DYNAVAX TECHNOLOGIES CORP
Form 10-Q
May 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

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)

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No ¨

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

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨	Smaller reporting company	¨

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

As of May 3, 2016, the registrant had outstanding 38,495,782 shares of common stock.

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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 develop and timely achieve regulatory approval for HEPLISAV-B™, our business, collaboration and regulatory strategy, our intellectual property position, our product development efforts, our ability to commercialize our product candidates, including HEPLISAV-B, 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 o 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	March 31, 2016 (unaudited)	December 31, 2015 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 38,858	$ 44,812
Marketable securities available-for-sale	127,989	151,313
Accounts receivable	1,164	1,394
Prepaid expenses and other current assets	2,728	2,427
Total current assets	170,739	199,946
Property and equipment, net	15,894	13,804
Goodwill	2,127	2,043
Restricted cash	617	609
Other assets	267	231
Total assets	$ 189,644	$ 216,633
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,476	$ 3,433
Accrued research and development	6,027	7,361
Accrued liabilities	13,251	15,337
Deferred revenues	1,759	2,654
Total current liabilities	24,513	28,785
Other long-term liabilities	700	769
Total liabilities	25,213	29,554
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	-	-
Common stock: $0.001 par value; 69,500 shares authorized at March 31, 2016 and December 31, 2015; 38,496 and 38,446 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	38	38
Additional paid-in capital	893,278	889,698
Accumulated other comprehensive loss	(2,135)	(2,930)
Accumulated deficit	(726,750)	(699,727)
Total stockholders' equity	164,431	187,079
Total liabilities and stockholders' equity	$ 189,644	$ 216,633

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Collaboration revenue	$895	$471
Grant revenue	39	148
Service and license revenue	8	8
Total revenues	942	627
Operating expenses:		
Research and development	20,067	22,220
General and administrative	8,169	4,859
Total operating expenses	28,236	27,079
Loss from operations	(27,294)	(26,452)
Other income (expense):		
Interest income	225	27
Interest expense	-	(247)
Other income, net	46	455
Net loss	$(27,023)	$(26,217)
Basic and diluted net loss per share	$(0.70)	$(0.97)
Weighted average shares used to compute basic and diluted net loss per share	38,472	27,065

Dynavax Technologies Corporation

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net loss	$(27,023)	$(26,217)
Other comprehensive income (loss):		

Unrealized gain on marketable securities available-for-sale	109	8
Cumulative foreign currency translation adjustments	686	(1,294)
Total other comprehensive income (loss)	795	(1,286)
Total comprehensive loss	$(26,228)	$(27,503)

See accompanying notes.

Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(27,023)	$(26,217)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	402	335
Accretion of discounts and amortization of premiums on marketable securities	75	171
Accretion of debt discount related to debt financing	-	(51)
Accretion of end of term payment related to debt financing	-	57
Cash-settled portion of stock-based compensation expense	328	-
Stock compensation expense	3,244	1,954
Changes in operating assets and liabilities:		
Accounts receivable	230	(182)
Prepaid expenses and other current assets	(301)	580
Restricted cash and other assets	(36)	-
Accounts payable	658	2,043
Accrued liabilities and other long term liabilities	(3,816)	(2,357)
Deferred revenues	(895)	(472)
Net cash used in operating activities	(27,134)	(24,139)
Investing activities		
Purchases of marketable securities	(61,057)	(18,654)
Proceeds from maturities of marketable securities	84,420	8,750
Purchases of property and equipment, net	(2,611)	(618)
Net cash provided by (used in) investing activities	20,752	(10,522)
Financing activities		
Proceeds from exercise of stock options and restricted stock awards	75	10
Proceeds from exercise of warrants	-	26
Proceeds from Employee Stock Purchase Plan	261	103
Net cash provided by financing activities	336	139
Effect of exchange rate changes on cash and cash equivalents	92	(276)
Net decrease in cash and cash equivalents	(5,954)	(34,798)
Cash and cash equivalents at beginning of period	44,812	49,511
Cash and cash equivalents at end of period	$38,858	$14,713
Supplemental disclosure of cash flow information		
Non-cash investing and financing activities:		
Cash paid during the period for interest	$-	$184
Disposal of fully depreciated property and equipment	$1,154	$4
Net change in unrealized gain on marketable securities	$109	$8

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 clinical-stage biopharmaceutical company that uses toll-like receptor ("TLR") biology to discover and develop novel vaccines and therapeutics. Our development programs are focused on vaccines and cancer immunotherapy. 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, 2015, 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, 2015, as filed with the Securities and Exchange Commission (the "SEC").

