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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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.)**

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(510) 848-5100
(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of May 3, 2019, the registrant had outstanding 65,066,944 shares of common stock.

INDEX

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 our ability to successfully commercialize HEPLISAV-B® and our anticipated level of sales of HEPLISAV-B, our ability to successfully develop and timely obtain regulatory approval of SD-101, DV281 and our other early stage compounds, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, our ability to manufacture commercial supply and meet regulatory requirements, the timing of the introduction of our products, uncertainty regarding our capital needs and future operating results and profitability, anticipated sources of funds, as well as our plans, objectives, strategies, expectations and intentions. These statements appear throughout this Quarterly Report on Form 10-Q and can be identified by the use of forward-looking language such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," or "intend," or the negative of these terms or other variations or comparable terminology.

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2019 (unaudited)	December 31, 2018 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 112,133	$ 49,348
Marketable securities available-for-sale	71,083	96,188
Accounts and other receivables, net	5,791	3,704
Inventories, net	27,569	19,022
Prepaid expenses and other current assets	5,948	6,102
Total current assets	222,524	174,364
Property and equipment, net	25,305	17,064
Intangible assets, net	9,445	11,717
Operating lease right-of-use assets	33,505	-
Goodwill	2,102	2,144
Restricted cash	615	619
Other assets	3,104	4,976
Total assets	$ 296,600	$ 210,884
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,868	$ 5,278
Accrued research and development	9,630	9,714
Accrued liabilities	12,384	16,041
Other current liabilities	8,369	7,000
Total current liabilities	42,251	38,033
Long-term debt, net	175,673	100,871
Long-term portion of lease liabilities	35,076	-
Other long-term liabilities	441	8,915
Total liabilities	253,441	147,819
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding at March 31, 2019 and December 31, 2018	-	-
Common stock: $0.001 par value; 139,000 shares authorized at March 31, 2019 and December 31, 2018; 65,020 and 62,862 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	65	63
Additional paid-in capital	1,151,421	1,131,241
Accumulated other comprehensive loss	(2,431)	(2,015)
Accumulated deficit	(1,105,896)	(1,066,224)
Total stockholders' equity	43,159	63,065
Total liabilities and stockholders' equity	$ 296,600	$ 210,884

See accompanying notes.

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product revenue, net	$ 5,627	$ 165
Collaboration revenue	146	-
Total revenues	5,773	165
Operating expenses:		
Cost of sales - product	1,800	205
Cost of sales - amortization of intangible assets	2,273	2,417
Research and development	21,206	18,966
Selling, general and administrative	18,348	16,891
Total operating expenses	43,627	38,479
Loss from operations	(37,854)	(38,314)
Other income (expense):		
Interest income	735	740
Interest expense	(2,734)	(1,161)
Other income (expense), net	181	(223)
Net loss	$ (39,672)	$ (38,958)
Basic and diluted net loss per share	$ (0.62)	$ (0.63)
Weighted average shares used to compute basic and diluted net loss per share	63,778	61,744

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

	Three Months Ended March 31,	
	2019	2018
Net loss	$ (39,672)	$ (38,958)
Other comprehensive (loss) income, net of tax:		
Unrealized gain (loss) on marketable securities available-for-sale	67	(22)
Foreign currency translation adjustments	(483)	690
Total other comprehensive (loss) income	(416)	668
Total comprehensive loss	$ (40,088)	$ (38,290)

See accompanying notes.

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

	Common Stock					
	Shares	Par Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2017	61,533	$ 62	$ 1,107,693	$ (881)	$ (907,325)	$ 199,549
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	663	-	(426)	-	-	(426)
Issuance of common stock under Employee Stock Purchase Plan	58	-	255	-	-	255
Stock compensation expense	-	-	4,799	-	-	4,799
Total other comprehensive income	-	-	-	668	-	668
Net loss	-	-	-	-	(38,958)	(38,958)
Balances at March 31, 2018	62,254	$ 62	$ 1,112,321	$ (213)	$ (946,283)	$ 165,887
Balances at December 31, 2018	62,862	$ 63	$ 1,131,241	$ (2,015)	$ (1,066,224)	$ 63,065
Issuance (withholding) of common stock upon exercise of stock options and restricted stock awards, net	740	-	(18)	-	-	(18)
Issuance of common stock under Employee Stock Purchase Plan	75	-	407	-	-	407
Issuance of common stock, net of issuance costs	1,343	2	13,621	-	-	13,623
Stock compensation expense	-	-	6,170	-	-	6,170
Total other comprehensive loss	-	-	-	(416)	-	(416)
Net loss	-	-	-	-	(39,672)	(39,672)
Balances at March 31, 2019	65,020	$ 65	$ 1,151,421	$ (2,431)	$ (1,105,896)	$ 43,159

See accompanying notes.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (39,672)	$ (38,958)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,702	823
Amortization of right-of-use assets	1,302	-
Accretion of discounts on marketable securities	(323)	(176)
Stock compensation expense	6,170	4,799
Cost of sales - amortization of intangible assets	2,273	2,417
Non-cash interest expense	814	348
Changes in operating assets and liabilities:		
Accounts and other receivables	(2,087)	91
Inventories, net	(8,547)	(238)
Prepaid expenses and other current assets	154	394
Other assets	1,872	3
Accounts payable	4,424	349
Lease liabilities	(106)	-
Accrued liabilities and other liabilities	(7,878)	276
Net cash used in operating activities	(39,902)	(29,872)
Investing activities		
Acquisition of technology licenses	(7,000)	(9,500)
Purchases of marketable securities	(29,205)	(141,103)
Proceeds from maturities of marketable securities	54,700	91,815
Purchases of property and equipment, net	(3,882)	(897)
Net cash provided by (used in) investing activities	14,613	(59,685)
Financing activities		
Proceeds from long-term debt, net	74,250	99,000
Proceeds from issuance of common stock, net	13,623	-
Tax withholding from exercise of stock options and restricted stock awards, net	(18)	(426)
Proceeds from Employee Stock Purchase Plan	407	255
Net cash provided by financing activities	88,262	98,829
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(192)	217
Net increase in cash, cash equivalents and restricted cash	62,781	9,489
Cash, cash equivalents and restricted cash at beginning of period	49,967	27,213
Cash, cash equivalents and restricted cash at end of period	$ 112,748	$ 36,702
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 1,940	$ 813
Non-cash investing and financing activities:		
Disposal of fully depreciated property and equipment	$ 851	$ 37
Non-cash acquisition of technology license	$ -	$ 12,773
Right-of-use assets obtained in exchange for operating lease liabilities	$ 34,807	$ -

See accompanying notes.

