possibility of such damages; *provided, however,* that the foregoing shall [*].

10.5Each Party will, at its own expense, maintain throughout the Term and for a minimum period of [*] thereafter product liability insurance with limits of [*] and general liability insurance with limits of [*], and AVECIA will, at its own expense, maintain throughout the Term workers' compensation insurance with not less than the minimum coverage required by applicable law. Each Party shall provide to the other Party, upon request, evidence that such insurance coverage is in effect by providing a duly signed certificate of insurance issued by the applicable insurance company or companies. Such insurance shall have been obtained from an insurance company or companies with an A.M. Best rating of A- or better.

11. REGULATORY; FACILITY ACCESS; RECORDS; AUDITS/REPORTS; TECHNOLOGY TRANSFER

11.1AVECIA shall be responsible for obtaining at its own expense all permissions, licenses, and approvals necessary to discharge its obligations under this Agreement. AVECIA shall comply with all Applicable Laws and GMP relating to the manufacture of

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Product. Upon CUSTOMER's request, AVECIA shall promptly furnish to CUSTOMER such information and documentation as CUSTOMER may reasonably request relating to the Product and its manufacture hereunder, including for purposes of IND, NDA or any other regulatory filings or submissions for the Product. CUSTOMER shall provide to AVECIA a copy of those portions of all proposed submissions by CUSTOMER to any Regulatory Authority associated with the manufacture of Product hereunder for AVECIA's review and verification.

11.2Subject to reasonable obligations of confidentiality, CUSTOMER has the right to [*], access to and review of all Records, Batch Records, and any other relevant documents.

11.3CUSTOMER shall have the right to conduct, upon reasonable notice and at its own expense, periodic technical, quality, and environmental health, and safety audits. AVECIA shall give reasonable access (under normal circumstances, considered to be once per calendar year) to CUSTOMER for purposes of auditing the Facility and the manufacture, testing and release of Product under this Agreement and relevant standard operating procedures, processes, systems, books, documents, and records. Generally, [*] days' prior written notice shall be reasonable, but [*]. All visitations of the Facility by CUSTOMER, its representatives, potential licensees or collaborators shall be subject to reasonable obligations of confidentiality and any reasonable requirements of AVECIA relating to health and safety.

11.4AVECIA shall maintain appropriate and complete Records relating to [*]. CUSTOMER and/or its authorized independent, certified public accountant (the "**Auditors**"), shall be entitled once a year, upon [*] days' notice to AVECIA, during normal business hours to [*]. AVECIA shall provide all reasonable assistance to CUSTOMER and/or its Auditors to have access to the applicable documentation [*] as well as reasonable assistance responding to questions and/or providing additional, appropriate documentation required for [*]. All [*] by CUSTOMER and/or its Auditors shall be subject to reasonable obligations of confidentiality and any reasonable requirements of AVECIA relating to the Facility. In addition, within [*] business days after the end of [*], AVECIA shall provide CUSTOMER and/or its Auditors a written report [*]. AVECIA shall provide all reasonable assistance to CUSTOMER and/or its Auditors in connection with the [*].

11.5AVECIA shall maintain complete and accurate records relating to the manufacture, testing and release of Product hereunder, including, without limitation, [*] (collectively, "**Records**"), in accordance with pharmaceutical manufacturing industry standards and the Product Requirements and as necessary to document its compliance with the Product Requirements. [*]. Upon CUSTOMER's request, AVECIA will promptly provide CUSTOMER with complete and accurate copies of Records. AVECIA will not transfer, deliver or otherwise provide any CUSTOMER Records (or copies thereof) to any person or entity other than CUSTOMER, without the prior written approval of CUSTOMER, except as required by Applicable Law or Regulatory Authority. While in the possession or control of

AVECIA, all Records will be made available for inspection, examination and copying by or on behalf of CUSTOMER. All such Records will be retained and archived by AVECIA in accordance with the Quality Agreement, GMP and Applicable Laws, but in no case for less than the longer of [*] or [*] (the "***Retention Period***"). Following the Retention Period, AVECIA will not destroy such CUSTOMER Records without first giving CUSTOMER written notice and the opportunity to further store such CUSTOMER Records at CUSTOMER's expense, or to have such CUSTOMER Records transferred to CUSTOMER [*].

