

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

November 02, 2012

[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 September 30, 2012

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 October 26, 2012, the registrant had outstanding 178,707,300 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>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011</u>	4
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2012 and 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011</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>	16
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	21
<b><u>PART II OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	22
Item 1A. <u>Risk Factors</u>	22
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 5. <u>Other Information</u>	32
Item 6. <u>Exhibits</u>	33
<b><u>SIGNATURES</u></b>	35

*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.*

**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. Forward-looking statements are based on our beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, potential, future, intend, certain, and similar expressions intended to identify forward-looking statements. Our forward-looking statements include discussions regarding our business and financing strategies, 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 and potential regulatory approval of our products, the effect of GAAP accounting pronouncements, the potential for entry into collaborative arrangements, uncertainty regarding our future operating results and prospects for profitability, anticipated sources of funds as well as our plans, objectives, expectations and intentions. 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>September 30, 2012 (Unaudited)</b>	<b>December 31, 2011 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 24,650	\$ 31,941
Marketable securities available-for-sale	123,629	82,020
Accounts receivable	3,685	9,527
Prepaid expenses and other current assets	2,419	1,130
<b>Total current assets</b>	<b>154,383</b>	<b>124,618</b>
Property and equipment, net	6,948	6,163
Goodwill	2,408	2,312
Restricted cash	645	647
Other assets	438	362
<b>Total assets</b>	<b>\$ 164,822</b>	<b>\$ 134,102</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,578	\$ 2,040
Accrued liabilities	9,163	8,159
Deferred revenues	4,172	4,210
Note payable to Symphony Dynamo Holdings LLC ( Holdings )	14,452	12,810
<b>Total current liabilities</b>	<b>29,365</b>	<b>27,219</b>
Deferred revenues, noncurrent	4,775	6,386
Other long-term liabilities	624	617
<b>Total liabilities</b>	<b>34,764</b>	<b>34,222</b>
<b>Commitments and contingencies (Note 5)</b>		
<b>Stockholders' equity:</b>		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2012 and December 31, 2011		
Common stock: \$0.001 par value; 250,000 shares authorized; 178,270 and 154,626 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively		
	178	155
Additional paid-in capital	545,767	466,276
Accumulated other comprehensive loss:		
Unrealized gain (loss) on marketable securities available-for-sale	29	(3)
Cumulative translation adjustment	(968)	(1,006)

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Total accumulated other comprehensive loss	(939)	(1,009)
Accumulated deficit	(414,948)	(365,542)
Total stockholders' equity	130,058	99,880
Total liabilities and stockholders' equity	\$ 164,822	\$ 134,102

*See accompanying notes.*

**Table of Contents**

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

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
Collaboration revenue	\$ 1,050	\$ 369	\$ 3,602	\$ 7,098
Grant revenue	1,219	658	3,188	2,437
Service and license revenue	605	147	1,118	652
<b>Total revenues</b>	<b>2,874</b>	<b>1,174</b>	<b>7,908</b>	<b>10,187</b>
<b>Operating expenses:</b>				
Research and development	12,850	11,777	36,631	39,706
General and administrative	7,121	4,217	18,871	13,025
Amortization of intangible assets				299
<b>Total operating expenses</b>	<b>19,971</b>	<b>15,994</b>	<b>55,502</b>	<b>53,030</b>
<b>Loss from operations</b>	<b>(17,097)</b>	<b>(14,820)</b>	<b>(47,594)</b>	<b>(42,843)</b>
Interest income	91	18	208	74
Interest expense	(589)	(485)	(1,765)	(1,462)
Other income (expense)	(196)	58	(255)	(99)
<b>Net loss</b>	<b>\$ (17,791)</b>	<b>\$ (15,229)</b>	<b>\$ (49,406)</b>	<b>\$ (44,330)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.10)</b>	<b>\$ (0.12)</b>	<b>\$ (0.30)</b>	<b>\$ (0.37)</b>
<b>Shares used to compute basic and diluted net loss per share</b>	<b>177,870</b>	<b>124,069</b>	<b>167,039</b>	<b>119,244</b>

**Condensed Consolidated Statements of Comprehensive Loss**

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	\$ (17,791)	\$ (15,229)	\$ (49,406)	\$ (44,330)
<b>Other comprehensive income (loss):</b>				
Unrealized gain (loss) on marketable securities available-for-sale	59	(8)	32	11
Cumulative translation adjustment	249	(438)	38	117

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Total other comprehensive income (loss)	308	(446)	70	128
Total comprehensive loss	\$ (17,483)	\$ (15,675)	\$ (49,336)	\$ (44,202)

*See accompanying notes.*



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

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Operating activities</b>		
Net loss	\$ (49,406)	\$ (44,330)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	898	1,009
Amortization of intangible assets		299
Loss (gain) on disposal of assets	6	(8)
Non-cash interest associated with the note payable to Holdings	1,642	1,403
Fair value adjustment of the warrant and contingent liabilities to Holdings		34
Accretion of discounts and amortization of premiums of marketable securities	970	895
Stock-based compensation expense	6,294	3,934
Changes in operating assets and liabilities:		
Accounts receivable	5,842	218
Prepaid expenses and other current assets	(1,289)	(33)
Restricted cash and other assets	(74)	(164)
Accounts payable	(462)	(1,016)
Accrued liabilities and other long term liabilities	1,011	(2,997)
Deferred revenues	(1,649)	(1,072)
Net cash used in operating activities	(36,217)	(41,828)
<b>Investing activities</b>		
Purchases of marketable securities	(169,634)	(38,007)
Proceeds from maturities of marketable securities	127,085	52,675
Purchases of property and equipment, net	(1,727)	(564)
Net cash (used in) provided by investing activities	(44,276)	14,104
<b>Financing activities</b>		
Proceeds from offering of common stock, net of issuance costs	69,619	24,078
Proceeds from exercise of warrants	1,505	7
Proceeds from employee stock purchase plan	307	132
Proceeds from exercise of stock options	1,789	169
Net cash provided by financing activities	73,220	24,386
Effect of exchange rate on cash and cash equivalents	(18)	(43)
Net decrease in cash and cash equivalents	(7,291)	(3,381)
Cash and cash equivalents at beginning of period	31,941	22,453
Cash and cash equivalents at end of period	\$ 24,650	\$ 19,072

**Supplemental disclosure of cash flow information**

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Disposal of fully depreciated property and equipment	\$	29	\$	845
Net change in unrealized gain on marketable securities	\$	32	\$	11

*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 ( we, our, us, Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines. A U.S. Biologics License Application ( BLA ) for HEPLISAV has been accepted for review by the U.S. Food and Drug Administration. A Marketing Authorization Application ( MAA ) has been accepted for review by the European Medicines Agency ( EMA ).

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline ( GSK ) and our therapy for asthma partnered with AstraZeneca AB ( AstraZeneca ). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory sequences ( ISS ) and immunoregulatory sequences. We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2000.

**Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting 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, 2011, has been derived from audited financial statements at that date, but excludes disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission (the SEC ).

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Rhein Biotech GmbH ( Rhein or Dynavax Europe ) and Dynavax International, B.V. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

**Liquidity and Financial Condition**

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2012, we had cash, cash equivalents and marketable securities of \$148.3 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as of September 30, 2012, as well as anticipated revenues and funding from existing agreements.

If we are unable to generate significant revenues from HEPLISAV, if it is approved, and to continue development of our product candidates, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient additional funding may not be available on acceptable terms, or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing shareholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or our other development programs while we seek strategic alternatives.

**Use of Estimates**

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

The preparation of financial statements in conformity with 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.

### **Summary of Significant Accounting Policies**

We believe that there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2012, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011. Below we describe our accounting policy related to revenue recognition.

---

**Table of Contents**

***Revenue Recognition***

Our revenues are derived from collaborative and service agreements as well as grants. We enter into license and manufacturing agreements and collaborative research and development arrangements with pharmaceutical and biotechnology partners that may include multiple deliverables. Our arrangements may include one or more of the following elements: upfront license payments, cost reimbursement for the performance of research and development activities, milestone payments, other contingent payments, contract manufacturing service fees, royalties and license fees. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

On January 1, 2011, we adopted on a prospective basis Financial Accounting Standards Board ( FASB ) Accounting Standards Update ( ASU ) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated.

Non-refundable upfront fees received for license and collaborative agreements entered into before January 1, 2011 and other payments under collaboration agreements where we have continuing performance obligations are deferred and recognized over our expected performance period. Revenue is recognized on a ratable basis, unless we determine that another methodology is more appropriate, through the date at which our performance obligations are completed. Management makes its best estimate of the period over which we expect to fulfill our performance obligations, which may include clinical development activities. Given the uncertainties of research and development collaborations, significant judgment is required to determine the duration of the performance period. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

On January 1, 2011, we elected to prospectively adopt the milestone method as described in FASB ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (1) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, (2) the event can only be achieved based in whole or in part on either the entity's performance or a specific outcome resulting from the entity's performance and (3) if achieved, the event would result in additional payments being due to the entity.

Our license and collaboration agreements with our partners provide for payments to be paid to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there is substantial uncertainty whether any such milestones would be achieved at the time we enter into these agreements. We evaluate whether the development milestones meet the criteria to be considered substantive. The conditions include: (1) the development work is contingent upon either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the deliverable item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (2) it relates solely to past performance and; (3) it is reasonable relative to all the deliverable and payment terms within the arrangement. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone.

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

Our license and collaboration agreements with certain partners also provide for contingent payments to be paid to us based solely upon the performance of our partner. For such contingent payments we expect to recognize the payments as revenue upon receipt, provided that collection is reasonably assured and the other revenue recognition criteria have been satisfied.

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

Revenue from royalty payments is contingent on future sales activities by our licensees. As a result, we recognize royalty revenue when reported by our licensees and when collection is reasonably assured.

---

## **Table of Contents**

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

### **Recent Accounting Pronouncements**

#### ***Accounting Standards Update 2011-04***

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS*. This ASU is the result of joint efforts by the FASB and International Accounting Standards Board to develop a single, converged fair value framework. While this ASU is largely consistent with existing fair value measurement principles in GAAP, it expands Accounting Standards Codification ( ASC ) Topic 820, *Fair Value Measurement* ( ASC 820 ) existing disclosure requirements for fair value measurements and makes other amendments. Many of these amendments were made to eliminate unnecessary wording differences between GAAP and International Financial Reporting Standards ( IFRS ), which could change how fair value measurement guidance in ASC 820 is applied. We adopted the disclosure requirements in the quarter ended March 31, 2012, and included the required disclosure in Note 2 Fair Value Measurements.

#### ***Accounting Standards Update 2011-05***

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*. This ASU gives an entity the option to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU No. 2011-05 was effective on a retrospective basis for us on January 1, 2012. We adopted this presentation of comprehensive income in the quarter ended March 31, 2012.

### **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 as follows:

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.

**Table of Contents****Recurring Fair Value Measurements**

The following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011 (in thousands):

	Level 1	Level 2	Level 3	Total
<b>September 30, 2012:</b>				
Money market funds	\$ 18,862	\$	\$	\$ 18,862
U.S. government agency securities		102,174		102,174
Corporate debt securities, secured by U.S. government		24,578		24,578
<b>Total</b>	<b>\$ 18,862</b>	<b>\$ 126,752</b>	<b>\$</b>	<b>\$ 145,614</b>
<b>December 31, 2011:</b>				
Money market funds	\$ 17,171	\$	\$	\$ 17,171
U.S. Government agency securities		35,920		35,920
Corporate debt securities, secured by U.S. government		58,580		58,580
<b>Total</b>	<b>\$ 17,171</b>	<b>\$ 94,500</b>	<b>\$</b>	<b>\$ 111,671</b>

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Marketable securities primarily comprise U.S. government sponsored and corporate debt securities which are measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

When determining if there are any other-than-temporary impairments on our investments, we evaluate: (1) whether the investment has been in a continuous unrealized loss position for over 12 months, (2) the duration to maturity of our investments, (3) our intention to hold the investments to maturity and if it is not more likely than not that we will be required to sell the investments before recovery of the amortized cost bases, (4) the credit rating of each investment and (5) the type of investments made. Through September 30, 2012, we have not recognized any other-than-temporary losses on our investments. There were no sales of marketable securities during the nine months ended September 30, 2012 and 2011.

**Liabilities for Which Fair Value Is Disclosed**

In connection with the acquisition of all of the outstanding equity of Symphony Dynamo, Inc. in December 2009, we issued to Symphony Dynamo Holdings LLC 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. As of September 30, 2012, the carrying value and estimated fair value of the note payable was \$14.5 million and this balance was classified as a short term liability. We estimated the fair value of the note using a net present value model with a discount rate of 17%. This approach resulted in the classification of the note as Level 3 in the fair value hierarchy. Imputed interest is recorded as interest expense over the term of the loan using the interest rate method. We recorded interest expense of \$0.5 million and \$1.6 million for the three and nine months ended September 30, 2012, respectively, and \$0.5 million and \$1.4 million for the three and nine months ended September 30, 2011, respectively. If we elect to pay all or a portion of the note in shares of our common stock, the number of shares issued will be equal to the portion of the outstanding principal amount of the note to be repaid using our common stock, divided by the average closing price of our common stock for the 30 trading days immediately preceding (but not including) the second trading day before the date of such payment multiplied by 1.15.