Dynavax Technologies Corporation
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Dynavax Technologies Corporation ("we," "our," "us," "Dynavax" or the "Company"), is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation. Our first commercial product, HEPLISAV-B® (Hepatitis B Vaccine (Recombinant), Adjuvanted), is approved by the United States Food and Drug Administration ("FDA") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018. Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents. Our lead investigational immuno-oncology product candidates are SD-101, currently being evaluated in Phase 2 clinical studies, and DV281, in a Phase 1b safety study. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which we consider necessary to present fairly our financial position and the results of our operations and cash flows. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted. Interim-period results are not necessarily indicative of results of operations or cash flows to be expected for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2018 has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (the "SEC").

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

Liquidity and Financial Condition

As of March 31, 2019, we had cash, cash equivalents and marketable securities of$183.2 million. On March 29, 2019, we borrowed the remaining $75.0 million under our term loan agreement with CRG Servicing LLC. The principal amount of $177.3 million, which includes paid-in-kind interest, borrowed under the loan agreement has a maturity date of December 31, 2023, unless earlier prepaid.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates, discovery research and development and tenant improvements and ongoing occupancy costs at our new corporate headquarters. Until we can 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. Adequate financing may not be available to us on acceptable terms, or at all.

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.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management's estimates are based on historical information available as of the date of the condensed consolidated financial statements and various other assumptions we believe are reasonable under the circumstances. Actual results could differ materially from these estimates.

Summary of Significant Accounting Policies

Revenue Recognition

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

Product Revenue, Net

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

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

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration such as product returns, chargebacks, discounts, rebates and other fees that are offered within contracts between us and our Customers, healthcare providers, and others relating to our product sales. We estimate variable consideration using either the most likely amount method or the expected value method, depending on the type of variable consideration and what method better predicts the amount of consideration we expect to receive. We take into consideration relevant factors such as industry data, current contractual terms, available information about Customers' inventory, resale and chargeback data and forecasted customer buying and payment patterns, in estimating each variable consideration. The variable consideration is recorded at the time product sales is recognized, resulting in a reduction in product revenue and a reduction in accounts receivable (if the Customer offsets the amount against its accounts receivable) or as an accrued liability (if we pay the amount through our accounts payable process). Variable consideration requires significant estimates, judgment and information obtained from external sources. The amount of variable consideration is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If our estimates differ significantly from actuals, we will record adjustments that would affect product revenue, net in the period of adjustment. If we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of revenue that we report in a particular period. There have been no material adjustments to these estimates for the three months ended March 31, 2019 and 2018.

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

Chargebacks: Our Customers subsequently resell our product to healthcare providers. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers that provide for chargebacks and discounts with respect to the

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

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

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

Collaboration Revenue

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

Leases

On January 1, 2019, we adopted ASC 842, Leases, using the modified retrospective approach. Prior period amounts continue to be reported in accordance with our historic accounting under previous lease guidance, ASC 840, Leases. We elected the package of practical expedients which, among other things, allowed us to carry forward the historical lease classification of leases in place as of January 1, 2019. As a result of adopting ASC 842, we recognized right-of-use asset and lease liabilities for operating leases of $34.8 million and $37.1 million, respectively on January 1, 2019. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption of ASC 842.

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

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

Inventories

Inventory is stated at the lower of cost or estimated net realizable value, on a first-in, first-out, or FIFO, basis. We primarily use actual costs to determine our cost basis for inventories. Our assessment of market value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of the future demand for our products, product expiration dates and current sales levels. Our assumptions of future demand for our products are inherently uncertain and if we were to change any of these judgments or estimates, it could cause a material increase or decrease in the amount of inventory reserves that we report in a particular period. For the three months ended March 31, 2019 and 2018, there was no inventory reserve recognized.

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

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

Research and Development Expenses and Accruals

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

We contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. Our accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. We may terminate these contracts upon written notice and we are generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances we may be further responsible for termination fees and penalties. We estimate research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to us at that time. There have been no material adjustments to the prior period accrued estimates for clinical trial activities through March 31, 2019.

Recent Accounting Pronouncements

Accounting Standards Update 2016-13

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments. The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. We are currently evaluating the impact this standard will have on our condensed consolidated financial statements.

Accounting Standards Update 2017-04

In January 2017, the FASB issued ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350), which simplifies the test for goodwill impairment by eliminating a previous requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption is not expected to have a material impact on our condensed consolidated financial statements.

Accounting Standards Update 2018-13

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820), that eliminates, adds and modifies certain disclosure requirements of fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption of this standard is not expected to have a material impact on our condensed consolidated financial statements.

Accounting Standards Update 2018-15

In August 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other –Internal-Use Software (Subtopic 350-40). This ASU requires a customer in a cloud computing arrangement (i.e. hosting arrangement) that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. ASC 350-40 requires that certain costs incurred during the application development stage be capitalized and other costs incurred

during the preliminary project and post-implementation stages be expensed as incurred. The ASU is effective for annual periods beginning after December 15, 2019 with early adoption permitted. The adoption of this standard is not expected to have a material impact on ourcondensed consolidated financial statements.

2. Fair Value Measurements

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

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

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy.

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.

As of March 31, 2019, we measured the fair value of our $7.0 million payment to Merck Sharpe & Dohme Corp., which is due in the first quarter of 2020, based on Level 3 inputs due to the use of unobservable inputs that cannot be corroborated by observable market data. We estimated the fair value of the liability using a discounted cash flow technique using the effective interest rate on our term loan. The liability had a fair value of $6.5 million as of March 31, 2019.

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
March 31, 2019				
Money market funds	$ 102,616	$ -	$ -	$ 102,616
U.S. treasuries	-	6,999	-	6,999
U.S. government agency securities	-	26,077	-	26,077
Corporate debt securities	-	46,006	-	46,006
Total	$ 102,616	$ 79,082	$ -	$ 181,698

	Level 1	Level 2	Level 3	Total
December 31, 2018				
Money market funds	$ 44,002	$ -	$ -	$ 44,002
U.S. treasuries	-	14,724	-	14,724
U.S. government agency securities	-	42,372	-	42,372
Corporate debt securities	-	41,291	-	41,291
Total	$ 44,002	$ 98,387	$ -	$ 142,389

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.

There were no transfers between Level 1 and Level 2 during the three months ended March 31, 2019.

