

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

May 10, 2010

Table of Contents

**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, 2010

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)

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0728374**  
(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  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  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  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

As of May 5, 2010, the registrant had outstanding 86,573,335 shares of common stock.

**Table of Contents**

**INDEX**

**DYNAVAX TECHNOLOGIES CORPORATION**

	<b>Page No.</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Consolidated Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets as of March 31, 2010 and December 31, 2009</u>	4
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2010 and 2009</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2010 and 2009</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	23
<b><u>PART II OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 6. <u>Exhibits</u>	34
<b><u>SIGNATURES</u></b>	36
<i>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.</i>	

**Table of Contents**

**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. Our forward-looking statements include discussions regarding our business and financing strategies, future research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development of our products, uncertainty regarding our future operating results and prospects for profitability. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in Item 1A Risk Factors and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.*

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****Dynavax Technologies Corporation****Condensed Consolidated Balance Sheets****(In thousands, except per share amounts)**

	<b>March 31, 2010 (unaudited)</b>	<b>December 31, 2009 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 30,080	\$ 36,720
Restricted cash	656	681
Accounts receivable	1,152	895
Prepaid expenses and other current assets	802	586
<b>Total current assets</b>	<b>32,690</b>	<b>38,882</b>
Property and equipment, net	7,199	7,997
Goodwill	2,312	2,312
Other intangible assets, net	1,034	1,279
Other assets	1,049	
<b>Total assets</b>	<b>\$ 44,284</b>	<b>\$ 50,470</b>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,091	\$ 1,686
Accrued liabilities	10,571	7,507
Deferred revenues	2,384	2,718
Warrant liability to Symphony Dynamo Holdings LLC (Holdings)	2,315	2,567
<b>Total current liabilities</b>	<b>16,361</b>	<b>14,478</b>
Deferred revenues, noncurrent	16,726	17,083
Long-term note payable to Holdings	9,741	9,342
Long-term contingent liability to Holdings	3,109	3,040
Other long-term liabilities	146	151
Commitments and contingencies (Note 7)		
Dynavax stockholders' equity (deficit):		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at March 31, 2010 and December 31, 2009		
Common stock: \$0.001 par value; 150,000 shares authorized at March 31, 2010 and December 31, 2009; 55,160 and 54,279 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	55	54
Additional paid-in capital	267,583	266,127
Accumulated other comprehensive loss:		
Cumulative translation adjustment	(616)	(168)
<b>Accumulated other comprehensive loss</b>	<b>(616)</b>	<b>(168)</b>
<b>Accumulated deficit</b>	<b>(268,821)</b>	<b>(259,637)</b>

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Total stockholders' equity (deficit)	(1,799)	6,376
Total liabilities and stockholders' equity (deficit)	\$ 44,284	\$ 50,470

See accompanying notes.

**Table of Contents**

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Operations**

(In thousands, except per share amounts)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Revenues:</b>		
Collaboration revenue	\$ 7,421	\$ 17,692
Grant revenue	862	1,139
Service and license revenue	61	513
<b>Total revenues</b>	<b>8,344</b>	<b>19,344</b>
<b>Operating expenses:</b>		
Research and development	12,480	10,332
General and administrative	4,570	4,424
Amortization of intangible assets	245	245
<b>Total operating expenses</b>	<b>17,295</b>	<b>15,001</b>
<b>Loss from operations</b>	<b>(8,951)</b>	<b>4,343</b>
Interest income	2	110
Interest expense	(399)	(15)
Other income (expense)	164	(346)
<b>Net income (loss)</b>	<b>(9,184)</b>	<b>4,092</b>
Add: Losses attributable to noncontrolling interest in SDI		1,009
<b>Net income (loss) attributable to Dynavax</b>	<b>\$ (9,184)</b>	<b>\$ 5,101</b>
<b>Basic and diluted net income (loss) per share attributable to Dynavax common stockholders</b>	<b>\$ (0.17)</b>	<b>\$ 0.13</b>
<b>Shares used to compute basic and diluted net income (loss) per share attributable to Dynavax common stockholders</b>	<b>54,364</b>	<b>39,889</b>

See accompanying notes.

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities</b>		
Net income (loss) attributable to Dynavax	\$ (9,184)	\$ 5,101
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	399	470
Amount attributed to noncontrolling interest in SDI		(1,009)
Amortization of intangible assets	245	245
Interest associated with note payable to Holdings	399	
Change in the fair value of the warrant and contingent consideration to Holdings	(183)	
Accretion and amortization of marketable securities		(30)
Stock-based compensation expense	541	519
Changes in operating assets and liabilities:		
Accounts receivable	(257)	3,429
Prepaid expenses and other current assets	(216)	(107)
Restricted cash and other assets	(1,024)	17
Accounts payable	(595)	183
Accrued liabilities and other long term liabilities	3,064	83
Deferred revenues	(691)	(16,948)
Net cash used in operating activities	(7,502)	(8,047)
<b>Investing activities</b>		
Change in investments held by SDI		1,321
Purchases of marketable securities		(12,271)
Proceeds from maturities of marketable securities		13,750
Purchases of property and equipment, net	394	435
Net cash provided by investing activities	394	3,235
<b>Financing activities</b>		
Proceeds from issuance of common stock under Equity Distribution Agreement, net of issuance costs	919	
Proceeds from issuance of common stock, net of issuance costs	(48)	
Proceeds from employee stock purchase plan	42	37
Proceeds from exercise of stock options	3	
Net cash provided by financing activities	916	37
Effect of exchange rate on cash and cash equivalents	(448)	(408)
Net decrease in cash and cash equivalents	(6,640)	(5,183)
Cash and cash equivalents at beginning of period	36,720	28,103
Cash and cash equivalents at end of period	\$ 30,080	\$ 22,920



**Supplemental disclosure of cash flow information**

Disposal of fully depreciated property and equipment	\$	\$	792
--	----	----	-----

See accompanying notes.

---

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

Dynavax Technologies Corporation ( Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

***Basis of Presentation***

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles 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 only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2009 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles ( GAAP ) for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission ( SEC ).

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Rhein Biotech GmbH ( Rhein or Dynavax Europe ) and Symphony Dynamo, Inc. ( SDI ), which we consolidate pursuant to the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification related to consolidation. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products. We have evaluated all subsequent events through the date the financial statements were filed with the SEC.

***Liquidity and Financial Condition***

We have incurred significant operating losses and negative cash flows from operations since our inception. As of March 31, 2010, we had cash and cash equivalents of \$30.1 million, restricted cash of \$0.7 million and working capital of \$16.3 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents on hand at March 31, 2010, net proceeds from our April 2010 equity offering, anticipated revenues, and reductions in spending levels.

In April 2010, we raised approximately \$41.1 million, after deducting the underwriting discount and estimated offering expenses of approximately \$3.0 million from the sale of 30,293,000 units. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.5 of a share of common stock. See Note 6 for additional disclosure relating to this equity financing transaction.

In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise additional funds through future public or private financings, and/or strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

The accompanying financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.