11.6AVECIA will promptly (and in any event within the period specified in the Quality Agreement) advise CUSTOMER [*]. CUSTOMER shall [*]. AVECIA shall promptly (and in any event within the period specified in the Quality Agreement) provide a report to CUSTOMER of any Product-related results of such inspection. Subject to the foregoing, [*]. In addition, AVECIA shall also promptly (and in any event within the period specified in the Quality Agreement) notify CUSTOMER [*] and any follow-up written communications between AVECIA and the relevant Regulatory Authority; *provided however*, before providing such reports to CUSTOMER, AVECIA may redact any confidential information of a Third Party from such reports. AVECIA will [*]. AVECIA will promptly and diligently [*].

11.7AVECIA shall cooperate with CUSTOMER, [*], to satisfy regulatory requirements regarding Product in [*]. AVECIA shall cooperate with CUSTOMER to satisfy regulatory requirements regarding Product in any other jurisdictions [*], and the Parties will [*]. CUSTOMER will [*]. Such cooperation shall include the providing of reasonable regulatory support, including AVECIA providing to CUSTOMER all data and information reasonably necessary [*].

11.8All approvals arising out of the matters addressed in Section 11.7 shall be in the name of CUSTOMER, and all related documentation and materials shall be the sole property of CUSTOMER; [*].

If CUSTOMER is required or requested by any Regulatory Authority to recall any Product supplied by AVECIA hereunder [*], and [*], and [*], then, subject to the limitation of liability provisions of Section 10.4 above, AVECIA shall [*]. If a recall is due to any reason other than [*], CUSTOMER shall pay all of the costs and expenses of the recall.

11.9To the extent [*] upon CUSTOMER's request, [*].

12. FORCE MAJEURE

12.1Neither Party is liable for any failure to perform or delay in performing any obligations under this Agreement, if such failure or delay is due to fire, flood, war, embargo, legal prohibition, terrorism, insurrection, regulatory or environmental issues, labor stoppages, [*]

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or any other cause beyond the reasonable control of such defaulting Party preventing or delaying the performance of such obligations. The Party so affected will, upon giving notice thereof to the other party, be excused from such performance to the extent of such prevention, restriction or delay. The affected Party is obligated to use its commercially reasonable efforts to avoid or to remove such causes of non-performance and to continue performance with the utmost dispatch whenever such causes are removed.

12.2For clarity, [*]; provided, however, that [*]. Neither Party shall be entitled to relief under this Section 12 for any delay or failure in performing any of its payment obligations under this Agreement.

13. TERMINATION; CONSEQUENCES OF TERMINATION

13.1Without prejudice to any other rights or remedies which may be available to them:

13.1.1 either Party may terminate this Agreement upon written notice of termination to the other Party if the other Party commits a material breach of any of the provisions of this Agreement; and, in the case of a breach capable of being remedied, fails to remedy that breach within [*] days of receiving written notice specifying that breach and requiring the same to be remedied;

13.1.2 either Party may terminate this Agreement upon written notice to the other Party in the event that the other Party (a) is adjudicated insolvent; (b) makes an assignment for the benefit of creditors; (c) files or has filed against it a petition in bankruptcy which, in the case of an involuntary petition in bankruptcy, is not dismissed within [*] days; (d) has a receiver appointed for its assets; or (e) is dissolved or liquidated;

13.1.3 CUSTOMER may terminate this Agreement upon written notice to AVECIA in the event of: (a) [*]; (b) [*]; (c) [*]; (d) [*]; or (e) [*];

13.1.4 CUSTOMER may terminate this Agreement upon written notice to AVECIA if, [*];

13.1.5 CUSTOMER may terminate this Agreement [*]; and

13.1.6 AVECIA may terminate this Agreement [*].

13.2Without prejudice to any other rights or remedies which a Party may have, upon the termination of this Agreement, howsoever the same occurs, each Party shall (i) promptly pay to the other all sums which at the date of termination are due and payable to the other hereunder (and no such amount shall be subject to any duplicative recovery by the other Party pursuant to Section 13.3 or Section 26); (ii) except as stated to the contrary in Section

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15 regarding each Party's rights to Intellectual Property, immediately cease all use of any property of the other, including without limitation any Intellectual Property of the other; and (iii) at the expense of the requesting Party, promptly return to the other Party, or certify to the other Party the destruction of, any property or Confidential Information of the other in its possession, custody or control, *provided however* (x) each Party may retain one (1) copy of the other Party's Confidential Information in its secure files solely for the purpose of monitoring compliance with the terms of this Agreement and (y) CUSTOMER shall have the right to retain and use such Confidential Information of AVECIA which is reasonably required for the continued exercise of any rights or licenses granted to CUSTOMER which survive the termination or expiration of this Agreement. The terms of Section 14 (Confidentiality) of this Agreement will apply to such post-termination retention or use of Confidential Information.