**Table of Contents****3. Cash, cash equivalents and marketable securities**

The following is a summary of cash, cash equivalents and available-for-sale marketable securities as of September 30, 2012 and December 31, 2011 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
<b>September 30, 2012:</b>				
Cash and cash equivalents:				
Cash	\$ 2,665	\$	\$	\$ 2,665
Money market funds	18,862			18,862
U.S. government agency securities	870			870
Corporate debt securities	2,253			2,253
<b>Total cash and cash equivalents</b>	<b>24,650</b>			<b>24,650</b>
Marketable securities available-for-sale:				
U.S. government agency securities	101,274	34	(4)	101,304
Corporate debt securities	22,326		(1)	22,325
<b>Total marketable securities available-for-sale</b>	<b>123,600</b>	<b>34</b>	<b>(5)</b>	<b>123,629</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 148,250</b>	<b>\$ 34</b>	<b>\$ (5)</b>	<b>\$ 148,279</b>
<b>December 31, 2011:</b>				
Cash and cash equivalents:				
Cash	\$ 2,290	\$	\$	\$ 2,290
Money market funds	17,171			17,171
U.S. government agency securities	9,438			9,438
Corporate debt securities	3,044		(2)	3,042
<b>Total cash and cash equivalents</b>	<b>31,943</b>		<b>(2)</b>	<b>31,941</b>
Marketable securities available-for-sale:				
U.S. Government agency securities	26,488		(6)	26,482
Corporate debt securities	55,533	9	(4)	55,538
<b>Total marketable securities available-for-sale</b>	<b>82,021</b>	<b>9</b>	<b>(10)</b>	<b>82,020</b>
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$ 113,964</b>	<b>\$ 9</b>	<b>\$ (12)</b>	<b>\$ 113,961</b>

The following is a summary of the amortized cost and estimated fair value of available-for-sale securities at September 30, 2012, by contractual maturity (in thousands):

	September 30, 2012	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	\$ 76,342	\$ 76,360
Mature after one year through two years	47,258	47,269



\$ 123,600	\$ 123,629
------------	------------

There were no realized gains or losses from the sale of marketable securities in the three and nine months ended September 30, 2012 and 2011. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity. The corporate debt securities held as of September 30, 2012 and December 31, 2011, were secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program.

#### **4. Public Financing**

On May 9, 2012, we sold 17,500,000 shares of our common stock at a price of \$4.25 per share in an underwritten public offering. The sale of common stock resulted in aggregate net proceeds to us of approximately \$69.6 million after deducting offering expenses.

**Table of Contents****5. Commitments and Contingencies**

We lease our facilities in Berkeley, California ( Berkeley Lease ) and Düsseldorf, Germany ( Düsseldorf Lease ) under operating leases that expire in September 2017 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense. Total net rent expense related to our operating leases for the three months ended September 30, 2012 and 2011, was \$0.4 million and \$0.4 million, respectively. Total net rent expense related to our operating leases for the nine months ended September 30, 2012 and 2011, was \$1.3 million and \$1.3 million, respectively. Deferred rent was \$0.6 million as of September 30, 2012 and December 31, 2011.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2012, excluding payments from sublease agreements, are as follows (in thousands):

<b>Year ending December 31,</b>	
2012 (remaining three months)	\$ 450
2013	1,799
2014	1,763
2015	1,799
2016	1,836
Thereafter	4,417
<b>Total</b>	<b>\$ 12,064</b>

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

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of September 30, 2012, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

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, if any, of certain products originating from the licensed technologies.

**6. Collaborative Research and Development Agreements****GlaxoSmithKline**

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop and commercialize toll-like receptor ( TLR ) inhibitors. We received an initial payment of \$10 million and agreed to conduct research and early clinical development in up to four programs. In 2011, we earned \$15 million in milestone payments related to the initiation of Phase 1 and proof-of-mechanism clinical trials of DV1179 in systemic lupus erythematosus patients and expansion of our collaboration with GSK to develop a TLR8 inhibitor. We are eligible to receive future development milestone payments which we have determined to be substantive milestones. GSK can exercise its exclusive option to license each program upon achievement of certain events and we are eligible to receive contingent option exercise payments. If GSK exercises an option, GSK would carry out further development and commercialization of the corresponding products. We are eligible to receive tiered, up to double-digit royalties on sales of any products originating from the collaboration and have retained an option to co-develop and co-promote one product under this agreement.

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

Revenue from the initial payment from GSK was deferred and is being recognized over the expected period of performance under the agreement which is estimated to be seven years. For the three months ended September 30, 2012 and 2011, we recognized revenue of \$0.4 million in each period, respectively, related to the initial payment. For the nine months ended September 30, 2012 and 2011, we recognized revenue of \$1.1 million in each period, respectively, related to the initial payment. As of September 30, 2012 and December 31, 2011, deferred revenue relating to the initial payment was \$4.6 million and \$5.7 million, respectively. For the three and nine months ended September 30, 2011, we recorded \$6 million in revenue from a milestone payment we received from GSK.

**Table of Contents**

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 the 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. We received an upfront payment of \$10 million. In 2008, we received a milestone payment of \$4.5 million for the nomination of the first candidate drug, AZD1419, for asthma. The research term of this agreement was extended through July 2010.

In October 2011, we amended our agreement with AstraZeneca to provide that we will conduct initial clinical development of AZD1419. Under the terms of the amended agreement, AstraZeneca will fund all program expenses to cover the cost of development activities through Phase 2a, estimated to total approximately \$20.0 million. We received an initial payment of \$3 million to begin the clinical development program. In the first quarter of 2012, we received a \$2.6 million payment to advance AZD1419 into preclinical toxicology studies. In the fourth quarter of 2012, we and AstraZeneca agreed to advance AZD1419 towards a Phase 1 clinical trial, which entitles us to a development milestone payment of \$6 million. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a \$20 million milestone payment and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. Additionally, we are eligible to receive potential future development payments and, upon commercialization, we are eligible to receive royalties based on product sales of any products originating from the collaboration. We have the option to co-promote in the United States products arising from the collaboration, if any. AstraZeneca has the right to sublicense its rights upon our prior consent.

Revenue from the 2011 amendment has been deferred and is being recognized as the development work is performed over the estimated performance period of approximately five years. For the three months ended September 30, 2012, we recognized revenue of \$0.2 million associated with the initial payment and \$0.5 million from performance of research services. For the nine months ended September 30, 2012, we recognized revenue of \$0.5 million related to the initial payment and \$2.0 million from performance of research services. Revenues from the agreement were immaterial for 2011. As of September 30, 2012 and December 31, 2011, deferred revenue from the initial payment and performance of research services was \$4.4 million and \$4.9 million, respectively.

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

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

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 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 our program under Contract No. HHSN272200800038C.

In July 2011, we were awarded a \$0.6 million grant from the NIH to fund research in preclinical models of skin autoimmune inflammation.