**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results may differ from these estimates.

***Significant Accounting Policies***

We believe that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2010 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

***Recent Accounting Pronouncements***

***Accounting Standards Update 2010-17***

In March 2010, the Financial Accounting Standards Board (FASB) reached a consensus on Accounting Standards Update (ASU) No. 2010-17, *Milestone Method of Revenue Recognition*. ASU 2010-17 provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under the Consensus, entities can make an accounting policy election to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. The scope of this Issue is limited to transactions involving research or development. ASU 2010-17 is effective for interim and annual periods beginning on or after June 15, 2010 with early adoption permitted. The impact of ASU 2010-17 is not expected to be material to the consolidated financial statements of the Company.

***Accounting Standards Update 2010-06***

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Improving Disclosures about Fair Value Measurements* (ASU 2010-06), which is included in the ASC Topic 820 (Fair Value Measurements and Disclosures). ASU 2010-06 requires new disclosures on the amount and reason for transfers in and out of Level 1 and 2 fair value measurements. ASU 2010-06 also requires disclosure of activities including purchases, sales, issuances, and settlements within the Level 3 fair value measurements and clarifies existing disclosure requirements on levels of disaggregation and disclosures about inputs and valuation techniques. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009. The adoption of ASU 2010-06 did not have a material impact on the consolidated financial statements of the Company.

***Accounting Standards Update 2009-13***

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Dynavax means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

previously reported interim periods in the fiscal year of adoption. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****2. Fair Value Measurements**

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 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 under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The 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 - 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.

The following table represents the fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2010 (in thousands):

<b>March 31, 2010</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Money market funds	\$ 27,837	\$	\$	\$ 27,837
<b>Total assets</b>	<b>\$ 27,837</b>	<b>\$</b>	<b>\$</b>	<b>\$ 27,837</b>
<b>Liabilities</b>				
Warrant liability to Symphony Dynamo Holdings LLC ( Holdings )	\$	\$	\$ 2,315	\$ 2,315
Long-term note payable to Holdings			9,741	9,741
Long-term contingent consideration liability to Holdings			3,109	3,109
<b>Total Liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 15,165</b>	<b>\$ 15,165</b>

**Assets**

As of March 31, 2010, we had no marketable securities, and there were no sales of marketable securities during the three months ended March 31, 2010 and 2009.

When determining if there are any other-than-temporary impairments on its investments, we evaluate: (i) whether the investment has been in a continuous realized loss position for over twelve months, (ii) the duration to maturity of our investments, (iii) our intention to hold the

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

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, (iv) the credit rating of each investment, and (v) the type of investments made. Through March 31, 2010, we have not recognized any other-than-temporary losses on our investments.

### *Liabilities*

In connection with our purchase of all of the outstanding equity of SDI on December 30, 2009, we issued warrants to Symphony which contained provisions for anti-dilution protection in the event that the Company issues other equity securities within six months from the closing date of the transaction. Due to this adjustment provision, the warrants do not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock. Accordingly, we have recorded these warrants as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. This fair value measurement is based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

Subsequent to the December 30, 2009 acquisition date, changes in the fair value of the warrant liability are recognized in Other income (expense) in the statement of operations in the period of the change. Based on our assumptions using the Black-Scholes Model, the change in fair value of the warrant liability resulted in other income of \$0.3 million for the three months ended March 31, 2010.

The following table represents a reconciliation of the change in the fair value measurement of the warrant liability for the quarter ended March 31, 2010 (in thousands):

<b>Warrant Liability to Holdings</b>	<b>Amount</b>
Acquisition date fair value measurement at December 30, 2009	\$ 2,567
Adjustment to fair value measurement	(252)
<b>Balance as of March 31, 2010</b>	<b>\$ 2,315</b>

In connection with the acquisition of SDI, we entered into a \$15 million non-interest bearing note. We estimated the fair value of the non-interest bearing note payable to Holdings using a net present value model using a discount rate of 17%. Imputed interest will be recorded as interest expense over the term of the loan. The principal amount of \$15 million is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. If we elect to pay the note solely in shares of our common stock, the number of shares issued will be determined based on the average closing price of our common stock for the 30 trading days immediately preceding but not including the second trading day prior to the date of such payment multiplied by 1.15. This fair value measurement is based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value.

The following table represents a reconciliation of the change in the carrying value of the note payable for the quarter ended March 31, 2010 (in thousands):

<b>Long-term Note Payable to Holdings</b>	<b>Amount</b>
Acquisition date fair value measurement at December 30, 2009	\$ 9,342
Accretion of interest expense	399
<b>Balance as of March 31, 2010</b>	<b>\$ 9,741</b>

We are also obligated to make future contingent cash payments to the former Holdings shareholders related to certain payments received by the Company from future partnering agreements pertaining to its hepatitis C and cancer therapy programs (see Note 4). We estimated the fair value of this contingent liability using a discounted cash flow model. The discounted cash flow model was derived from management's assumptions regarding the timing, amounts, and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at an 18% rate.

Subsequent to the December 30, 2009 acquisition date, changes in the fair value of the contingent consideration liability are recognized in Other income (expense) in the statement of operations in the period of the change. Certain events including, but not limited to, the timing and terms of any strategic partnership agreement of the hepatitis C therapy program could have a material impact on the fair value of the contingent consideration liability, and as a result, the Company's results of operations and financial position. Based on our assumptions regarding the Company's beta and risk free interest rate used in the discounted cash flow model, the change in fair value of the contingent consideration liability resulted in other expense of \$69 thousand for the three months ended March 31, 2010.



## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

The following table represents a reconciliation of the change in the fair value measurement of the contingent liability for the quarter ended March 31, 2010 (in thousands):

<b>Contingent Liability to Holdings</b>	<b>Amount</b>
Acquisition date fair value measurement at December 30, 2009	\$ 3,040
Adjustment to fair value measurement	69
<b>Balance as of March 31, 2010</b>	<b>\$ 3,109</b>

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****3. Intangible Assets**

Intangible assets consist primarily of the manufacturing process and customer relationships. The manufacturing process derives from the methods for making proteins in *Hansenula* yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at March 31, 2010 (in thousands, except years):

	Original Estimated Useful Life (in Years)	Gross	Accumulated Amortization	Net
Manufacturing process	5	\$ 3,670	\$ (2,895)	\$ 775
Customer relationships	5	1,230	(971)	259
<b>Total</b>	<b>5</b>	<b>\$ 4,900</b>	<b>\$ (3,866)</b>	<b>\$ 1,034</b>

The estimated future amortization expense of purchased intangible assets is as follows (in thousands):

<b>Year ending December 31,</b>	
2010 (remaining nine months)	\$ 735
2011	299
<b>Total</b>	<b>\$ 1,034</b>

**4. Symphony Dynamo, Inc.**

On April 18, 2006, we, Symphony Capital Partners, L.P. and certain of its affiliates (Symphony) and Symphony Dynamo Holdings LLC (Holdings) entered into a transaction involving a series of related agreements providing for the advancement of specific Dynavax immunostimulatory sequences-based programs for cancer, hepatitis B and hepatitis C therapy (collectively, the Programs). Pursuant to these agreements, Symphony and certain of its affiliates formed Symphony Dynamo Inc. (SDI) and invested \$50 million to fund the Programs, and we licensed to Holdings our intellectual property rights related to the Programs, which were assigned to SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

