

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

April 30, 2009

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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2009

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 001-34207

**Dynavax Technologies Corporation**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of*

*incorporation or organization)*

**33-0728374**  
*(IRS Employer*

*Identification No.)*

**2929 Seventh Street, Suite 100**

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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 April 28, 2009, the registrant had outstanding 39,992,469 shares of common stock.

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<i>This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners.</i>	

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**FORWARD-LOOKING STATEMENTS**

*This Quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. Our forward-looking statements include discussions regarding our business and financing strategies, future research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development of our products, uncertainty regarding our future operating results and prospects for profitability. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in Item 1A Risk Factors and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.*

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

	<b>March 31, 2009 (unaudited)</b>	<b>December 31, 2008 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,920	\$ 28,103
Marketable securities	13,783	15,264
Investments held by Symphony Dynamo, Inc. (SDI)	23,788	25,109
Restricted cash	651	668
Accounts receivable	2,978	6,407
Prepaid expenses and other current assets	1,098	991
<b>Total current assets</b>	<b>65,218</b>	<b>76,542</b>
Property and equipment, net	8,600	9,510
Goodwill	2,312	2,312
Other intangible assets, net	2,014	2,259
<b>Total assets</b>	<b>\$ 78,144</b>	<b>\$ 90,623</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,088	\$ 905
Accrued liabilities	6,878	6,816
Deferred revenues	16,154	33,133
<b>Total current liabilities</b>	<b>24,120</b>	<b>40,854</b>
Deferred revenues, noncurrent	18,543	18,512
Liability from program option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	117	101
Commitments and contingencies		
Dynavax stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at March 31, 2009 and December 31, 2008		
Common stock: \$0.001 par value; 100,000 shares authorized at March 31, 2009 and December 31, 2008; 39,922 and 39,854 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively		
Additional paid-in capital	263,135	262,579
Accumulated other comprehensive income (loss):		
Unrealized gain on marketable securities available-for-sale	17	49
Cumulative translation adjustment	(811)	(403)
<b>Accumulated other comprehensive income (loss)</b>	<b>(794)</b>	<b>(354)</b>
<b>Accumulated deficit</b>	<b>(243,642)</b>	<b>(248,743)</b>

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Total Dynavax stockholders' equity	18,739	13,522
Noncontrolling interest in SDI	1,625	2,634
Total stockholders' equity	20,364	16,156
Total liabilities and stockholders' equity	\$ 78,144	\$ 90,623

See accompanying notes.

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

(In thousands, except per share amounts)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>		
Collaboration revenue	\$ 17,692	\$ 5,774
Grant revenue	1,139	324
Service and license revenue	513	216
<b>Total revenues</b>	<b>19,344</b>	<b>6,314</b>
<b>Operating expenses:</b>		
Research and development	10,332	15,120
General and administrative	4,424	4,571
Amortization of intangible assets	245	245
<b>Total operating expenses</b>	<b>15,001</b>	<b>19,936</b>
<b>Income (loss) from operations</b>	<b>4,343</b>	<b>(13,622)</b>
Interest income	110	709
Interest expense	(15)	(1,344)
Other income (expense)	(346)	262
<b>Net income (loss)</b>	<b>4,092</b>	<b>(13,995)</b>
Add: Losses attributable to noncontrolling interest in SDI	1,009	1,566
<b>Net income (loss) attributable to Dynavax</b>	<b>\$ 5,101</b>	<b>\$ (12,429)</b>
<b>Basic and diluted net income (loss) per share attributable to Dynavax common stockholders</b>	<b>\$ 0.13</b>	<b>\$ (0.31)</b>
<b>Shares used to compute basic and diluted net income (loss) per share attributable to Dynavax common stockholders</b>	<b>39,889</b>	<b>39,785</b>