In May 2012, we were awarded a \$0.4 million grant from the NIH to fund research in screening for inhibitors of TLR8 for treatment of rheumatoid arthritis and a \$0.6 million grant to fund development of TLR8 inhibitors for treatment of autoimmune diseases.

In July 2012, we were awarded a \$0.3 million grant from the NIH to take a systems biology approach to study the differences between individuals that do or do not respond to vaccination against hepatitis B.

During the three and nine month periods the following revenue was recognized (in thousands):

Three Months Ended September 30,	Nine Months Ended September 30,
-------------------------------------	------------------------------------

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

	2012	2011	2012	2011
NIAID Contract	\$ 1,100	\$ 534	\$ 2,840	\$ 1,650
All other NIH grants	119	124	348	787
<b>Total NIH grant revenue recognized</b>	<b>\$ 1,219</b>	<b>\$ 658</b>	<b>\$ 3,188</b>	<b>\$ 2,437</b>

**Table of Contents****7. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, outstanding 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, stock options and stock awards to purchase approximately 34,400,000 and 37,200,000 shares of common stock as of September 30, 2012 and 2011, respectively, were excluded from the calculation of diluted net loss per share for the quarters ended September 30, 2012 and 2011, because the effect of their inclusion would have been anti-dilutive.

**8. Stockholders Equity**

As of September 30, 2012, we had the following stock-based compensation plans: the 1997 Equity Incentive Plan ( 1997 Plan ); the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program ( 2004 Plan ); the 2004 Employee Stock Purchase Plan ( Purchase Plan ); the 2010 Employment Inducement Award Plan ( 2010 Inducement Plan ); and the 2011 Equity Incentive Plan ( 2011 Plan ).

The 2011 Plan is administered by our Board of Directors ( Board ), or a designated committee of the Board, and awards granted under the 2011 Plan have a term of 10 years unless earlier terminated by the Board. No additional awards will be granted under the 1997 Plan, the 2004 Plan or the 2010 Inducement Plan. All shares currently subject to awards outstanding under the 1997 Plan, 2004 Plan or 2010 Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans.

Under our stock-based compensation plans, option awards generally vest over a four-year period contingent upon continuous service and expire ten years from the date of grant (or earlier upon termination of continuous service). The fair value-based measurement of each option is estimated on the date of grant using the Black-Scholes option valuation model. The fair value-based measurements and weighted-average assumptions used in the calculations of these measurements are as follows:

	Employee Stock Options				Employee Stock Purchase Plan	
	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Weighted-average fair value per share	\$ 3.42	\$ 2.36	\$ 3.30	\$ 2.76	\$ 2.85	\$ 2.19
Risk-free interest rate	0.5%	1.0%	0.5%	1.6%	0.2%	0.3%
Expected life (in years)	4.0	4.0	4.0	4.0	1.2	1.2
Volatility	1.5	1.6	1.6	1.6	1.5	1.6
Expected dividends						

Expected volatility is based on the historical volatility of our stock. 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 interest 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. The dividend yield is 0% for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value-based measurement is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value-based measurement is amortized to expense over the remaining vesting period commencing when the achievement of the vesting criteria becomes probable. As of September 30, 2012, the total unrecognized compensation cost related to non-vested equity awards deemed probable of vesting including all awards with time-based vesting amounted to \$13.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.37 years. As of September 30, 2012, the total unrecognized compensation cost related to non-vested equity awards not deemed probable of vesting amounted to \$6.6 million.

As of September 30, 2012, approximately 2,600,000 shares related to equity awards with performance-based vesting criteria were outstanding.



**Table of Contents**

Stock-based compensation expense for the three months ended September 30, 2012 and 2011, was \$1.9 million and \$1.3 million, respectively. We recognized stock-based compensation expense of \$6.3 million and \$3.9 million for the nine months ended September 30, 2012 and 2011, respectively. The components of stock-based compensation expense were (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development expense	\$ 824	\$ 528	\$ 2,565	\$ 1,571
General and administrative expense	1,079	759	3,729	2,363
<b>Total</b>	<b>\$ 1,903</b>	<b>\$ 1,287</b>	<b>\$ 6,294</b>	<b>\$ 3,934</b>

Activity under the stock-based compensation plans during the nine months ended September 30, 2012, was as follows (in thousands except per share amounts):

	Options and Awards Available for Grant	Number of Options and Awards Outstanding	Weighted- Average Price Per Share
Balance at December 31, 2011	11,524	11,101	\$ 3.10
Options granted	(4,094)	4,094	\$ 3.69
Awards granted	(1,815)	1,815	\$ 4.23
Options exercised		(1,049)	\$ 1.80
Awards vested		(115)	\$ 1.98
Options cancelled:			
Options forfeited (unvested)	412	(412)	\$ 3.27
Options expired (vested)	36	(36)	\$ 6.26
Awards cancelled (unvested)		(60)	\$ 4.22
 Balance at September 30, 2012	 6,063	 15,338	 \$ 3.46

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 September 30, 2012 (in thousands, except per share amounts and years):

	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding options (vested and expected to vest)	12,561	\$ 3.35	7.27	\$ 20,857
Options exercisable	6,729	\$ 3.55	5.99	\$ 11,002

**Employee Stock Purchase Plan**

As of September 30, 2012, 996,000 shares have been reserved and approved for issuance under 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 698,724 shares of our common stock under the Purchase Plan. As of September 30, 2012, 297,276 shares of our common stock remained available for future purchases.



**Warrants**

As of September 30, 2012, warrants to purchase an aggregate of approximately 19,000,000 shares of our common stock were outstanding. During the three and nine months ended September 30, 2012, warrants were exercised to purchase an aggregate of approximately 200,000 and 4,900,000 shares, respectively, of our common stock.

---

## **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, the period for which we estimate our cash resources are sufficient, the availability of additional funds, as well as those set forth under Risk Factors and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.*

*The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Quarterly Report and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2011.*

#### **Overview**

Dynavax Technologies Corporation ( we, our, us, Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines. A U.S. Biologics License Application ( BLA ) for HEPLISAV has been accepted for review by the U.S. Food and Drug Administration ( FDA ). A Marketing Authorization Application ( MAA ) has been accepted for review by the European Medicines Agency ( EMA ).

Our pipeline of product candidates includes: HEPLISAV, our autoimmune program partnered with GlaxoSmithKline ( GSK ) and our therapy for asthma partnered with AstraZeneca AB ( AstraZeneca ). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on our proprietary technology which uses immunostimulatory and immunoregulatory sequences.

#### **Recent Developments**

In June 2012, we reported that the FDA has established February 24, 2013, as the Prescription Drug User Fee Act ( PDUFA ) action date for our HEPLISAV BLA, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age. In August 2012, the FDA informed the Company that its Vaccines and Related Biological Advisory Committee ( VRBPAC ) is scheduled to discuss HEPLISAV at its meeting on November 15, 2012.