In connection with the transaction described above, Holdings granted to us an exclusive purchase option that gave us the right, but not the obligation, to acquire the outstanding equity securities of SDI, which would result in our reacquisition of the intellectual property rights that we licensed to Holdings (the Original Purchase Option). The Original Purchase Option would have been exercisable for a price of \$106.9 million as of October 1, 2009, which purchase price would have increased quarterly by a predetermined amount up to \$144.1 million if the Original Purchase Option were exercised on April 18, 2011. If not exercised, the Original Purchase Option would have expired on April 18, 2011. The exercise price of the Original Purchase Option could have been paid for in cash or a combination of cash and our common stock. In exchange for the Original Purchase Option, we granted Holdings five-year warrants to purchase up to 2,000,000 shares of our common stock at an exercise price of \$7.32 per share pursuant to a warrant purchase agreement (the Original Warrants), and granted certain registration rights to Holdings pursuant to a registration rights agreement.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (the Program Option ) during the first year of the arrangement. In April 2007, we exercised the Program Option for the hepatitis B program. We have remained primarily responsible for the development of the cancer and hepatitis C therapy programs in accordance with a development plan and related development budgets that we have agreed to with Holdings.

A variable interest entity, or VIE, is (i) an entity that has equity that is insufficient to permit the entity to finance its activities without additional subordinated financial support, or (ii) an entity that has equity investors that cannot make significant decisions about the entity's operations or that do not absorb their proportionate share of the expected losses or do not receive the expected residual returns of the entity. A VIE is required to be consolidated by the party that is deemed to be the primary beneficiary, which is the party that has exposure to a majority of the potential variability in the VIE's outcomes. Significant management judgment is required in the determination of an entity being considered a VIE.

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

Prior to the acquisition of all of the outstanding equity of SDI pursuant to the amended purchase option on December 30, 2009, as described below, we have consolidated the financial position and results of operations of SDI. We have not consolidated Holdings because we believe our variable interest, the Purchase Option, is on the stock of SDI. We believe SDI is a VIE because we have the Purchase Option to acquire its outstanding voting stock at prices that were fixed upon entry into the arrangement, with the specific price based upon the date the option is exercised. The fixed nature of the Purchase Option price limits Symphony's returns, as the investor in SDI.

Parties are deemed to be de facto agents if they cannot sell, transfer, or encumber their interests without the prior approval of an enterprise. Symphony is considered to be a de facto agent of the Company pursuant to this provision, and because we and Symphony as a related party group absorb a majority of SDI's variability, we evaluated whether we are most closely associated with SDI. We concluded that we are most closely associated with SDI and should consolidate SDI because (1) we originally developed the technology that was assigned to SDI, (2) we continued to oversee and monitor the Development Programs, (3) our employees continued to perform substantially all of the development work, (4) we significantly influenced the design of the responsibilities and management structure of SDI, (5) SDI's operations are substantially similar to our activities, and (6) through the Purchase Option, we had the ability to participate in the benefits of a successful development effort.

Symphony was required to absorb the development risk for its equity investment in SDI. Symphony's equity investment in SDI was classified as noncontrolling interest in the consolidated balance sheet. The noncontrolling interest held by Symphony has been reduced by the \$5.6 million fair value of the warrants it received and \$2.6 million of fees we immediately paid to Symphony upon the transaction's closing because the total consideration provided by us to Symphony effectively reduces Symphony's at-risk equity investment in SDI. While we performed the research and development on behalf of SDI, our development risk was limited to the consideration we provided to Symphony (the warrants and fees). We exercised the Program Option in April 2007, which resulted in the recognition of a \$15.0 million liability to Symphony. The noncontrolling interest was further reduced for this obligation as it would have been paid to Symphony at the expiration of the SDI collaboration in 2011 if we did not exercise the Purchase Option, or would be included as part of the applicable purchase price upon exercise of the Purchase Option.

Net losses incurred by SDI and charged to the noncontrolling interest were zero and \$1.0 million for the three months ended March 31, 2010 and 2009, respectively. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

In November 2009, we entered into an agreement with Holdings to modify the provisions of and to exercise the Purchase Option. We completed the acquisition of all of the outstanding equity of SDI pursuant to the amended Purchase Option on December 30, 2009. In exchange for all of the outstanding equity of SDI, we issued to the Symphony Investors: (i) 13,000,000 shares of common stock (Shares); (ii) 5-year warrants to purchase 2,000,000 shares of common stock with an exercise price of \$1.94 per share (Warrants); (iii) a note in the principal amount of \$15 million, due December 31, 2012, payable in cash, our common stock or a combination thereof at our discretion, which obligation was previously payable solely in cash on April 18, 2011; and (iv) agreed to contingent cash payments from us 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 the cancer and hepatitis C therapies. The outstanding warrants to purchase 2,000,000 shares of common stock held by the Symphony Investors were cancelled. The Shares and Warrants are subject to certain anti-dilution protection in the event that the Company issues other equity securities within six months from the closing date of the transaction. Due to this adjustment provision, the warrants do not meet the criteria set forth in ASC 815 to be considered indexed to the Company's own stock. Accordingly, we have recorded these warrants as a liability at fair value, which was estimated at the issuance date using the Black-Scholes Model. The warrants are revalued every reporting period using the Black-Scholes Model and the change in the fair value of the warrants is recognized in Other income (expense) in the consolidated statement of operations.

**6. Financing Agreements**

On August 17, 2009 we entered into an equity distribution agreement (the Agreement) with Wedbush Morgan Securities, Inc. (Wedbush) pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the quarter ended March 31, 2010, we sold 800,860 shares of common stock under the Agreement with Wedbush as our sales agent for net proceeds of \$0.9 million after deducting commissions paid to Wedbush and

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

offering expenses. As of March 31, 2010, we could offer and sell from time to time through Wedbush up to an additional \$11.1 million of our common stock under the Agreement.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of \$41.1 million, after deducting the underwriting discount and estimated offering expenses of approximately \$3.0 million, from the sale of 30,293,000 units at a per unit price of \$1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of \$1.50 per share, and is exercisable for a period of five years from the date of issuance. As a result of this offering, Symphony and certain related investors received an additional 1,076,420 shares of common stock and new warrants to purchase 7,038,210 shares of common stock having the same terms as the warrants sold in the offering, pursuant to the anti-dilution provisions of the Amended and Restated Purchase Option Agreement with Symphony. The warrants to purchase 2,000,000 shares of common stock previously issued to Symphony and its related investors in connection with the November 2009 Amended and Restated Purchase Option Agreement were cancelled.

**7. Commitments and Contingencies**

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were 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. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of March 31, 2010 and December 31, 2009. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2014. Total net rent expense related to our operating leases for the three months ended March 31, 2010 and 2009, was \$0.6 million in each year, respectively. Deferred rent was \$0.9 million as of December 31, 2009.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with the remaining scheduled payments to us totaling \$40 thousand until August 2010. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at March 31, 2010, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2010 (remaining nine months)	\$ 1,980
2011	2,691
2012	2,750
2013	2,794
2014	2,044
Thereafter	5,144
<b>Total</b>	<b>\$ 17,403</b>

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of March 31, 2009 and December 31, 2009. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of March 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of March 31, 2010.