*See accompanying notes.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating activities</b>		
Net income (loss) attributable to Dynavax	\$ 5,101	\$ (12,429)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	470	438
Amount attributed to noncontrolling interest in SDI	(1,009)	(1,566)
Amortization of intangible assets	245	245
Accretion and amortization on marketable securities	(30)	(331)
Interest associated with Deerfield financing agreement		1,323
Stock-based compensation expense	519	661
Changes in operating assets and liabilities:		
Accounts receivable	3,429	1,094
Prepaid expenses and other current assets	(107)	844
Restricted cash and other assets	17	(80)
Accounts payable	183	(1,654)
Accrued liabilities and other long term liabilities	83	(2,234)
Deferred revenues	(16,948)	(576)
<b>Net cash used in operating activities</b>	<b>(8,047)</b>	<b>(14,265)</b>
<b>Investing activities</b>		
Change in investments held by SDI	1,321	2,156
Purchases of marketable securities	(12,271)	(5,926)
Proceeds from maturities of marketable securities	13,750	16,750
Proceeds from sales of marketable securities		4,047
Purchases of property and equipment, net	435	(3,398)
<b>Net cash provided by investing activities</b>	<b>3,235</b>	<b>13,629</b>
<b>Financing activities</b>		
Proceeds from notes payable issued to Deerfield		2,000
Proceeds from employee stock purchase plan	37	136
Proceeds from exercise of stock options		5
<b>Net cash provided by financing activities</b>	<b>37</b>	<b>2,141</b>
Effect of exchange rate on cash and cash equivalents	(408)	60
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(5,183)</b>	<b>1,565</b>
Cash and cash equivalents at beginning of period	28,103	14,293
<b>Cash and cash equivalents at end of period</b>	<b>\$ 22,920</b>	<b>\$ 15,858</b>



**Supplemental disclosure of cash flow information**

Disposal of fully depreciated property and equipment	\$	792	\$
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*See accompanying notes.*

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**Dynavax Technologies Corporation**  
**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

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

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) product candidates. Based on our proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. We have partnerships with leading pharmaceutical companies such as GlaxoSmithKline (GSK), AstraZeneca, and Novartis Vaccines and Diagnostics, Inc. (Novartis), as well as funding from Symphony Dynamo, Inc. (SDI) and the National Institutes of Health (NIH). We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

**Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2008 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission, or SEC.

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiary, Rhein Biotech GmbH (Rhein or Dynavax Europe), as well as the accounts of a variable interest entity, Symphony Dynamo, Inc. (SDI), which we consolidate pursuant to Financial Accounting Standards Board Interpretation No. 46 (revised 2003), Consolidation of Variable Interest Entities, or FIN 46R. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

**Use of Estimates**

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

**Significant Accounting Policies**

The Company believes that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2009 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2008, except as discussed below with regards to the Company's adoption of Statement of Financial Accounting Standards 160, Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51 (SFAS 160) effective January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. We adopted SFAS 160 as January 1, 2009 and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI has been reclassified to equity.

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Consolidated net income or loss has been adjusted to include the net income or loss attributed to the noncontrolling interest in SDI.

Consolidated comprehensive income or loss has been adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

The Company must disclose for each reporting period the amounts of consolidated income or loss attributed to the Company and the noncontrolling interest in SDI. In addition, for each reporting period the Company must present a reconciliation at the beginning and end of the period of the carrying amount of total equity and equity attributable to the Company and the noncontrolling interest in SDI.

### **Recent Accounting Pronouncements**

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1 (EITF 07-1), *Accounting for Collaboration Agreements* which required certain income statement presentation of transactions with third parties and of payments between parties to the collaboration arrangement, along with disclosure about the nature of the arrangement. We adopted EITF 07-1 and our adoption did not have a material effect on our consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development (IPR&D) to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

In February 2008, the FASB issued FASB Staff Position No. (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore effective January 1, 2009, we implemented Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157, for our nonfinancial assets and liabilities that are remeasured at fair value on a non-recurring basis. The adoption of SFAS 157 for our nonfinancial assets and liabilities that are remeasured at fair value on a non-recurring basis did not impact our financial position or results of operations.

### **2. Fair Value Measurements**

SFAS 157 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 SFAS 157 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 SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 - Quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

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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.