In July 2012, the American Medical Association Current Procedural Terminology ( CPT ) Panel established a CPT code for an adult two dose hepatitis B vaccination schedule. CPT codes are designed to communicate uniform information about medical services and procedures among physicians and payers for administrative and financial purposes. If approved, HEPLISAV will be reported using the new two dose code, differentiating it from a three dose hepatitis B vaccine schedule.

In July 2012, the Company filed an MAA for HEPLISAV with the EMA for use in adults 18 through 70 years of age and in patients with chronic kidney disease. The Company was subsequently notified in August 2012 by the EMA that its MAA was accepted for review. The EMA is a European Union agency responsible for the evaluation of medicinal products through a single application for marketing authorization in all European Union and European Economic Area European Free Trade Association states.

In October 2012, we and AstraZeneca agreed to advance AZD1419, a proprietary second generation TLR-9 agonist for asthma, towards a Phase I clinical trial, which entitles us to a development milestone payment of \$6 million.

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

The accompanying discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) for interim financial information. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies and the valuation of certain liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not

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

readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2012, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

**Table of Contents****Results of Operations***Revenues*

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

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

	Three Months Ended		Increase (Decrease) from		Nine Months Ended		Increase (Decrease) from	
	September 30, 2012	September 30, 2011	2011 to 2012	%	September 30, 2012	September 30, 2011	2011 to 2012	%
	\$	\$	\$	%	\$	\$	\$	%
<b>Revenues:</b>								
Collaboration revenue	\$ 1,050	\$ 369	\$ 681	185%	\$ 3,602	\$ 7,098	\$ (3,496)	(49%)
Grant revenue	1,219	658	561	85%	3,188	2,437	751	31%
Service and license revenue	605	147	458	312%	1,118	652	466	71%
<b>Total revenues</b>	<b>\$ 2,874</b>	<b>\$ 1,174</b>	<b>\$ 1,700</b>	<b>145%</b>	<b>\$ 7,908</b>	<b>\$ 10,187</b>	<b>\$ (2,279)</b>	<b>(22%)</b>

Total revenues for the three months ended September 30, 2012, increased by \$1.7 million, or 145%, as compared to the same period in 2011. The increase was primarily due to revenue earned from our collaboration with AstraZeneca for work on asthma therapies. Grant revenue increased as compared to the same period in 2011, due to increased research activity under our NIAID contract related to adjuvant development. Service and license revenue increased as compared to the same period in 2011, due to royalties earned by Rhein Biotech GmbH ( Rhein or Dynavax Europe ).

Total revenues for the nine months ended September 30, 2012, decreased by \$2.3 million, or 22%, as compared to the same period in 2011. Collaboration revenue from our partnership with AstraZeneca was \$2.5 million higher during the nine month period ended September 30, 2012. However, during the nine months ended September 30, 2011, we recognized a \$6 million milestone payment from GSK for the initiation of a Phase 1 clinical trial. Grant revenue for the nine months ended September 30, 2012, increased from the same period in 2011 primarily due to an increase in research activity under our NIAID contract related to adjuvant development. Service and license revenue for the nine months ended September 30, 2012, increased as compared to the same period in 2011, due to royalties earned by Rhein.

*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 and manufacturing of product candidates.

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

	Three Months Ended		Increase (Decrease) from		Nine Months Ended		Increase (Decrease) from	
	September 30, 2012	September 30, 2011	2011 to 2012	%	September 30, 2012	September 30, 2011	2011 to 2012	%
	\$	\$	\$	%	\$	\$	\$	%
<b>Research and development:</b>								
Compensation and related personnel costs	\$ 5,169	\$ 4,862	\$ 307	6%	\$ 15,374	\$ 14,063	\$ 1,311	9%
Outside services	5,401	4,959	442	9%	14,352	19,792	(5,440)	(27%)
Facility costs	1,456	1,429	27	2%	4,340	4,281	59	1%
Non-cash stock-based compensation	824	527	297	56%	2,565	1,570	995	63%

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

Total research and development	\$ 12,850	\$ 11,777	\$ 1,073	9%	\$ 36,631	\$ 39,706	\$ (3,075)	(8%)
--------------------------------	-----------	-----------	----------	----	-----------	-----------	------------	------

Research and development expense for the three months ended September 30, 2012, increased by \$1.1 million, or 9%, as compared to the same period in 2011. During the three months ended September 30, 2012, outside services increased by \$0.4 million due primarily to costs associated with the regulatory approval process and manufacture of HEPLISAV, offset partially by lower clinical trial expense. In addition, compensation costs and non-cash stock-based compensation increased due to growth in employee headcount and related expense incurred for option grants.

Research and development expense for the nine months ended September 30, 2012, decreased by \$3.1 million, or 8%, as compared to the same period in 2011. This was the result of a decline of approximately \$5.4 million in outside services, in particular

**Table of Contents**

lower HEPLISAV clinical trial expenses. This decline was partially offset by an increase of approximately \$1.3 million in compensation and related personnel costs due primarily to increased headcount. In addition, non-cash stock-based compensation increased by \$1.0 million due to growth in employee headcount and related expense incurred for option grants.

*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 services; legal costs that include corporate and patent-related expenses; allocated facility costs and non-cash stock-based compensation.

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

	Three Months Ended		Increase (Decrease)		Nine Months Ended		Increase (Decrease)	
	September 30,		from 2011 to 2012		September 30,		from 2011 to 2012	
	2012	2011	\$	%	2012	2011	\$	%
<b>General and administrative:</b>								
Compensation and related personnel costs	\$ 2,480	\$ 1,898	\$ 582	31%	\$ 6,661	\$ 5,516	\$ 1,145	21%
Outside services	2,481	1,051	1,430	136%	6,137	3,104	3,033	98%
Legal costs	866	344	522	152%	1,750	1,507	243	16%
Facility costs	232	190	42	22%	651	589	62	11%
Non-cash stock-based compensation	1,062	734	328	45%	3,672	2,309	1,363	59%
<b>Total general and administrative</b>	<b>\$ 7,121</b>	<b>\$ 4,217</b>	<b>\$ 2,904</b>	<b>69%</b>	<b>\$ 18,871</b>	<b>\$ 13,025</b>	<b>\$ 5,846</b>	<b>45%</b>

General and administrative expense for the three and nine months ended September 30, 2012, increased by \$2.9 million, or 69%, and \$5.8 million, or 45%, respectively, as compared to the same periods in 2011. These increases are primarily due to higher legal and outside costs, including consulting and market research activities, as we prepare for the potential commercial launch of HEPLISAV. Compensation costs and non-cash stock-based compensation also increased due to growth in the number of administrative employees to support the organization and related expense incurred for option grants.

*Amortization of Intangible Assets*

Intangible assets consist of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and were amortized over five years from the date of acquisition through the second quarter of 2011. Amortization of intangible assets was \$0.3 million for the nine months ended September 30, 2011.