---

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

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 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. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of March 31, 2010, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$28.7 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Under the terms of our license agreements, we could be expected to pay approximately \$0.3 million in 2010 related to such fees and milestone payments to the Regents.

**8. Collaborative Research and Development Agreements**

***GlaxoSmithKline***

In December 2008, we entered into a worldwide strategic alliance with GlaxoSmithKline ( GSK ) to discover, develop, and commercialize toll-like receptor ( TLR ) inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We received an initial payment of \$10 million and in exchange, agreed to conduct research and early clinical development in up to four programs and granted to GSK options to license the programs. We are eligible to receive potential future development and commercialization milestones. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one product. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. For the three months ended March 31, 2010 and 2009, we recognized revenue of \$0.4 million in each year, respectively, related to the initial payment.

Absent early termination, the agreement will expire when all of GSK's payment obligations expire. Either party may terminate the agreement early upon written notice if the other party commits an uncured material breach of the agreement. Either party may terminate the agreement in the event of insolvency of the other party. GSK also has the option to terminate the agreement without cause, upon prior written notice within a specified window of time dependent upon stage of clinical development of the programs.

***AstraZeneca***

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The research term and research funding under the agreement was extended through July 2010. We received an upfront payment of \$10 million, a milestone payment of \$4.5 million for the nomination of a candidate drug and are eligible to receive potential future development milestones. We are also eligible to receive royalties based on product sales and have retained an option to co-promote in the United States products arising from the collaboration. AstraZeneca has the right to sublicense its rights with our prior consent.

Revenue from the upfront payment has been deferred until certain contractual obligations are fulfilled or amended. Revenue from the milestone payment received is deferred and is being recognized ratably over the estimated performance period of the collaboration agreement. For the three months ended March 31, 2010 and 2009, we recognized revenue of \$0.4 million and \$0.6 million, respectively, related to the milestone for



## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

the nomination of a candidate drug. Revenue resulting from the performance of research services amounted to \$2.7 million and \$1.0 million for the three months ended March 31, 2010, and 2009, 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.

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

***National Institutes of Health and Other Funding***

In September 2008, we were awarded a five-year \$17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) to develop novel vaccine adjuvant candidates that signal through receptors of the innate immune system. The contract supports adjuvant development for anthrax as well as other disease models. NIAID is funding 100% of the total \$17 million cost of Dynavax's program under Contract No. HHSN272200800038C. For the three months ended March 31, 2010, and 2009, we recognized revenue of approximately \$0.7 million and \$0.4 million, respectively.

In July 2008, we were awarded a two-year \$1.8 million grant from the NIH to develop a therapy for systemic lupus erythematosus (SLE), an autoimmune disease. Revenue associated with this grant is recognized as the related expenses are incurred. For the three months ended March 31, 2010, and 2009, we recognized revenue of approximately \$0.1 million and \$0.3 million respectively.

In 2003, we were awarded government grants to fund research and development totaling \$8.3 million, certain of which were extended through the second quarter of 2009. In August 2007, we were awarded a two-year \$3.3 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with these grants was recognized as the related expenses were incurred. For the three months ended March 31, 2009, we recognized revenue of approximately \$0.5 million; there were no revenues recognized from these grants in 2010.

***Merck & Co., Inc.***

In October 2007, we entered into a global license and development collaboration agreement and a related manufacturing agreement with Merck to jointly develop HEPLISAV, a novel investigational hepatitis B vaccine. Under the terms of the agreement, Merck received worldwide exclusive rights to HEPLISAV, and agreed to fund future vaccine development and be responsible for commercialization. We received a non-refundable upfront payment of \$31.5 million. Revenue from the initial payment was deferred and recognized ratably over the estimated performance period of the collaboration agreement. On December 18, 2008, Merck provided notice of its termination of the collaboration, upon which all development, manufacturing and commercialization rights to HEPLISAV reverted to Dynavax. As a result of Merck's termination, we accelerated the applicable performance period over which we ratably recognized revenue from the upfront fee through the effective date of the termination, which was June 2009. For the three months ended March 31, 2010 and 2009, we recognized revenue of zero and \$15.5 million, respectively, related to the upfront fee. Collaboration revenue resulting from the performance of research and development services are recognized as related research and development costs are incurred. Cost reimbursement revenue under this collaboration agreement totaled zero and 0.3 million for the three months ended March 31, 2010 and 2009, respectively. In March 2010, Merck agreed to make a \$4.0 million payment to us in satisfaction of its obligations for the wind down period following Merck's written notice of termination, which was recorded as collaboration revenue upon receipt.

**9. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and stock options to purchase 12.4 million and 11.6 million shares of common stock as of March 31, 2010 and 2009, respectively, were excluded from the calculation of diluted net loss per share for both the three months ended March 31, 2010 and 2009 because the effect would have been anti-dilutive.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****10. Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income or loss. Other comprehensive income or loss includes certain changes in stockholders' equity not included in net income (loss). Comprehensive income (loss) is as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net income (loss) attributable to Dynavax	\$ (9,184)	\$ 5,101
Decrease in unrealized gain on marketable securities available-for-sale		(32)
Decrease in cumulative translation adjustment	(448)	(408)
Comprehensive income (loss) attributable to Dynavax	\$ (9,632)	\$ 4,661

**11. Stockholders' Equity**

As of March 31, 2010, we have three share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; the 2004 Employee Stock Purchase Plan, and 2010 Employment Inducement Stock Awards Plan. The 2004 Stock Incentive Plan authorizes the issuance of various forms of stock-based awards including stock options, restricted stock, restricted stock units, and other equity awards to employees, consultants and members of the board of directors. The 1997 Equity Incentive Plan, or 1997 Plan, expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous service). The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

	<b>Employee Stock Options</b>		<b>Employee Stock Purchase Plan</b>	
	<b>Three Months Ended March 31,</b>		<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Weighted-average fair value per share	\$ 1.41	\$ 0.49	\$ 1.43	\$ 0.46
Risk-free interest rate	2.0%	1.7%	0.4%	0.8%
Expected life (in years)	4.0	4.0	0.7	1.3
Volatility	1.6	1.6	1.6	1.6
Expected dividends				

Expected volatility is based on historical volatility of our stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

We recognized the following amounts of stock-based compensation expense (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
Employee and director stock-based compensation expense	\$ 515	\$ 522
Other stock-based compensation expense	26	(3)
<b>Total</b>	<b>\$ 541</b>	<b>\$ 519</b>

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

	Three Months Ended March 31,	
	2010	2009
Research and development	\$ (59)	\$ 18
General and administrative	600	501
<b>Total</b>	<b>\$ 541</b>	<b>\$ 519</b>

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 15%. As of March 31, 2010, the total unrecognized compensation cost related to non-vested options granted amounted to \$4.3 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.6 years.