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In accordance with SFAS 157, the following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and investments held by SDI measured at fair value on a recurring basis as of March 31, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 35,216	\$	\$	\$ 35,216
U.S. Government agency securities		6,286		6,286
Guaranteed corporate debt securities		13,745		13,745
Total	\$ 35,216	\$ 20,031	\$	\$ 55,247

**3. Intangible Assets**

Intangible assets consist primarily of the manufacturing process and customer relationships. The manufacturing process derives from the methods for making proteins in *Hansenula* yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at March 31, 2009 (in thousands, except years):

	Original Estimated	Gross	Accumulated Amortization	Net
	Useful Life (in Years)			
Manufacturing process	5	\$ 3,670	\$ (2,161)	\$ 1,509
Customer relationships	5	1,230	(725)	505
Total	5	\$ 4,900	\$ (2,886)	\$ 2,014

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

Year ending December 31,	
2009 (remaining nine months)	\$ 735
2010	980
2011	299
Total	\$ 2,014

**4. Symphony Dynamo, Inc.**

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP and certain of its affiliates (Symphony) to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development (Development Programs). The material agreements included:

the Amended and Restated Limited Liability Corporation Agreement of Symphony Dynamo Holdings LLC (LLC Agreement);

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the Funding Agreement by and among Dynavax Technologies Corporation, Symphony Capital Partners LP, Symphony Dynamo Holdings LLC, and Symphony Dynamo Investors LLC (Funding Agreement);

the Amended and Restated Research and Development Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (R&D Agreement);

the Novated and Restated Technology License Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (License Agreement);

the Purchase Option Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (Purchase Option Agreement);

the Registration Rights Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Registration Rights Agreement); and

the Warrant Purchase Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (Warrant Agreement).

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The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC (Holdings) and its wholly-owned subsidiary, Symphony Dynamo, Inc. (SDI). Pursuant to the Funding Agreement, Symphony invested \$50 million in Holdings (\$20 million at closing and an additional \$30 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock, which Holdings distributed to Symphony, at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share if either of two events occurs: (a) we enter into a collaboration agreement with a third party for a specified oncology program; or (b) the Purchase Option is terminated or expires unexercised. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant, issued upon closing, was assigned a value of \$5.6 million using the Black-Scholes valuation model and was recorded in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option (Purchase Option) to acquire the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices that range from \$89.4 million as of March 31, 2009, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The intellectual property rights to the remaining cancer and hepatitis C therapy programs, if not purchased through the exercise of the Purchase Option, will remain with SDI.

We have determined, pursuant to the guidance in FIN 46R, that SDI is a variable interest entity and we are its primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006.

At March 31, 2009, the investments held by SDI were \$23.8 million. The investments held by SDI in the consolidated balance sheet include the aggregate \$50 million of funding, less funds spent on the Development Programs as of the end of each reporting period.

At March 31, 2009, the noncontrolling interest balance was \$1.6 million. The noncontrolling interest in SDI in the consolidated balance sheet represents Symphony's equity investment in SDI of \$50 million, reduced by the \$5.6 million fair value of the warrants we issued and \$2.6 million of fees we paid to Symphony upon the transaction's closing, and the losses attributed to the noncontrolling interest since its inception in April 2006. The noncontrolling interest was further reduced when we recorded the \$15 million liability upon our exercise of the Program Option in April 2007, as that amount will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option.

Net losses incurred by SDI and charged to the noncontrolling interest were \$1.0 million and \$1.6 million for the three months ended March 31, 2009 and 2008, respectively. In accordance with FAS 160, we have attributed net income or loss to Dynavax and the noncontrolling interest in SDI in our consolidated statements of operations.

**5. Financing Agreement**

On August 26, 2008, Dynavax and Deerfield Management, a healthcare investment fund, and its affiliates (Deerfield) entered into a Settlement Agreement and Mutual General Release (Settlement Agreement) under which the parties agreed to terminate the Loan Agreement dated July 18, 2007 (Loan Agreement) and also to provide for an amendment of the warrants previously issued to Deerfield pursuant to the Loan Agreement. The Settlement Agreement terminated any further obligations under the Loan Agreement.