*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. Interest expense relates to the note payable issued to Symphony Dynamo Holdings LLC ( Holdings ). Other income (expense) includes gains and losses on foreign currency transactions as well as gains and losses on disposals of property and equipment. The following is a summary of our interest income and expense and other income (expense) (in thousands, except for percentages):

	Three Months Ended		Increase (Decrease)		Nine Months Ended		Increase (Decrease)	
	September 30,		from 2011 to 2012		September 30,		from 2011 to 2012	
	2012	2011	\$	%	2012	2011	\$	%
Interest income	\$ 91	\$ 18	\$ 73	406%	\$ 208	\$ 74	\$ 134	181%
Interest expense	(589)	(485)	104	21%	(1,765)	(1,462)	303	21%
Other income (expense)	(196)	58	(254)	(438%)	(255)	(99)	156	158%

Interest income for the three and nine months ended September 30, 2012, increased over the same periods in 2011, due to higher investment balances primarily as a result of our May 2012 common stock offering which resulted in net proceeds to us of approximately \$69.6 million.

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

Interest expense for the three and nine months ended September 30, 2012, increased over the same period in 2011, due to interest from the accretion of the discount on the note payable to Holdings that, under the interest rate method, increases as the carrying value of the note increases.

**Table of Contents**

Other income (expense) for the three and nine months ended September 30, 2012 and 2011 primarily represents gains and losses on foreign currency transactions. Losses recorded in the 2012 periods were due to fluctuations in the value of the Euro compared to the U.S. dollar.

**Liquidity and Capital Resources**

As of September 30, 2012, we had \$148.3 million in cash, cash equivalents and marketable securities. Our funds are currently invested in short-term money market funds, U.S. government agency securities and corporate obligations, secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program.

During the nine months ended September 30, 2012, we used \$36.2 million of cash for our operations and primarily due to our net loss of \$49.4 million, of which \$9.8 million consisted of non-cash charges such as depreciation and amortization, non-cash interest and stock based compensation. By comparison, during the nine months ended September 30, 2011, we used \$41.8 million of cash for our operations primarily due to a net loss of \$44.3 million, of which \$7.6 million consisted of non-cash charges such as depreciation and amortization, non-cash interest and stock based compensation. Cash used in our operations for the first nine months of 2012 decreased by \$5.6 million compared to cash used in our operations for the first nine months of 2011, due primarily to a \$5.8 million net decrease in accounts receivable in the 2012 period related to payments received from our collaborations with GSK and AstraZeneca.

During the nine months ended September 30, 2012, we used \$44.3 million of cash for investing activities compared to \$14.1 million of cash provided by investing activities for the nine months ended September 30, 2011. Cash used for investing activities during the first nine months of 2012 included \$42.5 million of cash for net purchases of marketable securities to invest the net proceeds from our May 2012 sale of common stock. By comparison, during the nine months ended September 30, 2011, we generated \$14.7 million of net proceeds from the maturity of marketable securities.

During the nine months ended September 30, 2012, cash provided by financing activities was \$73.2 million, compared to \$24.4 million for the same period in 2011. Cash provided by financing activities in the first nine months of 2012 included the sale of 17,500,000 shares of common stock in a public offering for net proceeds of \$69.6 million as well as proceeds from stock option and warrant exercises of \$3.3 million. By comparison, during the nine months ended September 30, 2011, we sold 9,800,000 shares of common stock under the agreement with Aspire Capital for net proceeds of \$24.1 million and received proceeds from stock option and warrant exercises of \$0.2 million.

We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand as of September 30, 2012, and anticipated revenues and funding from existing agreements. We expect to continue to spend substantial funds in connection with the development and manufacturing of our product candidates, particularly HEPLISAV, various human clinical trials for our product candidates and protection of our intellectual property. If we are unable to generate significant revenues from HEPLISAV, if it is approved, and to continue development of our product candidates, we may need to raise additional funds. This may occur through strategic alliance and licensing arrangements and/or future public or private financings. Sufficient funding may not be available, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

**Contractual Obligations**

The following summarizes our significant contractual obligations as of September 30, 2012, and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	Total	2012	2013- 2014	2015- 2016	2017 and Thereafter
<b>Contractual Obligations:</b>					
Future minimum payments under our operating leases	\$ 12,064	\$ 450	\$ 3,562	\$ 3,635	\$ 4,417
Note payable to Symphony Dynamo Holdings	15,000	15,000			
Total	\$ 27,064	\$ 15,450	\$ 3,562	\$ 3,635	\$ 4,417

We lease our facilities in Berkeley, California ( Berkeley Lease ) and Düsseldorf, Germany ( Düsseldorf Lease ) under operating leases that expire in September 2017 and March 2023, respectively.



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

The principal amount of our non-interest bearing note payable to Symphony Dynamo Holdings LLC of \$15 million is due on December 31, 2012, and is payable in cash, our common stock or a combination thereof at our discretion. As of September 30, 2012, the carrying value of the note payable was \$14.5 million and was classified as a short term liability. Imputed interest is recorded as interest expense over the term of the loan using the interest rate method. If we elect to pay all or a portion of the note in shares of our

## **Table of Contents**

common stock, the number of shares issued will be equal to the portion of the outstanding principal amount of the note to be repaid using our common stock, divided by the average closing price of our common stock for the 30 trading days immediately preceding (but not including) the second trading day before the date of such payment multiplied by 1.15.

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. Also, 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 upfront fees, milestones, royalties on net sales of products originating from the licensed technologies or other payments contingent upon the occurrence of an event that cannot reasonably be estimated.

We rely on research institutions, contract research organizations, clinical investigators as well as clinical and commercial material manufacturers of our product candidates. As of September 30, 2012, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$10.5 million through 2015. These agreements are terminable by us upon written notice. Generally, we are liable only for actual effort expended by the organizations at any point in time during the contract through the notice period.

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 certain products, if any, originating from the licensed technologies.

### ***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.

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

***Interest Rate Risk.*** The primary objective of our investment activities is to preserve principal while at the same time maximizing 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, U.S. government agency securities and corporate obligations, secured by the Federal Deposit Insurance Corporation through the Temporary Liquidity Guarantee Program. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt or home equity loans. If interest rates were to rise or fall from current levels by 100 basis points or by 125 basis points, the change in our net unrealized loss on investments would be \$1.5 million or \$1.9 million, respectively.

We do not have derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

***Foreign Currency Risk.*** We have certain investments outside the United States for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the condensed consolidated balance sheet as of September 30, 2012, was \$1.0 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. As of September 30, 2012, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

**Table of Contents**

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

The Company s management, under the supervision and with the participation of the Company s Chief Executive Officer and Chief 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 Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of period covered by this report are effective at the reasonable assurance level.

**(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**

We are not a party to any material legal proceedings.