Activity under the stock option plans was as follows:

	Options and Awards Available for Grant	Number of Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2009	658,909	5,276,055	\$ 3.94
2004 Plan options authorized	400,000		
2010 Plan options authorized	1,500,000		
Options granted	(1,458,750)	1,458,750	\$ 1.56
Options exercised		(6,250)	\$ 0.54
Options cancelled:			
Options forfeited (unvested)	141,250	(141,250)	\$ 2.51
Options expired (vested)	27,978	(27,978)	\$ 4.11
Awards cancelled (unvested)	15,000		
 Balance at March 31, 2010	 1,284,387	 6,559,327	 \$ 3.44

In October 2008, the Company granted restricted stock units (RSUs) for a total of 435,000 shares with a grant date fair value of \$1.31 per share. Such RSUs will vest 100% on the third anniversary of the vest commencement date. Prior to this grant in October 2008, the Company had no RSUs outstanding. There were 15,000 RSU shares forfeited during the three months ended March 31, 2010. There were 270,000 unvested RSU shares as of March 31, 2010. There were no vested RSU shares delivered during the three months ended March 31, 2010.

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of March 31, 2010:

Number of Shares	Weighted- Average Exercise	Weighted-Average Remaining Contractual	Aggregate Intrinsic Value
------------------	----------------------------------	--	---------------------------------

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

		Price Per Share	Term (in years)	
Outstanding options (vested and expected to vest)	5,896,599	\$ 3.60	7.0	\$ 587,613
Options exercisable	3,504,980	\$ 4.49	5.7	\$ 188,586
<b><i>Employee Stock Purchase Plan</i></b>				

As of March 31, 2010, 746,000 shares were reserved and approved for issuance under the Employee Stock Purchase Plan (the Purchase Plan), subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees have acquired 403,898 shares of our common stock under the Purchase Plan. At March 31, 2010, 342,102 shares of our common stock remained available for future purchases.

**Table of Contents****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 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 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.

**Overview**

Dynavax Technologies Corporation (Dynavax or the Company), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines.

Our pipeline of product candidates includes: HEPLISAV; Our Universal Flu vaccine; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs including those partnered with AstraZeneca and GlaxoSmithKline (GSK) and our Universal Flu vaccine. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious diseases, asthma and inflammatory and autoimmune diseases.

**Recent Developments**

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of approximately \$41 million, which the Company primarily intends to use to further advance the development of HEPLISAV, including Phase 3 studies to support registration in the U.S., Canada and European Union. HEPLISAV is currently being evaluated in a Phase 3 study in subjects with chronic kidney disease at multiple centers in the U.S., Canada and Germany. An additional Phase 3 study in subjects over the age of 40 is being conducted to demonstrate lot-to-lot consistency and complete the safety database for HEPLISAV.

**Critical Accounting Policies and the Use of Estimates**

The Company believes that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2010 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2009.

**Results of Operations****Revenues**

Revenues consist of amounts earned from collaborations, government and private agency 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. Services and license fees include 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):

Revenues:	Three Months Ended		Increase (Decrease)	
	March 31,		from 2009 to 2010	
	2010	2009	\$	%
Collaboration revenue	\$ 7,421	\$ 17,692	\$ (10,271)	(58)%
Grant revenue	862	1,139	(277)	(24)%
Services and license revenue	61	513	(452)	(88)%

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Total revenues	\$ 8,344	\$ 19,344	\$ (11,000)	(57)%
----------------	----------	-----------	-------------	-------



**Table of Contents**

Collaboration revenue in 2009 included recognition of \$15.5 million of deferred revenue associated with the upfront payment from Merck, which was accelerated through June 2009 following Merck's termination of the collaboration for HEPLISAV. Collaboration revenue in 2010 included \$4.0 million from Merck in satisfaction of its obligations for the wind down period following termination. Grant revenue for the three months ended March 31, 2010 decreased from the same period in 2009 due primarily to the expiration of our NIH Flu grant in July 2009. Services and license revenue for the first quarter 2010 decreased as compared to 2009 as a result of a decline in royalty revenue and manufacturing services from Rhein Biotech GmbH (Rhein or Dynavax Europe).

*Research and Development Expense*

Research and development expense consists 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, manufacturing our product candidates, and cost of sales relating to service and license revenue.

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

	Three Months Ended		Increase (Decrease)	
	March 31,		from 2009 to 2010	
	2010	2009	\$	%
<b>Research and development expense:</b>				
Compensation and related personnel costs	\$ 3,402	\$ 4,134	\$ (732)	(18)%
Outside services	7,505	4,438	3,067	69%
Facility costs	1,632	1,741	(109)	(6)%
Non-cash stock-based compensation	(59)	19	(78)	(411)%
<b>Total research and development expense</b>	<b>\$ 12,480</b>	<b>\$ 10,332</b>	<b>\$ 2,148</b>	<b>21%</b>

Research and development expense for the three months ended March 31, 2010 increased as compared to the same periods in 2009. For the three months ended March 31, 2010, the increase in outside services over the same period in 2009 is primarily due to clinical development costs associated with HEPLISAV. For the three months ended March 31, 2010, the decrease in compensation and related personnel costs compared to the same periods in 2009 is primarily due to the decline in employee headcount.

*General and Administrative Expense*

General and administrative expense consists primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance; legal costs that include corporate and patent expenses; allocated facility costs and non-cash stock-based compensation.

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

	Three Months Ended		Increase (Decrease)	
	March 31,		from 2009 to 2010	
	2010	2009	\$	%
<b>General and administrative expense:</b>				
Compensation and related personnel costs	\$ 1,333	\$ 1,748	\$ (415)	(24)%
Outside services	1,038	1,124	(86)	(8)%
Legal costs	1,383	823	560	68%
Facility costs	223	235	(12)	(5)%
Non-cash stock-based compensation	593	494	99	20%
<b>Total general and administrative expense</b>	<b>\$ 4,570</b>	<b>\$ 4,424</b>	<b>\$ 146</b>	<b>3%</b>

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

General and administrative expense for the three months ended March 31, 2010 increased as compared to the same periods in 2009. The decrease in compensation and related personnel costs and outside services is due to an overall decline in the number of administrative employees, consulting fees and other professional fees incurred. These reductions were offset by increases in legal costs related to patent activities.

### *Amortization of Intangible Assets*

Intangible assets consist of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was \$0.2 million for both the three months ended March 31, 2010 and 2009.

**Table of Contents***Interest Income, Interest Expense, and Other Income (Expense)*

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment, and the change in fair value of financial assets and liabilities such as the warrants and contingent consideration liabilities assumed in connection with the acquisition of SDI on December 30, 2009. Interest expense relates to the note payable issued to Holdings in connection with our acquisition of SDI. The following is a summary of our interest and other income, and interest expense (in thousands, except for percentages):

	Three Months Ended		Increase	
	March 31,		(Decrease) from	
	2010	2009	\$	%
Interest income	\$ 2	\$ 110	\$ (108)	(98)%
Interest expense	\$ (399)	\$ (15)	\$ 384	2,560%
Other income (expense)	\$ 164	\$ (346)	\$ 510	147%

Interest income for the three months ended March 31, 2010 decreased by \$0.1 million, or 98%, compared to the same period in 2009 due primarily to lower investment balances and the decline in returns on our investment portfolio resulting from current market conditions.