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

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

	March 31, 2019	December 31, 2018	March 31, 2018	December 31, 2017
Cash and cash equivalents	$ 112,133	$ 49,348	$ 36,067	$ 26,584
Restricted cash	615	619	635	629
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 112,748	$ 49,967	$ 36,702	$ 27,213

Restricted cash balances relate to certificates of deposit issued as collateral to certain letters of credit issued as security to our facility leases in Berkeley, California and Düsseldorf, Germany. See Note 6.

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
March 31, 2019				
Cash and cash equivalents:				
Cash	$ 1,518	$ -	$ -	$ 1,518
Money market funds	102,616	-	-	102,616
U.S. treasuries	5,000	-	-	5,000
Corporate debt securities	2,999	-	-	2,999
Total cash and cash equivalents	112,133	-	-	112,133
Marketable securities available-for-sale:				
U.S. treasuries	1,999	-	-	1,999
U.S. government agency securities	26,085	-	(8)	26,077
Corporate debt securities	42,999	10	(2)	43,007
Total marketable securities available-for-sale	71,083	10	(10)	71,083
Total cash, cash equivalents and marketable securities	$ 183,216	$ 10	$ (10)	$ 183,216
December 31, 2018				
Cash and cash equivalents:				
Cash	$ 3,147	$ -	$ -	$ 3,147
Money market funds	44,002	-	-	44,002
Corporate debt securities	2,199	-	-	2,199
Total cash and cash equivalents	49,348	-	-	49,348
Marketable securities available-for-sale:				
U.S. treasuries	14,732	-	(8)	14,724
U.S. government agency securities	42,416	-	(44)	42,372
Corporate debt securities	39,108	-	(16)	39,092
Total marketable securities available-for-sale	96,256	-	(68)	96,188
Total cash, cash equivalents and marketable securities	$ 145,604	$ -	$ (68)	$ 145,536

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

	March 31, 2019	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 71,083	$ 71,083
Mature after one year through two years	-	-
	$ 71,083	$ 71,083

There were no realized gains or losses from the sale of marketable securities during the three months ended March 31, 2019 and 2018.

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

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

To date, there have been no declines in fair value that have been identified as other than temporary.

4. Inventories, net

The following table presents inventories (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ 15,919	$ 12,111
Work-in-process	11,352	6,562
Finished goods	298	349
Total	$ 27,569	$ 19,022

5. Intangible Assets, net

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

	March 31, 2019	December 31, 2018
Intangible assets	$ 19,773	$ 19,773
Less accumulated amortization	(10,328)	(8,056)
Total	$ 9,445	$ 11,717

We recorded $2.3 million and $2.4 million as cost of sales - amortization of intangible assets for the three months ended March 31, 2019 and 2018, respectively. See Note 7.

6. Commitments and Contingencies

Leases

As described in Note 1, we adopted ASC 842 as of January 1, 2019. We evaluated our contracts and have determined that, effective upon the adoption of ASC 842, our operating leases included laboratory, equipment and office/manufacturing facility leases.

We lease our facilities in Berkeley, California ("Berkeley Lease"), Emeryville, California and Düsseldorf, Germany.

On September 17, 2018, we entered into an Office/Laboratory Lease ("Lease") for office and laboratory space located at 5959 Horton Street, Emeryville, California ("Premises"). Under the terms of the Lease, we will lease 75,662 square feet in the Premises ("Rented Area") at the rate of $4.75 ("Base Rate") multiplied by the Rented Area, paid on a monthly basis, starting on the earlier of our commencement of our business operations at the Premises or April 1, 2019 ("Commencement Date"). The Base Rate is subject to scheduled annual increases, and we are also responsible for certain operating expenses and taxes throughout the life of the Lease. In connection with the Lease, we are entitled to a tenant improvement allowance of up to $8.3 million. The Lease has an initial term of 12 years, following the Commencement Date with an option to extend the lease for two successive five-year terms. The optional periods were not included in the lease term used in determining the right-of-use asset or the lease liability as we did not consider it reasonably certain that we would exercise the options. The operating lease right-of-use assets and liabilities on our March 31, 2019 condensed consolidated balance sheets primarily relate to this Lease.

In connection with our execution of the Lease, on September 17, 2018, we entered into a Lease Termination Agreement to terminate the Berkeley Lease effective as of the date we vacate the Berkeley premises. The rent payable for the Berkeley Lease is subject to a "hold-over" increase should we not vacate prior to July 31, 2019.

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

	Three Months Ended March 31,	
	2019	2018
Operating lease expense	$ 1,738	$ 696

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2019 was $0.7 million and was included in operating cash flows in our condensed consolidated statement of cash flows.

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

	March 31, 2019	December 31, 2018
Operating lease liabilities:		
Current portion of lease liabilities (included in other current liabilities)	$ 1,884	$ -
Long-term portion of lease liabilities	35,076	-
Total operating lease liabilities	$ 36,960	$ -

At March 31, 2019, the maturities of our operating lease liabilities were as follows (in thousands):

Years ending December 31,	
2019 (remaining)	$ 4,240
2020	5,353
2021	5,248
2022	5,290
2023	4,988
Thereafter	39,537
Total lease payments	64,656
Less:	
Present value adjustment	(27,696)
Total operating lease liabilities	$ 36,960

As of March 31, 2019, the weighted average remaining lease term is 11.1 years and the weighted average discount rate used to determine the operating lease liability was 10.1%.

Commitments

In February 2018, we entered into a $175.0 million term loan agreement. Borrowings under the term loan agreement in the amount of $177.3 million, which includes paid-in-kind interest, are payable at maturity on December 31, 2023, unless earlier prepaid. See Note 8.

In February 2018, we entered into a sublicense agreement with Merck Sharpe & Dohme Corp ("Merck"). Under the agreement, we are required to make a payment of $7.0 million in the first quarter of 2020. See Note 7.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B and SD-101. As of March 31, 2019, our non-cancelable purchase commitments totaled $11.9 million.

We have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In addition, in the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies, if any, or other payments contingent upon the occurrence of future events that cannot reasonably be estimated.

We rely on and have entered into agreements with research institutions, contract research organizations and clinical investigators. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

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.

In conjunction with a financing arrangement with Symphony Dynamo, Inc. and Symphony Dynamo Holdings LLC ("Holdings") in November 2009, we agreed to make contingent cash payments to Holdings equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of cancer and hepatitis C therapies originally licensed to Symphony Dynamo, Inc., including SD-101. We have made no payments and have not recorded a liability as of March 31, 2019.

7. Collaborative Research, Development and License Agreements

Serum Institute of India Pvt. Ltd.