**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.*

**Risks Related to our Finances and Capital Requirements**

*We have incurred substantial losses since inception and do not have any commercial products that generate revenue.*

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$414.9 million as of September 30, 2012. To date, our revenue has resulted from collaboration agreements, services and license fees from our customers, including the customers of Rhein Biotech GmbH ( Rhein or Dynavax Europe ), and government and private agency grants. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and our addition of infrastructure and operations to support commercialization of HEPLISAV™, if it is approved.

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 current development efforts will be sufficient to support approval of HEPLISAV; or if approved, whether the market for HEPLISAV will be sufficient for us to reach profitability. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales 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, license rights to HEPLISAV or raise additional capital on less than favorable terms.

*If we are unable to generate significant revenues or achieve profitability, we will require substantial additional capital to continue development of our product candidates, and, if our most advanced candidate, HEPLISAV, is approved, to commence sales and marketing activities.*

If we are unable to generate significant revenues from HEPLISAV, if it is approved, and to continue development of our product candidates, we may need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

development, manufacturing and commercialization of our product candidates, particularly HEPLISAV;

various human clinical trials for our product candidates; and

protection of our intellectual property.

We currently estimate that we have sufficient resources to meet our anticipated cash needs through at least the next 12 months based on cash and cash equivalents and marketable securities on hand and anticipated revenues and funding from existing agreements.

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

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

---

## **Table of Contents**

### **Risks Related to our Business**

*The success of our product candidates depends on regulatory approval. The U.S. Food and Drug Administration ( FDA ) or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with good manufacturing practice regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.*

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA and foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approvals for our most advanced product candidates. Approval processes in the United States and in other countries are uncertain, can take many years and require the expenditure of substantial resources.

For our lead product, HEPLISAV, our Biologics License Application ( BLA ) must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA by the FDA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for HEPLISAV for many reasons, including whether the data from our clinical trials, including the Phase 3 results, or the development program is satisfactory to the FDA; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party clinical research organizations; the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with good manufacturing practice regulations are insufficient for regulatory approval.

Failure to receive approval or significant delay in receiving approval of our BLA for HEPLISAV would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our potential partners may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor's manufacturing facilities meet current Good Manufacturing Practice ( GMP ) requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable current GMP regulations. Manufacturers of biologics must also comply with the FDA's general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product.

*The FDA may require more clinical trials for our product candidate than we currently expect before granting regulatory approval, if at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.*

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies. Any extension of our clinical trials could:

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

result in significant additional costs;

potentially diminish any competitive advantages for those products;

potentially limit the markets for those products;

adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;

cause us to abandon the development of the affected product candidate; or

limit our ability to obtain additional financing on acceptable terms, if at all.

---

## **Table of Contents**

***HEPLISAV and most of our earlier stage programs rely on Immunostimulatory Sequences ( ISS )-based technology. Serious adverse event data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.***

HEPLISAV 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 event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain ISS and, if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements. If adverse event 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 have no commercialization experience, and the time and resources to develop sales, marketing and distribution capabilities for HEPLISAV are significant. If we fail to achieve and sustain commercial success for HEPLISAV, either directly or with a partner, our business would be harmed.***

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. HEPLISAV product sales are currently expected to generate a substantial portion of our future revenue, if HEPLISAV is approved. To commercialize HEPLISAV, we must either develop sales, marketing and distribution capabilities or make arrangements with third parties to perform these services, which will require resources and time. If we decide to market HEPLISAV directly, we must commit significant resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities.

In October 2011, the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices ( ACIP ) voted to recommend that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age. This change significantly expands the potential number of persons for whom vaccination is recommended in the U.S. and we believe could significantly expand the revenue potential for HEPLISAV. To successfully market, sell and distribute HEPLISAV to patients with diabetes, we will need to establish a sales and marketing infrastructure and/or establish and maintain distribution arrangements. We may not be able to enter into these arrangements on acceptable terms. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV may significantly impact our ability to achieve commercial success in this potential patient population.

Factors that may inhibit our efforts to commercialize HEPLISAV directly or indirectly with a partner include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to administer our products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

our inability to expand and sustain qualified manufacturing capacity to meet demand, in particular if there is a significant increase in demand due to the recommendation to vaccinate persons with diabetes if we should obtain approval to market to those patients;

our inability to determine appropriate pricing and reimbursement strategies for HEPLISAV in the potential patient populations that may use HEPLISAV, particularly in the diabetes market;

possible claims against us, including enjoining sales of HEPLISAV, based on the patent rights of others; and

unanticipated delays, costs and expenses associated with manufacturing and commercialization of our products, including costs of creating and sustaining an independent sales and marketing organization in various territories.



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

If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing HEPLISAV, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, certain revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control.

---

## **Table of Contents**

*We rely on our facility in Düsseldorf, Germany and third parties to supply materials necessary to manufacture our product candidates. We have limited experience in manufacturing sufficient quantities of ISS for our commercial products and rely on limited third parties to produce the ISS we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.*

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

We currently use 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 that must be performed in compliance with current GMP 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/quality assurance 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. Moreover, if our HEPLISAV clinical trials are sufficient for approval and depending on the level of market acceptance of the product, we likely would not have the capacity in our existing facility to meet all of our commercial supply needs in the future. For example, the recent ACIP recommendation that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age could significantly increase the market demand for HEPLISAV. We believe that our current manufacturing capacity may allow us to supply up to approximately two million doses of HEPLISAV annually, which may not be sufficient to meet demand. Our ability to expand manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. If demand exceeds our current capacity plans, we may experience a shortage in supply of HEPLISAV and our clinical candidates, which could have a material adverse effect on the success of HEPLISAV and our other product candidates. If HEPLISAV is not approved, we would have to consider other alternatives for the facility in Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, time-consuming and difficult.

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

We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. 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/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, 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. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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

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



## **Table of Contents**

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.

*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, including HEPLISAV, in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States 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;

obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;

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

diverse tax consequences;

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

regional and geopolitical risks.

We have submitted HEPLISAV for marketing approval in Europe. 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.

*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, healthcare payors and the medical community.

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

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. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

---

## **Table of Contents**

***We face uncertainty regarding coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product 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 already marketed. 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 uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party 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.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. 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. In Europe, the success of our products, in particular HEPLISAV, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

***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. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our products and could have a material adverse effect on our business and operations.

***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 product candidates 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. Failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product. We also will need to enter into collaborative relationships to provide funding to support our other 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, manufacturing issues, a change in business strategy, a change of control or other reasons;

our shortage of capital resources may impact the willingness of companies to collaborate with us;

our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;

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

our partners may choose to pursue alternative technologies, including those of our competitors;

we may have disputes with a partner that could lead to litigation or arbitration;

we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;

our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;

## **Table of Contents**

we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

our partners may not devote sufficient capital or resources towards our product candidates; and

our partners may not comply with applicable government regulatory requirements.