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Dynavax GmbH and Dynavax International, B.V. Dynavax International, B.V. was dissolved in January 2015. 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 discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of March 31, 2016, we had cash, cash equivalents and marketable securities of $166.8 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of March 31, 2016, and anticipated revenues and expenditures.

We expect to continue to spend substantial funds in connection with seeking regulatory approval for, and manufacture and other costs relating to, preparation for the anticipated commercial launch of HEPLISAV-B™ in the United States, manufacturing and conducting clinical studies of our investigational cancer immunotherapeutic product candidate, SD-101, and other cancer immunotherapeutic product candidates and additional applications and advancement of our

technology. In order to continue these activities, we may need to raise additional funds. This may occur through strategic collaboration and licensing arrangements and/or future public or private debt and equity financings. Sufficient additional funding may not be available on acceptable terms, or at all. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or our other development programs while we seek strategic alternatives, which could have an adverse impact on our ability to achieve our intended business objectives.

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. Actual results could differ materially from these estimates.

Summary of Significant Accounting Policies

There have been no significant changes in our significant accounting policies during the three months ended March 31, 2016, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Revenue Recognition

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may involve multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the arrangement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Non-refundable upfront fees received for license and collaborative agreements entered into and other payments under collaboration agreements where we have continuing performance obligations related to the payments are deferred and recognized over our estimated performance period. Revenue is recognized on a ratable basis, unless we determine that another method is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Contingent consideration received for the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (i) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (ii) the event can only be achieved based in whole or in part on either the entity’s performance or a specific outcome resulting from the entity’s performance and (iii) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones will be achieved at the time we entered into these agreements. In addition, we evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (i) the development work is contingent on either of the following: (a) the vendor’s performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor’s performance to achieve the milestone; (ii) it relates solely to past performance and (iii) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

Milestone payments that are contingent upon the achievement of substantive at-risk performance criteria are recognized in full upon achievement of those milestone events in accordance with the terms of the agreement and assuming all other revenue recognition criteria have been met. All revenue recognized to date under our collaborative agreements has been nonrefundable.

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments

as revenue upon receipt, provided that revenue recognition criteria have been satisfied.

Revenues from manufacturing services are recognized upon meeting the criteria for substantial performance and acceptance by the customer.

Revenue from royalty payments is contingent on future sales activities by our licensees. Royalty revenue is recognized when all revenue recognition criteria have been satisfied.

Revenue from government and private agency grants is recognized as the related research expenses are incurred and to the extent that funding is approved. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards.

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. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company’s prior period accrued estimates for clinical trial activities through March 31, 2016.

Recent Accounting Pronouncements

Accounting Standards Update 2014-09

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance codified in ASC 606, Revenue Recognition — Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This Accounting Standards Update (“ASU”) is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods), with early application permitted. The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements.

Accounting Standards Update 2015-17

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Subtopic 740): Balance Sheet Classification of Deferred Taxes, The ASU requires entities to classify deferred tax liabilities and assets as noncurrent in a classified statement of financial position. The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, with early application permitted. The Company is currently evaluating the impact of this standard on its financial statements.

Accounting Standards Update 2016-02

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires management to recognize lease assets and lease liabilities by lessees for all operating leases. The ASU is effective for annual periods

beginning after December 15, 2018 and interim periods therein on a modified retrospective basis, with early application permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

Accounting Standards Update 2016-08

In March 2016, the FASB issued ASU No. 2016-08 “Revenue from Contracts with Customers (Topic 606) - Principal versus Agent Considerations (Reporting Revenue Gross versus Net).” ASU No. 2016-08 requires an entity to determine whether the nature of its promise to provide goods or services to a customer is performed in a principal or agent capacity and to recognize revenue in a gross or net manner based on its principal/agent designation. ASU No. 2016-08 is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017, with early application permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

Accounting Standards Update 2016-09

In March 2016, the FASB issued ASU No. 2016-09, “Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” (“ASU 2016-09”). The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. ASU 2016-09 is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2016, with early application permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

Accounting Standards Update 2016-10

In April 2016, the FASB issued ASU No. 2016-10 “Revenue from Contracts with Customers (Topic 606) – Identifying Performance Obligations and Licensing.” ASU No. 2016-10 clarifies the following two aspects of Topic 606: identifying performance obligations and the licensing implementation guidance, while retaining the related principles for those areas. ASU No. 2016-10 is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017, with early application permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

2. Fair Value Measurements

The Company measures 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.