In June 2017, we entered into an agreement to provide Serum Institute of India Pvt. Ltd. ("SIIPL") with technical support. In consideration, SIIPL agreed to pay us at an agreed-upon hourly rate for services and reimburse certain out-of-pocket expenses. In addition, we have rights to commercialization of certain potential products manufactured at the SIIPL facility. For the three months ended March 31, 2019, we recognized collaboration revenue of $0.1 million. No collaborative revenue was recognized for the comparative prior period.

Merck, Sharp & Dohme Corp.

In February 2018, we entered into a Sublicense Agreement (the "Sublicense Agreement") with Merck. The Sublicense Agreement grants us, under certain non-exclusive U.S. patent rights controlled by Merck which relate to recombinant production of hepatitis B surface antigen, the right to manufacture, use, offer for sale, sell and import HEPLISAV-B in the United States and includes the right to grant further sublicenses. Under the terms of the Sublicense Agreement, we are obligated to pay $21.0 million in three installments. The first and second installment of $7.0 million each was paid in February 2018 and February 2019, respectively and the remaining payment of $7.0 million is due in the first quarter of 2020. The payment in 2020 is classified on the condensed consolidated balance sheets as other current liabilities. At March 31, 2019 and December 31, 2018, the intangible asset, net balance was $9.4 million and $11.7 million, respectively. See Note 5. The Sublicense Agreement continues to be in effect through April 2020, at which time the license becomes perpetual, irrevocable, fully paid-up and royalty free.

8. Long-Term Debt

On February 20, 2018, we entered into a $175.0 million term loan agreement ("Loan Agreement") with CRG Servicing LLC. We initially borrowed $100.0 million (the "Initial Term Loan") under the Loan Agreement at closing and the remaining $75.0 million (the "Second Tranche Term Loan") in March 2019 (collectively, "Term Loans"). Net proceeds from the Initial Term Loan and Second Tranche Term Loan were $99.0 million and $74.3 million, respectively. The Term Loans under the Loan Agreement bear interest at a rate equal to 9.5% per annum. At March 31, 2019, the effective interest rate was 10.2%. At our option, until September 30, 2023, a portion of the interest payments may be paid in kind, and thereby added to the principal. Through March 31, 2019, a portion of our interest was paid in kind, which increased the principal amount of the Term Loans to $177.3 million. The Term Loans have a maturity date of December 31, 2023, unless earlier prepaid. The Term Loans and paid-in-kind interest will be entirely payable at maturity.

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

The Term Loans may be prepaid by us at any time. If the Term Loans are prepaid prior to the second anniversary of the initial borrowing date, we are subject to a repayment premium of up to 7.0% of the principal amount prepaid, depending on the date of prepayment.

We recorded $2.6 million and $1.1 million of interest expense related to the Term Loans during the three months ended March 31, 2019 and 2018, respectively.

9. Revenue Recognition

All of our product revenue consisted of sales of HEPLISAV-B in the U.S. For the three months ended March 31, 2019 and 2018, our three largest Customers represented approximately 66% and 86% of our product revenue, respectively. The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2019 (in thousands):

	Chargebacks, distribution fees, discounts and other fees	Returns	Total
Balance at December 31, 2018	$ 1,736	$ 569	$ 2,305
Provision related to current period sales	3,080	458	3,538
Credit or payments made during the period	(1,658)	(86)	(1,744)
Balance at March 31, 2019	$ 3,158	$ 941	$ 4,099

Reserves for chargebacks and discounts totaling $2.3 million were recorded as reductions of accounts receivable at March 31, 2019. The remaining reserves balances totaling $1.8 million were recorded as accrued liabilities at March 31, 2019.

10. Net Loss Per Share

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

Stock options and stock awards totaling approximately 8,946,000 and 8,394,000 shares of common stock as of March 31, 2019 and 2018, respectively, were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2019 and 2018, because the effect of their inclusion would have been anti-dilutive. For periods in which we have a net loss and no instruments are determined to be dilutive, such as the three months ended March 31, 2019 and 2018, basic and diluted net loss per share are the same.

11. Common Stock

Common Stock Outstanding

As of March 31, 2019, there were65,020,320 shares of our common stock outstanding.

On November 3, 2017, we entered into an At Market Sales Agreement ("2017 ATM Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell from time to time at our sole discretion, shares of our common stock having an aggregate offering price up to $150 million through Cowen as our sales agent. We pay Cowen a commission of up to 3% of the gross sales proceeds of any common stock sold through Cowen under the 2017 ATM Agreement. For the three months ended March 31, 2019, we received net cash proceeds of $13.6 million resulting from sales of1,343,337 shares of our common stock. As of March 31, 2019, we have $118.9 million remaining under the 2017 ATM Agreement. Subsequent to March 31, 2019 and through May 3, 2019, we sold 43,569 shares of common stock for net proceeds of $0.3 million under the 2017 ATM Agreement.

12. Equity Plans and Stock-Based Compensation

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

Option activity under our stock-based compensation plans during the three months ended March 31, 2019 was as follows (in thousands except per share amounts):

	Shares Underlying Outstanding Options (in thousands)	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2018	5,750	$ 18.20		
Options granted	1,121	10.32		
Options exercised	(7)	5.53		
Options cancelled:				
Options forfeited (unvested)	(73)	15.61		
Options expired (vested)	(19)	23.23		
Balance at March 31, 2019	6,772	$ 16.92	5.50	$ 230
Vested and expected to vest at March 31, 2019	6,500	$ 17.08	5.46	$ 229
Exercisable at March 31, 2019	3,673	$ 19.30	4.83	$ 186

Restricted stock unit activity under our stock-based compensation plans during the three months ended March 31, 2019 was as follows (in thousands except per share amounts):

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of December 31, 2018	1,594	$ 8.82
Granted	1,355	10.47
Vested	(738)	6.89
Forfeited	(37)	13.10
Non-vested as of March 31, 2019	2,174	$ 10.43

The aggregate intrinsic value of the restricted stock units outstanding as of March 31, 2019, based on our stock price on that date was $5.9 million. Fair value of restricted stock units is determined at the date of grant using our closing stock price.

As of March 31, 2019, approximately151,000 shares underlying stock options and approximately176,000 restricted stock unit awards with performance-based vesting criteria were outstanding. We recognized stock-based compensation expense for awards with performance-based vesting criteria of $0.2 million for each of the three months ended March 31, 2019 and 2018.