Under the Loan Agreement, Deerfield agreed to advance to Dynavax loans that could be drawn down over a three-year period in



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the aggregate principal amount of up to \$30 million, subject to achievement of specific milestones in relation to the development of certain products in Dynavax's allergy franchise. Repayment of a portion of the loans to Deerfield was contingent upon the positive outcome of studies related to TOLAMBA, Dynavax's product candidate for the treatment of ragweed allergy. If the TOLAMBA program was discontinued, Dynavax would have had no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal was slated to be due in July 2010. Deerfield received an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the VWAP in the 15-day period prior to achievement of certain milestones.

Under the Loan Agreement, through August 26, 2008 (date of termination), we had received \$7.5 million in cash from Deerfield, which was recorded as a long-term liability in our consolidated balance sheet. Additionally, we paid and recognized as interest expense \$1.7 million of commitment fees and, we issued to Deerfield warrants to purchase up to 3,550,000 shares of our common stock. The warrants were valued on the issuance date using the Black-Scholes valuation model. The original warrants issued and their related assumptions under the Black-Scholes option valuation model are as follows (in thousands, except for Black-Scholes Assumptions):

Warrant Issuance Date	Shares Issued	Black-Scholes Assumptions			Exercise Price per Share	Assigned Value using Black-Scholes
		Risk-Free Interest Rate	Expected Life (in years)	Volatility		
July 18, 2007	1,250	4.9%	5.5	0.7	\$ 5.13	\$ 3,350
October 18, 2007	1,300	4.2%	5.5	0.7	\$ 5.75	3,700
December 27, 2007	1,000	3.6%	5.5	0.7	\$ 5.65	2,746
Total	3,550					\$ 9,796

At the date of each issuance, the warrant valuation was recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost was amortized on a straight-line basis and recognized as interest expense through the termination of the Loan Agreement. We amortized \$0 and \$0.9 million of deferred transaction cost in interest expense for the three months ended March 31, 2009 and 2008, respectively.

Under the Settlement Agreement, \$5.0 million of funds received for the TOLAMBA program were forgiven, resulting in loan forgiveness in the statement of operations and a reduction in long-term liabilities as of and for the fiscal year ended December 31, 2008. All commitment fees paid to date, which totaled \$1.7 million, were applied to the loan, resulting in a reduction in interest expense and long-term liabilities as of and for the fiscal ended December 31, 2008. We paid the remaining loan balance of \$0.8 million in cash to Deerfield. In addition, the warrants previously issued to Deerfield were amended as follows:

Warrant Issuance Date	Shares Issued (in thousands)	Expiration Date	Exercise Price per Share
July 18, 2007	1,250	2/26/2014	\$ 5.13
October 18, 2007	1,300	2/26/2014	\$ 1.68
December 27, 2007	300	2/26/2014	\$ 5.65
December 27, 2007	700	2/26/2014	\$ 5.65 <sup>(1)</sup>
Total	3,550		

- (1) The warrants to purchase an aggregate of 700,000 shares of our common stock issued on December 27, 2007 were amended to provide for a termination date of February 26, 2014 at the existing exercise price of \$5.65 and if Dynavax's average daily volume weighted average price (VWAP) over the 15 trading days prior to August 26, 2009 is below \$4.00 per share then such warrants will be amended to provide an exercise price equal to the VWAP over the 15 trading days prior to August 26, 2009.

The amendments to the warrants resulted in a re-measurement of the fair value based on the amended terms and current period assumptions and were accounted for as modifications to equity awards under the provisions of SFAS 123R, Share-Based Payment. We recorded interest expense

and an increase of additional paid in capital of \$0.9 million for the fiscal year ended December 31, 2008 due to these modifications.