13.3In the event of any termination of this Agreement (except as otherwise expressly set forth below in this Section 13.3), and without prejudice to any right or remedy that a Party may have by reason of any breach of this Agreement by the other Party:

13.3.1 except as otherwise instructed by CUSTOMER in writing in the case of termination of this Agreement by CUSTOMER pursuant to Section 13.1.3:

(a) AVECIA shall Deliver in accordance with the terms and conditions of this Agreement, and CUSTOMER shall take Delivery of and pay for, at the Applicable Price in effect at the time the applicable order was placed, all quantities of Product ordered by CUSTOMER and manufactured prior to termination which conform to, and have been manufactured in accordance with, all the Product Requirements and other applicable terms of this Agreement but not yet Delivered;

(b) AVECIA shall complete manufacture of all in-process inventory of Product under purchase orders accepted prior to termination and Deliver such completed Product in accordance with the terms and conditions of this Agreement, and CUSTOMER shall take Delivery of and pay for, at the Applicable Price in effect at the time the applicable order was placed, all such Product that conforms to, and has been manufactured in accordance with, all the Product Requirements and other applicable terms of this Agreement; and

(c) with respect to any quantity of Product under purchase orders accepted prior to termination with respect to which AVECIA has not commenced manufacture, AVECIA shall manufacture and Deliver such Product in accordance with the terms and conditions of this Agreement, and CUSTOMER shall take Delivery of and pay for, at the Applicable Price in effect at the time the applicable order was placed, all such Product that

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conforms to, and has been manufactured in accordance with, all the Product Requirements and other applicable terms of this Agreement;

13.3.2 except in the case of [*]; and

13.3.3 except in the case of termination of this Agreement [*], to the extent that, prior to receipt or delivery of notice of termination, and [*], AVECIA [*], CUSTOMER shall [*] and AVECIA shall [*].

13.4All terms of this Agreement applicable to Product manufactured or Delivered, or required to be manufactured or Delivered, under this Agreement or the Delivery thereof (including, without limitation, Sections 6, 7, 8.1 and 9.1 hereof) remain applicable after termination or expiration of this Agreement whether the actual manufacture or Delivery occurs before or after termination or expiration of this Agreement.

14. CONFIDENTIALITY

14.1In consideration of the Disclosing Party (either AVECIA or CUSTOMER or their respective Representative, as the case may be) disclosing Confidential Information to the Receiving Party (either AVECIA or CUSTOMER or their respective Representative, as the case may be), the Receiving Party hereby undertakes to maintain confidential all such Disclosing Party's Confidential Information and it will accordingly not use or disclose any of the Disclosing Party's Confidential Information in whole or in part except for the purposes of performing the Receiving Party's obligations or exercising the Receiving Party's rights under this Agreement.

Confidential Information does not include information that the Receiving Party can demonstrate by competent evidence:

14.1.1 was already in its possession and at its free disposal, without burden of confidentiality, before the disclosure to it by the Disclosing Party;

14.1.2 is hereafter disclosed to the Receiving Party on a non-confidential basis by, or purchased or otherwise legally acquired by the Receiving Party on a non-confidential basis from, a Third Party who has not derived it directly or indirectly from the Disclosing Party and was not legally or contractually restricted from disclosing such information;

14.1.3 is or becomes generally available to the public whether in printed publications or otherwise through no act or omission on the part of the Receiving Party or its Representatives in breach of this Agreement or any other agreement between the Parties; or

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14.1.4 the Receiving Party can prove to the reasonable satisfaction of the Disclosing Party has been developed independently of the Disclosing Party (and, in the case of AVECIA as the Receiving Party, independently of activities conducted on behalf of CUSTOMER pursuant to this Agreement or any other agreement between the Parties), by any Representative of the Receiving Party without access to, use of, reliance on, or reference to any of the Confidential Information disclosed by the Disclosing Party (and, in the case of AVECIA as the Receiving Party, any information deemed to be the Confidential Information of CUSTOMER as expressly provided in this Agreement), as shown by contemporaneous written records.