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

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

	Stock Options		Employee Stock Purchase Plan	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2019	2018	2019	2018
Weighted-average fair value per share	$ 6.85	$ 10.84	$ 5.19	$ 10.39
Risk-free interest rate	2.5%	2.6%	2.5%	2.1%
Expected life (in years)	4.5	4.5	1.2	1.3
Volatility	0.9	0.8	0.8	1.1

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures.The components of stock-based compensation expense were (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 2,180	$ 2,187
Selling, general and administrative	3,080	2,589
Cost of sales - product	572	23
Inventory	338	-
Total	$ 6,170	$ 4,799

As of March 31, 2019, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to $38.0 million, which is expected to be recognized over the remaining weighted-average vesting period of2 years. Additionally, as of March 31, 2019, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria amounted to $1.6 million.

Employee Stock Purchase Plan

The Amended and Restated 2014 Employee Stock Purchase Plan (the “Purchase Plan”) provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. On May 31, 2018, our stockholders approved an amendment to the Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance by 600,000 shares. The purchase price per share is the lesser of (i) 85% of the fair market value of the common stock on the commencement of the offer period (generally, the sixteenth day in February or August) or (ii) 85% of the fair market value of the common stock on the exercise date, which is the last day of a purchase period (generally, the fifteenth day in February or August). For the three months ended March 31, 2019, employees have acquired 74,562 shares of our common stock under the Purchase Plan and498,472 shares of our common stock remained available for future purchases under the Purchase Plan.

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 related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2018.

Overview

We are a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor ("TLR") stimulation.

Our first commercial product, HEPLISAV-B (Hepatitis B Vaccine (Recombinant), Adjuvanted), is approved by the United States Food and Drug Administration ("FDA") for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. We commenced commercial shipments of HEPLISAV-B in January 2018.

Our development efforts are primarily focused on stimulating the innate immune response to treat cancer in combination with other immunomodulatory agents.

Our lead investigational immuno-oncology product is SD-101. SD-101 is currently being evaluated in Phase 2 clinical studies in melanoma, head and neck squamous cell carcinoma and neoadjuvant treatment of breast cancer.

Our second immuno-oncology product candidate is DV281, a novel investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases as an inhaled aerosol. In October 2017, we announced initiation of dosing in a Phase 1b study of inhaled DV281, in combination with anti-PD-1 therapy, in patients with non-small cell lung cancer.

Product revenue is dependent on our ability to successfully market HEPLISAV-B and our product candidates, if they are approved.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates, discovery research and development and tenant improvements and ongoing occupancy costs at our new corporate headquarters. Until we can 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. 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 delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

Critical Accounting Policies and the Use of Estimates

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

While our significant accounting policies are more fully described in Note 1 to the condensed consolidated financial statements, we believe the following accounting policy reflects the new and the more critical and significant judgments and estimates used in the preparation of our condensed consolidated financial statements, that has been adopted since our latest Annual Report on Form 10-K for the year ended December 31, 2018

Leases

On January 1, 2019, we adopted ASC 842, Leases, using the modified retrospective approach. Prior period amounts continue to be reported in accordance with our historic accounting under previous lease guidance, ASC 840, Leases. We elected the package of practical expedients which, among other things, allowed us to carry forward the historical lease classification of leases in place as of January 1, 2019. As a result of adopting ASC 842, we recognized right-of-use asset and lease liabilities for operating leases of $34.8 million and $37.1 million, respectively on January 1, 2019. There was no adjustment to the opening balance of accumulated deficit as a result of the adoption of ASC 842.

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

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

Results of Operations

Revenues

Revenues consisted of amounts earned from product revenue and collaborations. The following is a summary of our revenues (in thousands, except for percentages):

	Three Months Ended March 31,		Increase (Decrease) from 2018 to 2019	
Revenues:	**2019**	**2018**	**$**	**%**
Product revenue, net	$ 5,627	$ 165	$ 5,462	3310%
Collaboration revenue	146	-	146	NM
Total revenues	$ 5,773	$ 165	$ 5,608	3399%

NM=Not Meaningful

Product revenue, net, reflects sales of HEPLISAV-B of $5.6 million and $0.2 million for the three months ended March 31, 2019 and 2018, respectively. We commenced commercial shipments of HEPLISAV-B in January 2018 and deployed our field sales force in February 2018. Sales efforts continue to focus on advancing HEPLISAV-B through the complex and protracted approval and procurement processes in large institutional accounts across the country. We expect quarterly sales will increase during 2019 as additional healthcare providers complete their reviews and the operational activities required to switch to HEPLISAV-B and existing customers place repeat orders.

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

Cost of Sales – Product

	Three Months Ended March 31,		Increase (Decrease) from 2018 to 2019	
	2019	2018	$	%
Cost of sales - product	$ 1,800	$ 205	$ 1,595	778%

Cost of sales - product of $1.8 million for the three months ended March 31, 2019 includes certain fill, finish and overhead costs for pre-filled syringes ("PFS") of HEPLISAV-B. Our HEPLISAV-B PFS inventory includes components whose manufacturing costs were previously expensed to research and development prior to its FDA approval in March 2018. We expect to use this HEPLISAV-B PFS inventory over approximately the next nine months. Afterwards, we expect our cost of sales of HEPLISAV-B PFS to increase as a percentage of net sales in future periods as we produce and then sell inventory that reflects the full cost of manufacturing the product.

Cost of sales – product of $0.2 million for the three months ended March 31, 2018 includes certain finish and overhead costs for HEPLISAV-B vials incurred after FDA approval in November 2017. Prior to FDA approval of HEPLISAV-B vials, costs to manufacture HEPLISAV-B were expensed to research and development as there was no alternative future use.

At March 31, 2019 and December 31, 2018, inventories, net were $27.6 million and $19.0 million, respectively.

Cost of Sales - Amortization of Intangible Assets

Cost of sales - amortization of intangible assets of $2.3 million and $2.4 million for the three months ended March 31, 2019 and 2018, respectively, consists of amortization of the intangible asset recorded as a result of a regulatory milestone and sublicense fees to Coley Pharmaceutical Group, Inc. ("Coley"), Merck, Sharpe & Dohme Corp. ("Merck") and GlaxoSmithKline Biologicals SA ("GSK"), upon or after FDA approval of HEPLISAV-B in November 2017. At March 31, 2019, the intangible assets related to Coley and GSK have been fully-amortized and the intangible asset related to Merck of $9.4 million has an estimated remaining useful life through the patent expiration date in April 2020.