Interest expense for the three months ended March 31, 2010 increased by \$0.4 million, or 2,560%, compared to the same period in 2009 due primarily to interest accreted on the note payable to Holdings.

Other income (expense) for the three months ended March 31, 2010 includes the change in fair value of the warrant and contingent liabilities to Holdings and foreign currency translation adjustments. For the quarter ended March 31, 2010, we recognized a gain of \$0.3 million from the change in fair value of the warrant liability, which was offset by a loss of \$69 thousand from the change in fair value of the contingent liability and a loss of \$18 thousand from foreign currency translation.

*Losses Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.*

Pursuant to the agreements that we entered into with SDI in April 2006, we have attributed net income or loss to Dynavax and the noncontrolling interest in SDI in our consolidated statements of operations. For the three months ended March 31, 2009, the loss attributed to the noncontrolling interest was \$1.0 million. We ceased to charge net losses incurred by SDI against the noncontrolling interest upon our acquisition of SDI on December 30, 2009.

**Recent Accounting Pronouncements***Accounting Standards Update 2010-17*

In March 2010, the Financial Accounting Standards Board (FASB) reached a consensus on Accounting Standards Update (ASU) No. 2010-17,

Milestone Method of Revenue Recognition . ASU 2010-17 provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. Under the Consensus, entities can make an accounting policy election to recognize arrangement consideration received for achieving specified performance measures during the period in which the milestones are achieved, provided certain criteria are met. The scope of this Issue is limited to transactions involving research or development. ASU 2010-17 is effective for interim and annual periods beginning on or after June 15, 2010 with early adoption permitted. The impact of ASU 2010-17 is not expected to be material to the consolidated financial statements of the Company.

*Accounting Standards Update 2010-06*

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, Improving Disclosures about Fair Value Measurements (ASU 2010-06), which is included in the ASC Topic 820 (Fair Value Measurements and Disclosures). ASU 2010-06 requires new disclosures on the amount and reason for transfers in and out of Level 1 and 2 fair value measurements. ASU 2010-06 also requires disclosure of activities including purchases, sales, issuances, and settlements within the Level 3 fair value measurements and clarifies existing disclosure requirements on levels of disaggregation and disclosures about inputs and valuation techniques. ASU 2010-06 is effective for interim and annual reporting

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

periods beginning after December 15, 2009. The adoption of ASU 2010-06 did not have a material impact on the consolidated financial statements of the Company.

---

**Table of Contents**

*Accounting Standards Update 2009-13*

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU No. 2009-13). ASU No. 2009-13, which amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Dynavax means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships.

***Liquidity and Capital Resources***

As of March 31, 2010, we had \$30.1 million in cash and cash equivalents which is currently invested in institutional money market funds.

Cash used in operating activities was \$7.5 million during the three months ended March 31, 2010 compared to \$8.0 million for the same period in 2009. The decrease in cash usage compared to the prior year was due primarily to timing of payment of accrued liabilities.

Cash provided by investing activities was \$0.4 million during the three months ended March 31, 2010 compared to \$3.2 million for the same period in 2009. The decrease was attributed to the decline in net proceeds from sales and maturities of marketable securities.

Cash provided by financing activities was \$0.9 million during the three months ended March 31, 2010 compared to \$37 thousand for the same period in 2009. The increase was primarily attributed to the proceeds from the sales of our common stock under an equity distribution agreement entered into with Wedbush Morgan Securities (Wedbush) on August 17, 2009. Pursuant to the agreement we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the three months ended March 31, 2010, we sold 800,860 shares of common stock under the agreement with Wedbush as our sale agent for net proceeds of \$0.9 million after deducting commissions paid to Wedbush and offering expenses. As of March 31, 2010, we could offer and sell from time to time through Wedbush up to an additional \$11.1 million in common stock under this agreement.

On April 16, 2010, we completed an underwritten public offering resulting in net proceeds of \$41.1 million, after deducting the underwriting discount and estimated offering expenses of approximately \$3.0 million, from the sale of 30,293,000 units at a per unit price of \$1.4525. Each unit consisted of one share of common stock and one warrant to purchase 0.5 of a share of common stock. Each warrant has an exercise price of \$1.50 per share, and is exercisable for a period of five years from the date of issuance. As a result of this offering, Symphony and certain related investors received an additional 1,076,420 shares of common stock and new warrants to purchase 7,038,210 shares of common stock having the same terms as the warrants sold in the offering, pursuant to the anti-dilution provisions of the Amended and Restated Purchase Option Agreement with Symphony. The warrants to purchase 2,000,000 shares of common stock previously issued to Symphony and its related investors in connection with the November 2009 Amended and Restated Purchase Option Agreement were cancelled.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents on hand at March 31, 2010, net proceeds from our April 2010 equity offering, anticipated revenues, and reductions in spending levels.

We expect to continue to spend substantial funds in connection with development and manufacturing of our product candidates, particularly HEPLISAV; various human clinical trials for our product candidates; and protection of our intellectual property.

**Table of Contents**

In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise additional funds through future public or private financings, and/or strategic alliance and licensing arrangements. We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

Our independent registered public accounting firm has included in their audit opinion for the year ended December 31, 2009 a statement with respect to our ability to continue as a going concern. However, our consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The reaction of investors to the inclusion of a going concern statement by our auditors may materially adversely affect our share price and our ability to raise new capital or to enter into strategic alliances.

**Contractual Obligations**

The following summarizes our significant contractual obligations as of March 31, 2010 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More than 5 years</b>
Future minimum payments under our operating lease, excluding payments from the sublease agreement	\$ 17,403	\$ 1,980	\$ 8,235	\$ 2,668	\$ 4,520
Long-term note payable to Symphony Dynamo Holdings	15,000		15,000		
<b>Total</b>	<b>\$ 32,403</b>	<b>\$ 1,980</b>	<b>\$ 23,235</b>	<b>\$ 2,668</b>	<b>\$ 4,520</b>

We lease our facilities in Berkeley, California (the Berkeley Lease) and Düsseldorf, Germany (the Düsseldorf Lease) under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$40 thousand in 2010. The sublease rental income is offset against rent expense.

As part of the consideration transferred from Dynavax to Holdings for the acquisition of SDI, the Company is obligated to make contingent cash payments 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 the cancer and hepatitis C therapies. Using a discounted cash flow model, we estimated the fair value of the contingent liability to be \$3.1 million as of March 31, 2010.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of March 31, 2009 and December 31, 2009. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of March 31, 2010 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of March 31, 2010.

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 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,

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

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. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

---

**Table of Contents**

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of March 31, 2010, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$28.7 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Under the terms of our license agreements, we could be expected to pay approximately \$0.3 million in 2010 related to such fees and milestone payments to the Regents.