The carrying amounts of cash equivalents, accounts receivable, accounts payable and accrued liabilities are considered reasonable estimates of their respective fair value because of their short-term nature.

Recurring Fair Value Measurements

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015 (in thousands):

	Level 1	Level 2	Level 3	Total
March 31, 2016				
Money market funds	$24,982	$-	$ -	$24,982
U.S. Treasuries	-	6,574	-	6,574
U.S. Government agency securities	-	29,611	-	29,611
Corporate debt securities	-	99,650	-	99,650
Total	$24,982	$135,835	$ -	$160,817

	Level 1	Level 2	Level 3	Total
December 31, 2015				
Money market funds	$21,193	$-	$ -	$21,193
U.S. Government agency securities	-	17,622	-	17,622
Corporate debt securities	-	152,749	-	152,749
Total	$21,193	$170,371	$ -	$191,564

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, 2016.

3. Cash, cash equivalents and marketable securities

The following is a summary of cash, cash equivalents and marketable securities available-for-sale as of March 31, 2016 and December 31, 2015 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
March 31, 2016				
Cash and cash equivalents:				
Cash	$6,030	$ -	$ -	$6,030
Money market funds	24,982	-	-	24,982
U.S. Government agency securities	4,999	-	-	4,999
Corporate debt securities	2,847	-	-	2,847
Total cash and cash equivalents	38,858	-	-	38,858
Marketable securities available-for-sale:				
U.S. Treasuries	6,573	2	(1)	6,574
U.S. Government agency securities	24,604	8	-	24,612
Corporate debt securities	96,691	112	-	96,803
Total marketable securities available-for-sale	127,868	122	(1)	127,989
Total cash, cash equivalents and marketable securities	$166,726	$ 122	$ (1)	$166,847
December 31, 2015				
Cash and cash equivalents:				
Cash	$4,561	$ -	$ -	$4,561
Money market funds	21,193	-	-	21,193
Corporate debt securities	19,052	7	(1)	19,058
Total cash and cash equivalents	44,806	7	(1)	44,812

Marketable securities available-for-sale:				
U.S. Government agency securities	17,628	-	(6)	17,622
Corporate debt securities	133,679	71	(59)	133,691
Total marketable securities available-for-sale	151,307	71	(65)	151,313
Total cash, cash equivalents and marketable securities	$196,113	$ 78	$ (66)	$196,125

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

	March 31, 2016	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$127,868	$127,989
Mature after one year through two years	-	-
	$127,868	$127,989

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, with unrealized gains and losses included in accumulated other comprehensive income (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 investments 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. Commitments and Contingencies

We lease our facilities in Berkeley, California ("Berkeley Lease") and Düsseldorf, Germany ("Düsseldorf Lease") under operating leases that expire in June 2018 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space.

Total net rent expense related to our operating leases for both three month periods ended March 31, 2016 and 2015, was $0.5 million. Deferred rent was $0.4 million and $0.5 million as of March 31, 2016 and December 31, 2015, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at March 31, 2016, excluding payments from sublease agreements, are as follows (in thousands):

Year ending December 31,	
2016 (remaining)	$1,757
2017	2,385

2018	1,327
2019	485
2020	485
Thereafter	1,091
Total	$7,530

In addition to the non-cancelable commitments included above, 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 research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of March 31, 2016, under the terms of our agreements, including certain agreements relating to HBV-23, we are obligated to make future payments of approximately $10.5 million through 2016. 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.

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, financial statements, results of operations, or cash flows in a particular period.

5. Collaborative Research and Development Agreements

AstraZeneca

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca AB ("AstraZeneca") for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease.

In October 2011, we amended our agreement with AstraZeneca to provide that we would conduct initial clinical development of AZD1419 and AstraZeneca agreed to fund all program expenses to cover the cost of development activities through Phase 2a. Under the terms of the amended agreement, we received an initial payment of $3.0 million in 2011 to begin the clinical development program. We and AstraZeneca agreed to advance AZD1419 towards a Phase 1 clinical trial, which resulted in a development funding payment of $6.0 million received in the fourth quarter of 2012.