Research and Development Expense

Research and development expense consists, primarily, of compensation and related personnel costs (which include benefits, recruitment, travel and supply costs), outside services, allocated facility costs and non-cash stock-based compensation. Outside services consist of costs associated with clinical development, preclinical discovery and development, regulatory filings and research, including fees and expenses incurred by contract research organizations, clinical study sites, and other service providers and costs of manufacturing product candidates prior to approval. The following is a summary of our research and development expense (in thousands, except for percentages):

	Three Months Ended March 31,		Increase (Decrease) from 2018 to 2019	
Research and Development:	2019	2018	$	%
Compensation and related personnel costs	$ 7,904	$ 8,599	$ (695)	(8)%
Outside services	8,731	5,666	3,065	54%
Facility costs	2,391	2,513	(122)	(5)%
Non-cash stock-based compensation	2,180	2,188	(8)	NM
Total research and development	$ 21,206	$ 18,966	$ 2,240	12%

NM=Not Meaningful

Compensation and related personnel costs includes costs of developing and manufacturing HEPLISAV-B prior to FDA approval in late March 2018. After the approval of PFS of HEPLISAV-B, costs incurred at our Düsseldorf facility to resume operating activities were charged to cost of sales – product, while costs incurred to manufacture HEPLISAV-B for commercial sale were accounted for as inventory. The quarter ended March 31, 2019 includes an overall increase in headcount and costs for outside services to support the ongoing development of SD-101 and earlier stage immuno-oncology programs.

Spending on immuno-oncology clinical trials is currently focused on completing current trials and we do not anticipate beginning additional trials without financial support from a collaborator.

Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of compensation and related costs for our commercial support personnel, medical education professionals and personnel in executive and other administrative functions, including legal, finance and information technology; costs for outside services such as costs for 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 expense (in thousands, except for percentages):

	Three Months Ended March 31,		Increase (Decrease) from 2018 to 2019	
Selling, General and Administrative:	**2019**	**2018**	**$**	**%**
Compensation and related personnel costs	$ 5,114	$ 3,548	$ 1,566	44%
Outside services	8,568	9,048	(480)	(5)%
Legal costs	526	1,211	(685)	(57)%
Facility costs	1,060	496	564	114%
Non-cash stock-based compensation	3,080	2,588	492	19%
Total selling, general and administrative	$ 18,348	$ 16,891	$ 1,457	9%

Compensation and related personnel costs and non-cash stock-based compensation increased due to an increase in employee headcount to support HEPLISAV-B commercial activities. Legal costs decreased primarily due to outside counsel costs incurred in connection with the loan financing in the first quarter of 2018. Facility costs, which includes an overhead allocation primarily comprised of occupancy and related expenses, increased due to lease expense related to our new corporate headquarters.

Interest Income, Interest Expense and Other Expense, Net

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest expense includes the stated interest and accretion of discount and end of term fee related to our long-term debt agreement entered into in February 2018. Other income (expense), net includes gains and losses on foreign currency transactions and disposal of property and equipment.

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

	Three Months Ended March 31,		Increase (Decrease) from 2018 to 2019	
	2019	**2018**	**$**	**%**
Interest income	$ 735	$ 740	$ (5)	(1)%
Interest expense	$ (2,734)	$ (1,161)	$ 1,573	135%
Other income (expense), net	$ 181	$ (223)	$ 404	181%

Interest expense increased due to timing of the $100.0 million term loan that we borrowed on February 20, 2018 under a term loan agreement with CRG Servicing LLC (“Loan Agreement”). The change in other income (expense), net is primarily due to foreign currency transactions resulting from fluctuations in the value of the Euro compared to the U.S. dollar.

Liquidity and Capital Resources

As of March 31, 2019, we had $183.2 million in cash, cash equivalents and marketable securities. Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, borrowings, government grants and revenues from collaboration agreements to fund our operations. Our funds are currently invested in money market funds, U.S. treasuries, U.S. government agency securities and corporate debt securities. We currently anticipate that our cash, cash equivalents and short-term marketable securities and anticipated revenues from HEPLISAV-B will be sufficient to fund our operations for at least the next 12 months.

At March 31, 2019, $118.9 million of common stock remained available for sale under our At Market Sales Agreement with Cowen and Company, LLC ("2017 ATM Agreement").

During the three months ended March 31, 2019, we used $39.9 million of cash for our operations primarily due to our net loss of $39.7 million, of which $11.9 million consisted of non-cash charges such as stock-based compensation, amortization of intangible assets, amortization of right-of-use assets, depreciation and amortization, non-cash interest expense and accretion and amortization on marketable securities. By comparison, during the three months ended March 31, 2018, we used $29.9 million of cash for our operations primarily due to our net loss of $39.0 million, of which $8.2 million consisted of non-cash charges such as stock-based compensation, amortization of intangible assets, depreciation and amortization, non-cash interest expense and accretion and amortization on marketable securities. Cash used in our operations during the first three months of 2019 increased by $10.0 million. During the first quarter of 2019, we invested approximately $4.6 million in HEPLISAV-B inventory. Net cash used in operating activities is also impacted by changes in our operating assets and liabilities due to timing of cash receipts and expenditures.

During the three months ended March 31, 2019, net cash provided by investing activities was $14.6 million compared to $59.7 million in net cash used in investing activities for the three months ended March 31, 2018. Cash provided by investing activities during the first three months of 2019 included $25.5 million of net proceeds from maturities of marketable securities, compared to $49.3 million of net purchases of marketable securities during the first three months of 2018. During the first three months of 2019, we paid $7.0 million of sublicense payment to Merck, compared to $9.5 million of milestone and sublicense payments to Coley and Merck during the first three months of 2018. Cash used in net purchases of property plant and equipment increased by $3.0 million during the first three months of 2019 compared to the same period in 2018. The increase is, primarily, due to the installation of facility improvements at our new corporate headquarters.

During the three months ended March 31, 2019 and 2018, net cash provided by financing activities was $88.3 million and $98.8 million, respectively. Cash provided by financing activities in the first three months of 2019 included net proceeds of $74.3 million from the second tranche of the Loan Agreement and net proceeds of $13.6 million from the issuance of common stock under our 2017 ATM Agreement. Cash provided by financing activities in the first three months of 2018 included net proceeds of $99.0 million from the Loan Agreement.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates, discovery research and development and tenant improvements and ongoing occupancy costs at our new corporate headquarters. Until we can 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. 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 delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

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. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

Contractual Obligations

On March 29, 2019, we borrowed the remaining $75.0 million (the "Second Tranche Term Loan") from the $175.0 million term loan agreement with CRG Servicing LLC. We initially borrowed $100.0 million (the "Initial Term Loan") at closing on February 20, 2018. The principal amounts of Initial Term Loan and Second Tranche Term Loan totaling $177.3 million, which includes paid-in-kind interest, have a maturity date of December 31, 2023, unless earlier prepaid.