***Off-balance Sheet Arrangements***

We do not have any off-balance sheet arrangements as defined by rules enacted by the SEC and accordingly, no such arrangements are likely to have a current or future effect on our financial position. As described above, SDI is considered a variable interest entity and is included in our financial statements through December 30, 2009, the date we acquired all the outstanding equity in SDI. Our financing arrangement with SDI does not qualify as an off-balance sheet arrangement as defined by applicable SEC regulations.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including money market funds, government agency securities and corporate obligations, some of which are government-secured. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents, we do not expect any material loss with respect to our investment portfolio.

*Foreign Currency Risk.* We have certain investments outside the U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of March 31, 2010 was negative \$0.6 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

**ITEM 4. CONTROLS AND PROCEDURES**

***(a) Evaluation of disclosure controls and procedures***

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer ( CEO ) and Vice President ( VP ), Finance, our principal financial officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and VP, Finance concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of period covered by this report are effective.

***(b) Changes in internal controls***

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.



**Table of Contents**

**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 do not believe any of the current claims or allegations are material to our current business or operations.

**ITEM 1A. RISK FACTORS**

*Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future products, timing of development activities, 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 incurred substantial losses since inception and do not have any commercial products that generate significant revenue.***

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$268.8 million as of March 31, 2010. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; whether our future development efforts will be sufficient to support product approval; or whether the market for HEPLISAV will be substantial enough for us to reach profitability.

Clinical trials for certain of our other product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

demonstrating in clinical trials that our product candidates are safe and effective, in particular, in the current and planned trials for our product candidates;

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company, or raise additional capital on less than favorable terms.

***We require substantial additional capital to continue development of our product candidates, in particular our most advanced candidate, HEPLISAV. We cannot be certain that funds will be available and, if they are not available, we may not be able to continue as a going concern which may result in actions that could adversely impact our stockholders.***

In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise significant additional funds through future public or private financings and/or strategic alliance and licensing arrangements. We expect to continue to spend substantial funds in connection with:

development and manufacturing of our product candidates, particularly HEPLISAV;

various human clinical trials for our product candidates; and

protection of our intellectual property.

We are also exploring various initiatives to reduce costs across our operations in order to preserve our cash resources.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through the next twelve months based on cash and cash equivalents on hand at March 31, 2010, net proceeds from our April 2010 equity offering, anticipated revenues, and reductions in spending levels.

## **Table of Contents**

Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program, and potentially our other development programs while we seek strategic alternatives. In any event, we may be required to reduce costs and expenses within our control, including potentially significant personnel-related costs and other expenditures that are part of our current operations.

***Our independent registered public accountants have indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.***

Our independent registered public accounting firm has included in their audit opinion on our consolidated financial statements for the year ended December 31, 2009 a statement with respect to our ability to continue as a going concern. However, our consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The reaction of investors to the inclusion of a going concern statement by our independent auditors may materially adversely affect our share price and our ability to raise new capital or to enter into strategic alliances.

***We may not realize the expected benefits of our initiatives to reduce costs across our operations.***

We may pursue a number of initiatives to reduce costs across our operations, including workforce reductions and renegotiation of our leases and other long-term obligations. We may incur some amount of restructuring charges as we implement these cost reduction initiatives and may not realize some or all of the expected benefits of our future initiatives to reduce costs. In addition to restructuring or other charges, the changes may result in significant disruptions in our operations now and in the future as a result of these initiatives.

***The success of our product candidates depends on timely achievement of successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.***

None of our product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to timely enroll patients in clinical trials, achieve successful clinical results and obtain regulatory approvals for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, take many years and require the expenditure of substantial resources.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. Despite the time and money expended, regulatory approvals are uncertain. In addition, failure to timely and successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations. Even if approved, the labeling of the product may significantly limit the commercial opportunity for such product.

***Our clinical trials may be extended, suspended, delayed or terminated at any time. Even short delays in the commencement and progress of our trials may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.***

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects, failure to enroll patients in a timely manner, or delays due to inadequate supply of the product candidate. Even a short delay in a trial for any product candidate could require us to delay commencement or continuation of a trial until the target population is available for testing, which could result in a delay of a year or more.

Our registration and commercial timelines depend on successful completion of current and planned clinical trials, successful results from such trials, and further discussions with the FDA and corresponding foreign regulatory agencies. Any extension, suspension, modification, termination or unanticipated delays of our clinical trials could:

adversely affect our ability to timely and successfully commercialize or market these product candidates;

result in significant additional costs;

---

**Table of Contents**

potentially diminish any competitive advantages for those products;

potentially limit the markets for those products;

adversely affect our ability to enter into collaborations, 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.

***If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.***

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 long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, we or our contract manufacturers will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. 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.

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.

***Our most advanced product candidate and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.***

Our most advanced product candidate in clinical trials is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. For example, from March 2008 until September 2009, the two IND applications for HEPLISAV were placed on clinical hold by the FDA following a serious adverse event that occurred in one of our clinical trials. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease but the other IND application for HEPLISAV remains on clinical hold. In addition, most of our clinical product candidates contain ISS, and a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based 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 necessary to manufacture our clinical product candidates for our clinical trials. If we reduce our clinical product candidates, we may not require this manufacturing capacity. We have limited experience in manufacturing our product candidates in commercial quantities. Failure to comply with applicable regulatory requirements or loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.***

We rely on our facility in Düsseldorf and a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to

circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

We and these third parties are required to comply with applicable current good manufacturing practice regulations and other international regulatory requirements. If one of these parties fails to maintain compliance with these regulations, the production of our product candidates could be interrupted, resulting in delays and additional costs. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates.

## **Table of Contents**

***We have limited experience in manufacturing sufficient quantities of ISS for our clinical trials and rely on a single third party to produce the ISS we need for our clinical trials.***

We have relied on a single supplier to produce our ISS for clinical trials. To date, we have manufactured only small quantities of ISS ourselves for research purposes. If we were unable to maintain or replace our existing source for ISS, we would have to establish internal ISS manufacturing capability which would result in increased capital and operating costs and delays in developing and commercializing our product candidates. We or other third parties may not be able to produce ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with current good manufacturing practices regulations. We may not be able to comply with these and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. Noncompliance with these regulations or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates and could result in significant expense.

If HEPLISAV cannot be successfully developed or is not commercially viable, we will have to use the Düsseldorf facility for alternative manufacturing or research activities that may not fully utilize the facility's capacity, resulting in continued operating costs that may not be offset by corresponding revenues. We may also consider other alternatives for the Düsseldorf facility, including its sale or closure which would result in certain costs of disposal or discontinuation of operations. Discontinuation of operations in Düsseldorf would be complex, expensive, time-consuming and difficult to execute without significant additional costs due to among other things, international legal and tax considerations related to those operations. As a result, we may not realize cost savings associated with closure of the Düsseldorf operations in a reasonable time frame, if at all.

***We rely on contract research organizations to conduct 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 third parties to conduct 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. Any extension, delay, modification or termination of our clinical trials could delay or otherwise adversely affect our ability to commercialize our products and could have a material adverse effect on our business and operations.

***If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications or marketing claims, we may be unable to generate significant revenues, if any.***

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community.

The degree of market acceptance of any of our 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

sufficient third-party reimbursement.