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

***The financial terms of future collaborative licensing or financing arrangements could result in 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 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 and inflammatory diseases. For example, if it is approved, HEPLISAV will compete in the United States with established hepatitis B vaccines marketed by Merck & Co. ( Merck ) and GlaxoSmithKline ( GSK ) and outside the United States with vaccines from those companies and several additional established pharmaceutical companies. 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.

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. Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified 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 obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

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

As we advance HEPLISAV through the development stage towards commercialization, we will need to expand our organization, including adding marketing and sales capabilities or contracting with third parties to provide these capabilities for us. As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. In addition, we expect to enhance our senior management group as we prepare to become a commercial organization. Our future financial performance and our ability to commercialize HEPLISAV and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our development efforts effectively, and to hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

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



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

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, or our President, Dr. J. Tyler Martin. We currently have no key person insurance on any of our employees. We intend to strengthen our senior management group as we prepare to become a commercial organization, and during the second quarter 2012, our Board of Directors initiated a process for Dr. Dina's succession.

## **Table of Contents**

***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 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 believe 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.

## **Risks Related to our Intellectual Property**

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

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In addition, we must make timely payments or meet diligence obligations 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.

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

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

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of recombinant hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to

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

aspects of production of recombinant hepatitis B surface antigen. While some of these patents have expired or will soon expire outside the United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States while these patents remain in force, Merck, GSK or their respective licensors (The Regents of the University of California, Biogen Idec Inc. and possibly others), or the Institut Pasteur may bring claims against us.

## **Table of Contents**

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, 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 to commercialize one or more of our formulations of ISS 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 United States, 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 United States 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 United States, where we may only be able to obtain limited patent protection.

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

we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;

the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;

we might not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

patents issued to other parties may limit our intellectual property protection or harm our ability to do business;

other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and

other parties may design around technologies we have licensed, patented or developed.

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

## **Table of Contents**

### **Risks Related to an Investment in our Common Stock**

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

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

progress or results of any of our clinical trials or regulatory 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

the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action 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. We may in the future be the target of such litigation. Securities

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

litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

***The anti-takeover provisions of our certificate of incorporation, our bylaws, 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.

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 our 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 (1) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (2) 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.

**Table of Contents**

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

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 30, 2012, we had 178,269,631 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

In addition, we have filed shelf registration statements on Form S-3 under the Securities Act of 1933, as amended, to register securities that we may choose to issue in the future and on Form S-8 to register the shares of our common stock reserved for issuance under our stock option plans.

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

In connection with the exercise of stock options held by an executive officer, the Company received 11,052 shares of Company Common Stock otherwise owned by the executive officer as payment of the exercise price.

**ITEM 5. OTHER INFORMATION**

None.



**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Document</b>
3.1 <sup>(1)</sup>	Sixth Amended and Restated Certificate of Incorporation.
3.2 <sup>(1)</sup>	Amended and Restated Bylaws.
3.3 <sup>(2)</sup>	Form of Certificate of Designation of Series A Junior Participating Preferred Stock.
3.4 <sup>(3)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5 <sup>(4)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2 <sup>(5)</sup>	Registration Rights Agreement.
4.3 <sup>(5)</sup>	Form of Warrant.
4.4 <sup>(6)</sup>	Form of Specimen Common Stock Certificate.
4.5 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC.
4.6 <sup>(2)</sup>	Form of Rights Certificate.
4.7 <sup>(7)</sup>	Form of Restricted Stock Unit Award Agreement.
4.8 <sup>(8)</sup>	Form of Amended Warrant.
4.9 <sup>(9)</sup>	Form of Warrant.
4.10 <sup>(10)</sup>	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
10.69 <sup>(11)</sup> +	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, Amended April 17, 2012.
10.70+	Employment Offer Letter to Christine R. Larson dated August 1, 2012.
10.71+	Consulting Agreement dated as of May 1, 2012, by and between Frank Cano and Dynavax Technologies Corporation.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President and Chief Financial Officer 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 and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000- 50577).



**Table of Contents**

- (2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on November 6, 2008.
- (3) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on January 4, 2010.
- (4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on January 5, 2011.
- (5) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (6) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.
- (7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 6, 2009.
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 16, 2010.
- (9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on April 13, 2010.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on September 20, 2010.
- (11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Quarterly Report on Form 10-Q, as filed with the SEC on August 3, 2012.  
 The certifications attached as Exhibits 32.1 and 32.2 accompanying this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.
- \* Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.
- + Indicates management contract or compensatory plan.

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: November 2, 2012

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

Date: November 2, 2012

By: /s/ CHRISTINE R. LARSON  
Christine R. Larson  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Document</b>
3.1 <sup>(1)</sup>	Sixth Amended and Restated Certificate of Incorporation.
3.2 <sup>(1)</sup>	Amended and Restated Bylaws.
3.3 <sup>(2)</sup>	Form of Certificate of Designation of Series A Junior Participating Preferred Stock.
3.4 <sup>(3)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5 <sup>(4)</sup>	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2 <sup>(5)</sup>	Registration Rights Agreement.
4.3 <sup>(5)</sup>	Form of Warrant.
4.4 <sup>(6)</sup>	Form of Specimen Common Stock Certificate.
4.5 <sup>(2)</sup>	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC.
4.6 <sup>(2)</sup>	Form of Rights Certificate.
4.7 <sup>(7)</sup>	Form of Restricted Stock Unit Award Agreement.
4.8 <sup>(8)</sup>	Form of Amended Warrant.
4.9 <sup>(9)</sup>	Form of Warrant.
4.10 <sup>(10)</sup>	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
10.69 <sup>(11)</sup> +	Amended and Restated 2004 Non-Employee Director Option Program and Amended and Restated 2005 Non-Employee Director Cash Compensation Program, Amended April 17, 2012.
10.70+	Employment Offer Letter to Christine R. Larson dated August 1, 2012.
10.71+	Consulting Agreement dated as of May 1, 2012, by and between Frank Cano and Dynavax Technologies Corporation.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President and Chief Financial Officer 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 and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Amendment No. 4 to Registration Statement on Form S-1/A, as filed with the SEC on February 5, 2004 (Commission File No. 000-50577).

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

- (2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on November 6, 2008.

**Table of Contents**

- (3) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on January 4, 2010.
- (4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on January 5, 2011.
- (5) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.
- (6) Incorporated by reference to Dynavax Technologies Corporation's Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.
- (7) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 6, 2009.
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 16, 2010.
- (9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on April 13, 2010.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Current Report on Form 8-K, as filed with the SEC on September 20, 2010.
- (11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation's Quarterly Report on Form 10-Q, as filed with the SEC on August 3, 2012.  
The certifications attached as Exhibits 32.1 and 32.2 accompanying this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.
- \* Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.
- + Indicates management contract or compensatory plan.