We have entered into material purchase commitments with commercial manufacturers for the supply of HEPLISAV-B and SD-101. As of March 31, 2019, our non-cancelable purchase commitments totaled $11.9 million.

There were no other material changes to the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Off-balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ended March 31, 2019, 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, 2018.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

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

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

(b) Changes in internal controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future efforts to obtain regulatory approval, timing of development activities, commercialize approved products, 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 the following risk factors. 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, 2018 that was filed with the Securities and Exchange Commission on February 27, 2019.

Risks Related to our Business and Capital Requirements

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

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

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

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

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

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

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

products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

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

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

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

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

Also, there has been heightened governmental scrutiny recently in the U.S. over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, and restrictions on certain product access. In some cases, such legislation and regulations have been designed to encourage importation from other countries and bulk purchasing. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or the effect any such initiatives may have on our business.

We are also dependent on the success of our development stage products including SD-101, which depend on regulatory approval. Failure to maintain or obtain regulatory approvals could require us to discontinue operations.

In addition to the potential commercial success of HEPLISAV-B, we are dependent on our development stage immuno-oncology pipeline of early stage oncology product candidates, and early stage development is inherently risky. Even if we have early indications of success in clinical development, in order to be able to market our products in the U.S., we must obtain approval from the FDA, and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining FDA marketing approval and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The FDA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials or the development program are satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or proposed post-marketing study, or a conclusion that the data fails to meet statistical or clinical significance or safety requirements; acceptability of data generated at our clinical trial sites that are monitored by third party contract research organizations ("CROs"); and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, we received Complete Response Letters from the FDA for HEPLISAV-B in 2013 and 2016 before obtaining approval in November 2017.

In the event that we determine to commercialize HEPLISAV-B outside the United States, such as in Europe, the product is not approved and our opportunity will depend upon our receiving regulatory approval, which can be costly and time consuming, and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and/or take other measures which will take time and require that we incur significant additional expense. In addition, there is the risk that we may not receive approval in one or more jurisdictions.

In 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.

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

Our HEPLISAV-B regulatory approval is subject to certain post-marketing obligations and commitments to the FDA. We must conduct an observational comparative study of HEPLISAV-B to another hepatitis B vaccine to assess occurrence of acute myocardial infarction; must conduct an observational surveillance study to evaluate the incidence of new onset immune-mediated diseases, herpes zoster and anaphylaxis; and must establish a pregnancy registry to provide information on outcomes following pregnancy exposure to HEPLISAV-B. These studies will require significant effort and resources, and failure to timely conduct these studies to the satisfaction of FDA could result in withdrawal of our BLA approval. The results of post-marketing studies may also result in additional warnings or precautions for the HEPLISAV-B label or expose additional safety concerns that may result in product liability and withdrawal of the product from the market, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

We have generated limited revenue from the sale of products and have incurred losses in each year since we commenced operations in 1996. Our net losses for the three months ended March 31, 2019 and 2018 were $39.7 million and $39.0 million, respectively. As of March 31, 2019, we had an accumulated deficit of $1.1 billion.

With our investment in the launch and commercialization of HEPLISAV-B in the U.S. in addition to our investment in our oncology product candidates, we expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. Our expenses have increased substantially as we established and maintain our HEPLISAV-B commercial infrastructure, including investments in internal infrastructure to support our plans for converting our contracted field sales force to Dynavax employees and investments in manufacturing and supply chain commitments to maintain commercial supply of HEPLISAV-B. The timing for uptake of our product in the U.S. has further increased losses related to commercialization, and the advancement of our oncology pipeline has increased our costs as we conduct more and larger studies to invest in clinical development. Due to the numerous risks and uncertainties associated with developing and commercializing vaccine and pharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

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

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in commercialization of HEPLISAV-B, including investment in HEPLISAV-B inventory, clinical trials and other development, manufacturing and regulatory activities for our immuno-oncology product candidates and discovery research and development and tenant improvements and ongoing occupancy costs at our new corporate headquarters. Until we can generate a sufficient amount of revenue, we will need to finance our operations through strategic alliance and licensing arrangements and/or public or private debt and equity financings. 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 delay, reduce the scope of or put on hold one or more programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our business objectives.

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. Raising additional funds through the issuance of equity or debt securities could result in dilution to our existing stockholders, increased fixed payment obligations, or both. In addition, these securities may have rights senior to those of our common stock and could include covenants that would restrict our operations.

The FDA may require more clinical trials for our development stage 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 the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

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

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

Clinical trials, including post-marketing studies, to generate sufficient data to meet FDA requirements are expensive and time consuming.

We are currently undertaking clinical trials of SD-101 and DV281, including combination studies with other oncology agents, and expect to commence clinical trials for other product candidates in our immuno-oncology pipeline in the future. Our strategy with respect to development of SD-101 and DV281 involves combination studies with other oncology agents. While we believe that this combination agent approach increases the potential for success, these clinical trials are dependent on continuing access to the other oncology agents, and for combination studies that are pursuant to a collaboration they are contingent on agreement with our

combination agent study partners regarding the use of the other agents, concurrence on a protocol and supply of clinical materials. Most of our combination agent study partners, such as Merck & Co. ("Merck"), are significantly larger than we are and are conducting various other combination studies with other immuno-oncology agents and collaborators. We are not certain these clinical trials will be successful, or that even if successful we would be able to reach agreement to conduct larger, more extensive clinical trials required to achieve regulatory approval for a combination product candidate regimen. 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 or a combination of product candidates.

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

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 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 they fail to comply with GCP standards, fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

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

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

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

- the inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- the inability to retain participants who have initiated a clinical trial but may withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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

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

HEPLISAV-B, SD-101 and most of our earlier stage programs rely on oligonucleotide TLR agonists. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue our operations.

Most of our programs, including HEPLISAV-B and SD-101, 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 many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing HEPLISAV-B and our product candidates, including SD-101 and DV281, certain antigens, the combination of the oligonucleotide and the antigens, and formulation, fill and finish. The FDA approved our pre-filled presentation of HEPLISAV-B in 2018 and we expect such presentation will be the sole presentation for HEPLISAV-B going forward. We have limited experience in manufacturing and supplying this presentation, and there can be no assurance that we can successfully manufacture sufficient quantities of pre-filled syringes in compliance with GMP in order to meet market demand.