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. For example, in connection with the removal of the clinical hold on HEPLISAV in September 2009 and related discussions with the FDA, it is expected that, further development of HEPLISAV in the U.S. initially will be limited to individuals who are less responsive to current licensed vaccines, including adults over 40 years of age and individuals with chronic kidney disease. If we are unable to successfully market any approved product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.



## **Table of Contents**

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

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV. We also will need to enter into collaborative relationships to provide funding to support our research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;

our shortage of capital resources may impact a willingness on the part of potential companies to collaborate;

our contracts for collaborative arrangements are terminable for convenience 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 do not have day to day control over the activities of our partners and have limited control over their decisions;

our ability to generate future event 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 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 utilize 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.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related 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.

*The financial terms of future collaborative or licensing or financing arrangements could result in significant dilution of our share value.*

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in significant dilution in the value of our issued and outstanding shares.

***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 despite 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 therapies to prevent or treat infectious diseases, asthma and inflammatory and autoimmune diseases. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. If we are unable to compete successfully, we may not be able to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

## **Table of Contents**

*The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.*

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, Dr. Dino Dina. We currently have no key person insurance on any of our employees.

*Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel.*

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. There is intense competition for the services of these personnel. 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 implement our current initiatives.

*We may develop, seek regulatory approval for and market our product candidates outside the United States, 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 introduce certain of our product candidates in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;

compliance with varying international regulatory requirements, laws and treaties;

securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;

adverse tax consequences;

the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and

regional and geopolitical risks.

To date, we have not filed for marketing approval for any of our product candidates outside the U.S. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. 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.

***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 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 in order 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 not able to cure or obtain waivers for such failures or amend the term of 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 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 addition, we must make timely payments or meet diligence obligations in order to maintain any such licenses in effect. 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.

---

## **Table of Contents**

***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. 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.

Two of our potential competitors, Merck, and GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV in the U.S. while these patents remain in force, Merck, GSK or the Institut Pasteur may bring claims against us.

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 the commercialization of HEPLISAV or any similar product candidate in the U.S., 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.

One of our potential competitors, Pfizer Inc. ( Pfizer ), has issued patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office and foreign patent offices, that may be asserted against our ISS products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies in order to commercialize one or more of our formulations of ISS in other than with respect to HEPLISAV, for which we have a license. A license for other uses may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

***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 or are 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.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

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;

## Table of Contents

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.

***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 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. 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.

***We face uncertainty related to coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our 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 or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV where existing products are approved for our target indications. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or 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 particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

The President of the United States recently signed into law the Health Care and Education Reconciliation Act of 2010. We are unable to predict what impact reform legislation will have on our business or future prospects and the uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business and to manage our business accordingly.

***We use hazardous materials in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials 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. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, 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.



## **Table of Contents**

*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 efforts, in particular any announcements regarding the progress or results of our planned trials and communications from the FDA or other regulatory agencies;

our ability to establish and maintain collaborations for the development and commercialization of our product candidates;

our ability to raise additional capital to fund our operations;

technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;

changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;

our ability to obtain component materials and successfully enter into manufacturing relationships for our 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;

issuance of new or changed securities analysts' reports or recommendations;

actual or anticipated fluctuations in our quarterly financial and operating results;

our ability to maintain continued listing on the NASDAQ markets or similar exchanges; and

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 October 2008, we experienced a decline in our market capitalization of nearly 80% based on the FDA's communication to us regarding the continuation of a clinical hold on two U.S. IND applications for HEPLISAV. While the FDA has removed the clinical hold on the IND application for individuals with chronic kidney disease, our market capitalization remains well below levels prior to the announcement of the FDA's clinical hold. In November 2008, we transferred our listing of Dynavax shares to The NASDAQ Capital Market from The NASDAQ Global Market. We may be delisted from The NASDAQ Capital Market if our share price or market value of publicly held shares does not meet certain thresholds. In addition, securities class action

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities 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, bylaws, Delaware law and our share purchase rights plan 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.

**Table of Contents**

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by the Company's Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of the Common Shares or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. 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 may need to implement additional financial and accounting systems, procedures or controls as our business and organization changes and to comply with reporting requirements.*

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls in order 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, 2010, we had 55,160,171 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.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended (the Securities Act), to register the shares of our common stock reserved for issuance under our stock option plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

*Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC collectively control a substantial percentage of the voting power of our outstanding common stock as well as \$15 million of our debt.*

Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, Symphony) currently collectively control approximately 9,031,431 shares of our common stock and warrants to purchase approximately 4,515,717 shares of our common stock. Based on the number of shares of our common stock that are outstanding following our recent public offering which closed on April 16, 2010, Symphony owns approximately 11% of our total outstanding shares of common stock. If Symphony exercises all of the warrants held by it and assuming no other issuances of shares, based on the number of shares of common stock that will be outstanding following our recent public offering, Symphony would own approximately 15% of our total outstanding shares of common stock. In addition, Symphony Dynamo Holdings LLC (Holdings), an affiliate of Symphony holds a promissory note in the principal amount of \$15 million, which may be satisfied in cash, Dynavax common stock or a combination of cash and Dynavax common stock, at our election. Finally, under the terms of the Standstill and Corporate Governance Letter Agreement we entered into with Holdings on December 30, 2009, for as long as Holdings and its affiliates, which include Symphony, beneficially own 10% or more of our outstanding common stock, we agreed to use our commercially reasonable efforts to cause to be elected and remain as directors on our Board of Directors one individual designated by Holdings and a second individual who shall be an independent third party designated by Holdings and reasonably acceptable to us. Holdings has designated Mark Kessel, a partner of Symphony Capital LLC, as its designee and Mr. Kessel has been appointed to our Board of Directors. The independent nominee has not been designated at this time. As a result, Symphony, Holdings and their affiliates will be able to exercise substantial influence over the direction of the Company.

**Table of Contents**

*Sales of our common stock from our recent public offering could trigger a limitation on our ability to use our net operating losses and tax credits in the future.*

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carryforwards could be limited. Any additional equity issuances could trigger a limitation on our ability to use our net operating losses and tax credits in the future under Sections 382 and 383 of the Internal Revenue Code as enacted by the Tax Reform Act of 1986.

**ITEM 6. EXHIBITS****Exhibit**

<b>Number</b>	<b>Document</b>
10.51 <sup>(1)</sup>	Settlement Agreement, dated as of March 12, 2010 between Dynavax Technologies Corporation and Merck Sharp & Dohme Corp. f/k/a Merck & Co., Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on March 16, 2010.

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

**Number**

**Document**

10.51 <sup>(1)</sup>	Settlement Agreement, dated as of March 12, 2010 between Dynavax Technologies Corporation and Merck Sharp & Dohme Corp. f/k/a Merck & Co., Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on March 16, 2010.

**Table of Contents**

**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 due authorized, in the City of Berkeley, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

Date: May 7, 2010

By: */s/* DINO DINA, M.D.  
**Dino Dina, M.D.**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: May 7, 2010

By: */s/* JENNIFER LEW  
**Jennifer Lew**  
**Vice President, Finance**  
**(Principal Accounting and Financial Officer)**