In January 2014, we amended our agreement with AstraZeneca for the clinical development of AZD1419 whereby responsibility for conducting clinical trials was transferred from Dynavax to AstraZeneca upon completion of the Phase 1 trial. In the first quarter of 2014, we received a $5.4 million payment that was due upon execution of this amended agreement.

In December 2014, we amended our agreement with AstraZeneca whereby AstraZeneca would fully fund and Dynavax will conduct a Phase 2a safety and efficacy trial of AZD1419 in patients with asthma. In the fourth quarter of 2014, we received an $8.0 million payment upon execution of this amendment, to be applied towards research and development expenses incurred in conducting the Phase 2a study.

In January 2016, we amended our agreement with AstraZeneca whereby AstraZeneca will conduct the Phase 2a safety and efficacy trial of AZD1419 in patients with asthma that originally was to be conducted by Dynavax. We therefore revised the estimated remaining period of performance of development from June 2018 to September 2016. The remaining balance as of December 31, 2015 related to deferred payments of $5.4 million, received in the first quarter of 2014, and $3.0 million, received in 2011, are nonrefundable and are being recognized starting in January 2016 over the estimated remaining period of performance of development work through September 2016.

Under the terms of the January 2016 amendment, the $8.0 million payment received in December 2014, which was also deferred and is being recognized as research and development expenses are incurred, will be returned to AstraZeneca or applied to future milestone payments that may be earned by us under the agreement, net of amounts we recognize as development work is performed. In December 2015, we reclassified $7.4 million of the $8.0 million payment from deferred revenue to a current liability. As of March 31, 2016, the current liability related to the payment was $7.3 million on the accompanying condensed consolidated balance sheet.

Under the terms of this agreement, as amended, we are eligible to receive up to $100 million in additional milestone payments, based on the achievement of certain development and regulatory objectives. Additionally, upon commercialization, we are eligible to receive tiered royalties ranging from the mid to high single-digits based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

The following table summarizes the revenues earned under our agreement with AstraZeneca, included as collaboration revenue in our condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2016	2015
Initial payment	$174	$63
Subsequent payment	651	237
Performance of research activities	70	171
Total	$895	$471

As of March 31, 2016 and December 31, 2015, total deferred revenue from the initial payment, subsequent payment and development funding payments was $1.8 million and $2.7 million, respectively.

Absent early termination, the agreement will expire when all of AstraZeneca's payment obligations expire. AstraZeneca has the right to terminate the agreement at any time upon prior written notice and either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement.

National Institutes of Health ("NIH") and Other Funding

We have been awarded various grants from the NIH and the NIH's National Institute of Allergy and Infectious Disease ("NIAID") in order to fund research. The awards are related to specific research objectives and we earn revenue as the related research expenses are incurred. We have earned revenue during the three month periods ended March 31, 2016 and 2015 from the following awards:

- August 2014, the NIH awarded us $0.2 million to fund research in developing a transgenic mouse model to study human TLR9 role in disease.
- May 2012, the NIH awarded us $0.4 million to fund development of TLR8 inhibitors for treatment of rheumatoid arthritis. In February 2016, the NIH awarded us an additional $0.5 million to fund this study.
- August 2010, the NIAID awarded us a grant to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus. This study is one of several projects conducted under a grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. We have been awarded a total of $1.4 million under this grant.

The following table summarizes the revenues recognized under the various arrangements with the NIH (in thousands):

	Three Months Ended March 31,	
	2016	2015
NIH contracts	$39	$148
Total grant revenue	$39	$148

6. 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, common stock subject to repurchase by us, outstanding options, stock awards, Series B Convertible Preferred Stock, and warrants 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, Series B Convertible Preferred Stock, warrants and stock awards totaling approximately 3,610,000 and 5,310,000 shares of common stock as of March 31, 2016 and 2015, respectively, were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2016 and 2015, because the effect of their inclusion would have been anti-dilutive. For periods in which the Company has a net loss and no instruments are determined to be dilutive, such as the three months ended March 31, 2016 and 2015, basic and diluted net loss per share are the same.

7. Common Stock

Common Stock Outstanding

As of March 31, 2016, there were 38,495,502 shares of our common stock outstanding.