We have also relied on a limited number of suppliers to produce oligonucleotides for clinical trials and a single supplier to produce our 1018 for HEPLISAV-B. To date, we have manufactured only small quantities of oligonucleotides ourselves for development purposes. If we were unable to maintain our existing suppliers for 1018 and SD-101, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV-B. We or other third parties may not be able to produce product at a cost, quantity and quality that are available from our current third-party suppliers or at all.

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

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.

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

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

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

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

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

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

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities upon favorable terms;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

We withdrew our MAA for HEPLISAV-B in Europe in 2014. We may not be able to provide sufficient data or respond to other comments to our previously filed MAA sufficient to obtain regulatory approval in Europe in a reasonable time period or at all.

Any failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If 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 our products or limits our marketing claims, we may be unable to generate significant revenues, if any.

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

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

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

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

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

We may need to establish collaborative relationships to obtain domestic and/or international sales, marketing, research, development and distribution capabilities for our product candidates, including SD-101 and DV281, and our discovery research programs. Failure to obtain a collaborative relationship for those product candidates and programs or HEPLISAV-B in markets outside the U.S. requiring extensive sales efforts, may significantly impair the potential for those products and programs and we may be required to raise additional capital to continue them. The process of establishing and maintaining collaborative relationships is difficult and time-consuming, and even if we establish such relationships, they may involve significant uncertainty, including:

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

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

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

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. 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.

Despite our efforts, we may be unable to secure collaborative arrangements. If we are unable to enter into a collaborative relationship to advance SD-101, DV281 or other research programs, we may not be able to adequately fund them, if at all, in the absence of a third-party partner and may not be able to obtain significant value for the programs without further investment, which may not be available on acceptable terms, or at all.

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 revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing and marketing therapies to prevent or treat cancer and infectious and inflammatory diseases. For example, HEPLISAV-B competes in the U.S. with established hepatitis B vaccines marketed by Merck and GlaxoSmithKline plc ("GSK") and if approved outside the U.S., with vaccines from those companies as well as several additional established pharmaceutical companies.

Oncology is also a highly competitive market, with numerous biotechnology and pharmaceutical companies developing therapies for all of the targets we are pursuing. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier approval or patent protection or commercialization of their products. These competitive products may render our product candidates obsolete, change the standard of care against which our products much show safety and efficacy or limit our ability to generate revenues from our product candidates.

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

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

In February, 2018, we entered into a term loan agreement under which we have borrowed $177.3 million, which includes paid-in-kind interest. The agreement contains covenants that restrict our ability to take various actions, including, among other things, incur additional indebtedness, pay dividends or distributions or make certain investments, create or incur certain liens, transfer, sell, lease or dispose of assets, enter into transactions with affiliates, consummate a merger or sell or other dispose of assets. The agreement also requires us to comply with a daily minimum liquidity covenant and an annual revenue requirement based on the sales of HEPLISAV-B, which is $30 million for fiscal year 2019. The agreement specifies a number of events of default, some of which are subject to applicable grace or cure periods, including, among other things, non-payment defaults, covenant defaults, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults, and non-payment of material judgments.

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

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

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

As we are evolving from a company primarily involved in research and development to a company increasingly involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

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

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

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

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

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

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

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

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

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. For example, the PPACA, 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. Some of the provisions of PPACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA 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". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and on our business.

Other legislative changes have also been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to two percent per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding.

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

The loss of key personnel, including our Chief Executive Officer, 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 key scientific and other personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer. We currently have no key person insurance on any of our employees.

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

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

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

The comprehensive tax reform bill passed in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law legislation, known as the Tax Cuts and Jobs Act of 2017, that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected.

We use hazardous materials and controlled substances in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials and substances could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste, and controlled substances. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials, substances, and certain waste products. We believe we are currently in compliance with all government permits that are required for the storage, use and disposal of these materials and controlled substances. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials, or that controlled substances will be accidentally stored or used in violation of relevant federal, state and local requirements. In the event of an accident related to hazardous materials or a violation of requirements pertaining to controlled substances, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations, and laws and regulations pertaining to the storage and use of controlled substances.

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. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

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

On June 28, 2018, California adopted the California Consumer Privacy Act of 2018 ("CCPA"). The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions in the GDPR. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. The effective date of the CCPA is January 1, 2020, however, legislators have stated that they intend to propose amendments to the CCPA before it goes into effect. We are continuing to analyze the CCPA in order to determine its applicability and impact to our business.

If we are unable to prevent 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. 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 to protect our data security and information technology systems, such measures may not prevent such events.

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

Risks Related to our Intellectual Property

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

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our

agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time.

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

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

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

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

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

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection.

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

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

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

Risks Related to an Investment in our Common Stock

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

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

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

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

The anti-takeover provisions of our certificate of incorporation, our bylaws,and Delaware law may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

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

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

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 31, 2019 we had 65,020,320 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

Under our universal shelf registration statement filed by us in August 2017, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, including pursuant to our 2017 ATM Agreement with Cowen under which we can offer and sell our common stock from time to time up to aggregate sales proceeds of $150 million. As of March 31, 2019, we have $118.9 million remaining under this agreement.The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

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

None.

ITEM 5. OTHER INFORMATION

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	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 and 3.8 above					
4.2	Form of Specimen Common Stock Certificate	4.2	S-1/A	January 16, 2004	333-109965	
31.1	Certification of Chief 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 Chief 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	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	XBRL Taxonomy Extension Schema Document
EX—101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX—101.DEF	XBRL Taxonomy Extension Definition Linkbase
EX—101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
EX—101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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 Berkeley, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

Date: May 9, 2019

By: /s/ EDDIE GRAY
Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2019

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

Date: May 9, 2019

By: /s/ DAVID JOHNSON
David Johnson
Vice President, Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

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

CERTIFICATIONS

I, Eddie Gray, 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/ EDDIE GRAY

Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2019

Exhibit 31.2

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

CERTIFICATIONS

I, Michael Ostrach, certify that:

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

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

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

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

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

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

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

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

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

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

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

By: /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

Date: May 9, 2019

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, Eddie Gray, Chief Executive Officer of Dynavax Technologies Corporation (the "Company"), hereby certify that, to the best of my knowledge:

(i) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019 (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 9th day of May, 2019.

By: /s/ EDDIE GRAY

Eddie Gray
Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

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

(i) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019 (the "Periodic Report"), to which this Certificate is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 9th day of May, 2019.

By: /s/ MICHAEL OSTRACH

Michael Ostrach
Chief Financial Officer
(Principal Financial Officer)

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