No combination of elements within the Confidential Information shall be deemed to be part of the public domain merely because the individual elements of such combination are part of the public domain, unless the entire combination itself, or the entire principle of use or operation of such combination (if any), is part of the public domain. In addition, no element within the Confidential Information shall be deemed to be a part of the public domain merely because it is embraced by more general information or data that is part of the public domain.

14.2In order to secure the obligations set out in this Section 14, the Receiving Party agrees to exercise reasonable precaution to prevent and restrain the unauthorized disclosure and use of Confidential Information of the Disclosing Party, including restricting access to such Confidential Information to such of its Representatives who are bound by the terms of this Agreement or other written obligations of confidentiality no less restrictive than those contained herein, to keep such information confidential and who need to have such access for the purpose of exercising rights or performing obligations pursuant to this Agreement. Each Party will be liable for the breach of this Section 14 by any of its Representatives.

14.3The Receiving Party shall not be prohibited from disclosing Confidential Information of the Disclosing Party to the extent such Confidential Information is required to be disclosed by Applicable Law or valid order of a governmental agency or court of competent jurisdiction; provided, however, that the Receiving Party shall provide prior written notice thereof to the Disclosing Party, consult with the other Party with respect to such disclosure and, at the Disclosing Party's request and expense, cooperate with the Disclosing Party's efforts to contest the requirement or to obtain a protective order or other confidential treatment of such information.

14.4The provisions of this Section 14 shall survive termination or expiry of this Agreement and shall continue for a period of [*] years from the date of that termination or expiry, except with respect to the [*] of the Disclosing Party, with respect to which the provisions of this Section 14 shall survive beyond such [*]-year period for as long as such information [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

14.5[*] pursuant to this Agreement [*], including, without limitation, [*] of CUSTOMER and are deemed CUSTOMER's Confidential Information and for the purposes of this Agreement, and CUSTOMER shall be deemed the Disclosing Party with respect thereto.

14.6Except as required by AVECIA to perform its obligations under this Agreement or as required by applicable law, regulation or valid legal order, on a written request from CUSTOMER, AVECIA shall promptly, at CUSTOMER's option, either return to CUSTOMER or destroy (and provide written certification by an officer of AVECIA of such destruction) all documents and materials that embody or set forth CUSTOMER's Confidential Information, provided that AVECIA may retain one (1) copy of CUSTOMER's Confidential Information in its secure files solely for the purpose of monitoring compliance with the terms of this Agreement. AVECIA shall continue to be bound by the terms and conditions of this Agreement with respect to such retained Confidential Information.

14.7Notwithstanding Section 14.1, CUSTOMER may disclose AVECIA's Confidential Information to the extent such disclosure is reasonably necessary: (a) [*]; (b) [*]; (c) [*]; (d) if required to comply with Applicable Laws (including, without limitation, regulations relating to regulatory approvals; (e) [*]; (f) [*]; or (g) [*]; subject to, in the case of circumstances noted in Clauses (a) through (f) above, [*].

15. INTELLECTUAL PROPERTY; LICENSES

15.1Nothing in this Agreement shall affect the ownership by either Party of (i) any Intellectual Property or process in existence and owned by that Party before the Effective Date or (ii) Intellectual Property developed on or after the Effective Date independently of the work undertaken under this Agreement and without access to, use of, or reliance on any of the Confidential Information disclosed by the other Party (***"Independent Intellectual Property"***). Without limiting the generality of the foregoing, the Specifications, all [*] of CUSTOMER. [*].

15.2All Intellectual Property generated, developed, discovered or invented by or on behalf of AVECIA [*] (such Intellectual Property, collectively, "***CUSTOMER-Owned Project IP***") shall be owned solely by CUSTOMER. Any Intellectual Property generated, developed, discovered or invented by or on behalf of AVECIA [*] (such Intellectual Property called "***AVECIA-Owned Project IP***"). AVECIA hereby assigns and transfers to CUSTOMER all right, title and interest in and to CUSTOMER-Owned Project IP and agrees to take all further acts reasonably necessary or desirable to evidence such assignment and transfer to CUSTOMER, at CUSTOMER's expense.

15.3AVECIA hereby grants to CUSTOMER [*] license, [*] under any AVECIA-Owned Project IP to develop, make, have made, use, sell, have sold, offer for sale, import and export the Product [*]. AVECIA hereby grants to CUSTOMER [*] license, [*] under [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

15.4CUSTOMER hereby grants to AVECIA a royalty-free, worldwide, non-exclusive, non-transferable, non-assignable, non-sublicensable license, under CUSTOMER's Independent Intellectual Property, solely to manufacture Product for CUSTOMER during the Term and under this Agreement, and any such license shall immediately terminate upon expiration or termination of this Agreement.