On November 12, 2015, we entered into an At Market Issuance Sales Agreement (the "2015 ATM Agreement") with Cowen under which we could offer and sell our common stock from time to time up to aggregate sales proceeds of $90 million through Cowen as our sales agent. As of March 31, 2016, we have sold no shares of common stock under the 2015 ATM Agreement.

8. Equity Plans and Stock-Based Compensation

Option activity under our stock-based compensation plans during the three months ended March 31, 2016 was as follows (in thousands except per share amounts):

	Shares Underlying Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands)		(years)	(in thousands)
Balance at December 31, 2015	2,891	$ 23.34		
Options granted	229	21.48		
Options exercised	(12)	13.69		
Options cancelled:				
Options forfeited (unvested)	(9)	17.87		
Options cancelled (vested)	(36)	49.30		
Balance at March 31, 2016	3,063	22.97	7.02	$ 4,835
Vested and expected to vest at March 31, 2016	2,996	23.09	6.98	$ 4,663
Exercisable at March 31, 2016	1,509	26.49	5.11	$ 2,204

Restricted stock unit activity under our stock-based compensation plans during the three months ended March 31, 2016 was as follows (in thousands except per share amounts):

	Number of Shares (In thousands)	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2015	195	$ 17.52
Granted	379	$ 21.48
Vested	(23)	$ 15.55
Forfeited or expired	(1)	$ 16.00
Non-vested as of March 31, 2016	550	$ 20.34

The aggregate intrinsic value of the restricted stock units outstanding as of March 31, 2016, based on our stock price on that date, was $10.6 million.

As of March 31, 2016, approximately 189,000 shares underlying stock options and restricted stock units awards with performance-based vesting criteria were outstanding. Vesting criteria for these performance-based awards have not been met as of March 31, 2016.

Under our stock-based compensation plans, option awards generally vest over a four-year period contingent upon continuous service and expire 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 Three Months Ended March 31,		Employee Stock Purchase Plan Three Months Ended March 31,	
	2016	2015	2016	2015
Weighted-average fair value	$13.11	$10.85	$8.18	$17.32
Risk-free interest rate	1.5 %	1.6 %	0.6 %	0.4 %
Expected life (in years)	5.6	5.8	1.2	1.2
Volatility	0.7	0.8	0.6	2.4

We recognized stock-based compensation expense of $3.2 million and $2.0 million for the three months ended March 31, 2016 and 2015, respectively. The components of stock-based compensation expense were (in thousands):

	Three Months Ended March 31,	
	2016	2015
Research and development	$1,515	$885
General and administrative	1,729	1,069
Total	$3,244	$1,954

As of March 31, 2016, the total unrecognized compensation cost related to non-vested equity awards including all awards with time-based vesting amounted to $22.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.6 years. Additionally, as of March 31, 2016, the total unrecognized compensation cost related to equity awards with performance-based vesting criteria not deemed probable of vesting amounted to $5.9 million.

Employee Stock Purchase Plan

In May 2014, stockholders of the Company approved the 2014 Employee Stock Purchase Plan (the “Purchase Plan”), pursuant to which the Company may issue up to 50,000 shares of its common stock, subject to adjustment, to its employees. The Purchase Plan provides for the purchase of common stock by eligible employees and became effective on May 28, 2014. 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). As of March 31, 2016, employees have acquired 40,670 shares of our common stock under the Purchase Plan and 9,330 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, clinical development timing and progress, the period for which we estimate our cash resources are sufficient, the availability of additional funds, and ability to enter into strategic and licensing arrangements, 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 ("SEC").

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, 2015.

Overview

We are a clinical-stage biopharmaceutical company that uses toll-like receptor ("TLR") biology to discover and develop novel vaccines and therapeutics. Our development programs are focused on vaccine adjuvants and cancer immunotherapy. Our lead product candidates are HEPLISAV-B, an investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several phase 1/2 studies.

In March 2016, the U.S. Food and Drug Administration ("FDA") accepted for review the Biologics License Application ("BLA") for HEPLISAV-B and established September 15, 2016 as the Prescription Drug User Fee Act ("PDUFA") action date. In April 2016, in response to an FDA request, Dynavax submitted individual trial data sets that had been provided as integrated data in the March 2016 BLA submission. FDA then determined that the addition of these large data sets represented a major amendment to the BLA and thus extended the PDUFA action date to December 15, 2016 to allow for a full review. The HEPLISAV-B BLA is based on the results from clinical trials that have generated data in more than 14,000 total patients. If the FDA elects to have an advisory committee meeting regarding our application, we currently anticipate the meeting likely would be in November 2016. If this timing is correct and HEPLISAV-B is approved upon completion of the review period, we expect to launch the product in the first quarter of 2017.