15.5AVECIA will [*]. CUSTOMER will [*]. AVECIA will [*]. AVECIA shall [*].

15.6Except as expressly set forth in this Agreement, neither Party will acquire, by implication, estoppel, usage or otherwise under this Agreement, any right, title or interest in or to any inventions (whether patentable or not), patents, Know-How, information, data, writings, trademarks, service marks, copyrights or other property belonging to the other Party, and each Party hereby reserves all rights in and to its intellectual property not specifically granted hereunder.

16. INDEPENDENT CONTRACTOR

Nothing in this Agreement shall create, or be deemed to create, a partnership or the relationship of principal and agent or employer and employee between the Parties. Each Party agrees to perform under this Agreement solely as an independent contractor.

17. ENTIRE AGREEMENT; INTERPRETATION

17.1This Agreement, including the Schedules, Appendices, and Exhibits attached hereto, and the Quality Agreement, contain the entire agreement between the Parties regarding the subject matter hereof and supersede any previous agreements relating to the subject matter hereof and any understandings between the Parties with respect thereto; *provided, however,* that (a) [*] (which shall also be subject to Sections 7.2-7.6 and 11.8 of this Agreement) and shall remain in full force and effect for purposes of any future development projects mutually agreed by the Parties in writing; (b) without limiting the generality of the preceding clause (a), the provisions of Sections 1, 5, 7 and 11 of that certain Scope of Work under the MSA dated September 15, 2020 relating to the procurement, inventory maintenance, cost and disposition of raw materials and the potential refund of a portion of the Capacity Reservation Fees (as such term is defined in such Scope of Work) allocable to raw materials used in the manufacture of other products by Avecia in the event of termination of such Scope of Work, shall remain in full force and effect in accordance with the terms of such Scope of Work; and (c) the 2012 Supply Agreement shall remain in full force and effect in accordance with its terms with respect to Product ordered by CUSTOMER for production using the [*] "**Current Process**" (as such term is defined in the 2012 Supply Agreement). This Agreement may not be modified except by an instrument in writing signed by the duly authorized representatives of the Parties.

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17.2The headings of clauses contained in this Agreement preceding the text of the Sections, subsections, paragraphs and exhibits hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The word "including" (and variations thereof) as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word "or" has the inclusive meaning represented by the phrase "and/or." Unless otherwise specified, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references in this Agreement to any agreement, instrument or other document will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified. All references in this Agreement to any specific law, rule or regulation will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation.

18. ANNOUNCEMENTS; PUBLICITY

18.1The Parties agree that they will not make any press release, announcement or other publicity relating to the transactions which are the subject of this Agreement, without first obtaining in each case the prior written consent of the other Party (which consent will not be unreasonably withheld); provided, however, that such consent obligation will not apply to communications required by Applicable Laws, disclosures of information for which consent has previously been obtained, or information that has been previously disclosed publicly, and CUSTOMER shall have the right to identify AVECIA to Third Parties as the manufacturer of Product supplied hereunder.

19. ASSIGNMENT

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective legal successors and permitted assigns. Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, [*] may assign this Agreement: (a) [*]; or (b) [*]. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 19. Any purported assignment not in compliance with this Section 19 shall be void.

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20. VARIATION

No variation or amendment of this Agreement shall bind a Party unless made in writing in the English language and agreed to in writing by duly authorized officers of both Parties.

21. ILLEGALITY

If any provision of this Agreement is agreed by the Parties to be illegal, void or unenforceable under any law that is applicable hereto or if any court of competent jurisdiction in a final decision so determines, this Agreement shall continue in force save that such provision shall be deemed to be excised here from with effect from the date of such agreement or decision or such earlier date as the Parties may agree.

22. WAIVER

A failure by either Party hereto to exercise or enforce any rights conferred upon it by this Agreement shall not be deemed to be a waiver of any such rights or operate so as to bar the exercise or enforcement thereof at any subsequent time or times. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time, and shall be effective only if signed by an authorized representative of such Party.

23. NOTICES

23.1All notices and other communications given or made in relation to this Agreement shall be in English and in writing and delivered by hand, registered post or by electronic mail (with confirmation of receipt) to the appropriate address of the party shown in Section 23.2.

23.2If to AVECIA:

Nitto Denko Avecia Inc.
125 Fortune Boulevard
Milford, MA 01757
Attention: Vice President, Business Development
Email: [*]

If to CUSTOMER:

Dynavax Technologies Corporation
2100 Powell Street, Suite 720
Emeryville, CA 94608
Attention: President and Chief Operating Officer
Email: [*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

With a copy to:

Dynavax Technologies Corporation
2100 Powell Street, Suite 720
Emeryville, CA 94608
Attention: General Counsel
Email: [*]

24. DUTY TO MITIGATE

Each of the Parties shall use all reasonable endeavors to mitigate any costs, losses or expenses due to be incurred or suffered by the other Party in connection with the performance or non- performance of this Agreement.

25. LAW; JURISDICTION

25.1The laws of the State of Delaware, U.S.A. (without giving effect to its conflicts of law principles) govern all matters arising out of or relating to this Agreement. Any proceedings between the Parties shall be conducted in the English language. The United Nations Convention on Contracts for the International Sale of Goods is hereby expressly excluded.

25.2During the Term, the Parties shall use good faith efforts to resolve amicably any dispute arising out of or relating to this Agreement or the breach thereof. If such resolution cannot be achieved within thirty (30) days, the dispute will be referred to the chief executive officers or presidents of the Parties. These individuals will make a good faith effort to reach an agreement that is acceptable to both Parties through direct negotiations. If the Parties fail to resolve any such dispute through such escalation procedure within thirty (30) days of the date the dispute is referred to such individuals, then such dispute shall be settled by arbitration administered by the American Arbitration Association ("***AAA***") under its Commercial Arbitration Rules (the "**Rules**"), and judgment on the award rendered by the arbitrator shall be binding and may be entered in any court having jurisdiction thereof. Such arbitration shall be filed and conducted at an office of the AAA in Wilmington, Delaware (unless otherwise mutually agreed by the Parties in writing) and shall be conducted in English by [*] selected in accordance with the Rules. [*]. Any dispute regarding the scope or applicability of this agreement to arbitrate and the propriety of commencing the arbitration shall be determined by arbitration by the AAA. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrator [*]. Without prejudice to Section 25.3, the arbitral tribunal shall have full authority to grant provisional or interim remedies.

25.3Notwithstanding the foregoing provisions of this Section 25, in the event of the actual or threatened breach by a Party of any of the terms of Section 14 or Section 15 hereof, the

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aggrieved Party shall have the right to seek enforcement of this Agreement and its provisions by injunction, specific performance or other equitable relief in any court of competent jurisdiction. The rights granted by this Section 25.3 are in addition to all other remedies and rights available at law or in equity.

26. SURVIVAL

Neither expiration nor termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement Sections 1 (as necessary for the interpretation of the other surviving provisions of this Agreement), 3.5, 4.4, 6.3, 7.1.2, 8.2, 8.3, 9.4, 10, 11.4, 11.5, 11.7, 11.8, 11.9, 13.2-13.4, 14, 15, 17, 19, and 20-26 of this Agreement, and any other provisions of this Agreement which are reasonably intended by the Parties to have effect beyond the Term, shall survive expiration or termination of this Agreement.

27. COUNTERPARTS

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

[Signatures follow on next page]

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IN WITNESS WHEREOF, this Agreement has been entered into the day and year first above written.

NITTO DENKO AVECIA INC.	**DYNAVAX TECHNOLOGIES CORPORATION**
By */s/ Tammy Cooper*	By */s/ David Novack*
Name Tammy Cooper	Name David Novack
Title VP of Business Development	Title President and COO

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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 and Director
(Principal Executive Officer)

Date: November 2, 2023

Exhibit 31.2

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

CERTIFICATIONS

I, Kelly MacDonald, certify that:

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

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

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

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

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

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

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

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

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

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

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

By: /s/ KELLY MACDONALD

Kelly MacDonald
Chief Financial Officer
(Principal Financial Officer)

Date: November 2, 2023

Exhibit 32.1

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

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

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 (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 2nd day of November, 2023.

By: /S/ RYAN SPENCER

Ryan Spencer
Chief Executive Officer and Director
(Principal Executive Officer)

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

Exhibit 32.2

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

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

(i) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 (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 2nd day of November, 2023.

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.