Our lead cancer immunotherapy candidate is SD-101, a C Class CpG TLR9 agonist that was selected for characteristics optimal for treatment of cancer, including high interferon induction. Our SD-101 clinical program is intended to assess the preliminary efficacy of SD-101 in a range of tumors and in combination with a range of treatments. Several Phase 1/2 clinical trials are ongoing or planned for 2016.

Our most advanced inflammatory disease candidate is AZD1419, which is partnered with AstraZeneca AB ("AstraZeneca"). AZD1419 is designed to change the basic immune response to environmental allergens, such as house dust and pollens, leading to prolonged reduction in asthma symptoms. We are currently working with AstraZeneca to design a Phase 2 trial, which AstraZeneca will fully fund and conduct, and is expected to begin in the second half of 2016.

Our revenues consist of amounts earned from collaborations, grants and fees from services and licenses. Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our drug candidates. We have yet to generate any revenues from product sales and have recorded an accumulated deficit of $726.8 million as of March 31, 2016. These losses have resulted principally from costs incurred in connection with research and development activities, compensation and other related personnel costs and general corporate expenses. Research and development activities include costs of outside contracted services including clinical trial costs, manufacturing and

process development costs, research costs and other consulting services. Salaries and other personnel-related costs include non-cash stock-based compensation associated with options and other equity awards granted to employees. General corporate expenses include outside services such as accounting, consulting, business development, commercial, investor relations, insurance services and legal costs. Our operating results may fluctuate substantially from period to period principally as a result of the timing of preclinical activities and other activities related to clinical trials for our drug candidates.

Since our inception, we have relied primarily on the proceeds from public and private sales of our equity securities, government grants and revenues from collaboration agreements to fund our operations. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV-B and our investigational cancer immunotherapeutic product candidate, SD-101, human clinical trials for our other product candidates and additional applications and advancement of our technology. Costs relating to our HEPLISAV-B clinical trial, HBV-23, declined following the last subject visit in October 2015 while costs relating to seeking regulatory approval and preparing for the anticipated commercial launch of HEPLISAV-B in the United States, as well as costs related to the ongoing development of SD-101 and our other cancer immunotherapeutic research and development programs, are increasing. In order to continue these activities, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private debt and equity financings. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV-B program or other development programs while we seek strategic alternatives.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, assumptions and judgments described below that have the greatest potential impact on our condensed consolidated financial statements, including those related to revenue recognition, research and development activities and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Accounting assumptions and estimates are inherently uncertain and actual results may differ materially from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies during the three months ended March 31, 2016, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, grants and services and license fees. Collaboration revenue includes amounts recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Service and license fees include revenues related to research and development and contract manufacturing services, license fees and royalty payments.

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

	Three Months Ended March 31,		Increase (Decrease) from 2015 to 2016	
Revenues:	2016	2015	$	%
Collaboration revenue	$895	$471	$ 424	90 %
Grant revenue	39	148	(109)	(74)%

Service and license revenue	8	8	-	0	%
Total revenues	$942	$627	$ 315	50	%

Total revenues for the three months ended March 31, 2016 increased by $0.3 million, or 50%, as compared to the same period in 2015. Collaboration revenue increased by $0.4 million due to revision of the performance period, from June 2018 to September 2016, related to payments previously made to us, in the amount of $5.4 million, received in 2014, and $3.0 million, received in 2011, by AstraZeneca under a research collaboration and license agreement for the clinical development for AZD1419. Grant revenue decreased by $0.1 million due to various contracts with the National Institute of Health that expired in 2015.

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 relate to our preclinical experiments and clinical trials, regulatory filings and manufacturing of our product candidates. For the three months ended March 31, 2016 and 2015, approximately 72% and 86%, respectively, of our total research and development expense, excluding non-cash stock-based compensation, is related to our lead product candidate, HEPLISAV-B. The remainder of our research and development expense results primarily from earlier-stage programs.

The following is a summary of our research and development expense (in thousands, except for percentages):