**6. Commitments and Contingencies**

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under

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operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated in February 2011 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of March 31, 2009 and December 31, 2008. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2014. Total net rent expense related to our operating leases for the years ended March 31, 2009 and 2008, was \$0.6 million and \$0.6 million, respectively. Deferred rent was \$0.8 million as of March 31, 2009.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$58 thousand in 2009 and \$40 thousand in 2010. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at March 31, 2009, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2009 (remaining nine months)	\$ 1,877
2010	2,551
2011	2,609
2012	2,668
2013	2,714
Thereafter	6,526
<b>Total</b>	<b>\$ 18,945</b>

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of March 31, 2009 and December 31, 2008. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of March 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of March 31, 2009.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of March 31, 2009, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$8.2 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Under the terms of our license agreements, we could be expected to pay approximately \$1.3 million in 2009 related to such fees and milestone payments to the Regents.



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**7. Collaborative Research and Development Agreements**

**GlaxoSmithKline**

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop, and commercialize TLR inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We received an initial payment of \$10 million and agreed to conduct research and early clinical development in up to four programs and are eligible to receive future potential development and commercialization milestones totaling approximately \$200 million per program. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one product. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. For the three months ended March 31, 2009, we recognized revenue of \$0.4 million related to the initial payment.

**AstraZeneca**

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration. We received an upfront payment of \$10 million, and are eligible to receive research funding, preclinical milestone payments, and potential future development milestones of up to \$126 million. Upon commercialization, we are also eligible to receive royalties based on product sales.

In September 2008, we received a \$4.5 million milestone payment from AstraZeneca for the nomination of the first candidate drug, AZD1419. We are currently working on a second candidate drug, and in February 2009, we extended our research collaboration with AstraZeneca through July 2010 to provide funding for a third candidate drug. Revenue from milestones received during the development plan is deferred and recognized ratably over estimated performance period of the collaboration agreement. For the three months ended March 31, 2009, we recognized revenue of \$0.6 million related to the milestone for the nomination of AZD1419. Collaboration revenue resulting from the performance of research services amounted to \$1.0 million and \$0.7 million for the three months ended March 31, 2009 and 2008, respectively. As of March 31, 2009, we had recorded cumulative deferred revenue of \$11.9 million associated with the milestone for the nomination of a candidate drug, upfront fee and amounts billed in advance for research services per the contract terms.

**National Institutes of Health and Other Funding**

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

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

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the second quarter of 2009. In August 2007, we were awarded a two-year \$3.3 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with these grants is recognized as the related expenses are incurred. For the three months ended March 31, 2009 and 2008, we recognized revenue of approximately \$0.5 million and \$0.3 million, respectively.

**Table of Contents****Merck & Co., Inc.**

In October 2007, we entered into a global license and development collaboration agreement and a related manufacturing agreement with Merck to jointly develop HEPLISAV, a novel investigational hepatitis B vaccine. Under the terms of the agreement, Merck received worldwide exclusive rights to HEPLISAV, and agreed to fund future vaccine development and be responsible for commercialization. We received a non-refundable upfront payment of \$31.5 million. Revenue from the initial payment was deferred and recognized ratably over the estimated performance period of the collaboration agreement.

On December 18, 2008, Merck provided notice of its termination of the collaboration. As a result of the termination, all development, manufacturing and commercialization rights to HEPLISAV reverted to Dynavax. Merck is obligated to make payments to Dynavax for the 180-day wind down period following Merck's written notice of termination. As a result of Merck's termination, we accelerated the applicable performance period over which we ratably recognize revenue from the upfront fee through the effective date of the termination, which is June 2009. For the three months ended March 31, 2009 and 2008, we recognized revenue of \$15.5 million and \$0.7 million, respectively, related to the upfront fee. Collaboration revenue resulting from the performance of research and development services are recognized as related research and development costs are incurred. Cost reimbursement revenue under this collaboration agreement totaled \$0.3 million and \$4.3 million for the three months ended March 31, 2009 and 2008, respectively.

**8. Net Income (Loss) Per Share**

Basic net income (loss) per share is calculated by dividing the Net income (loss) attributable to Dynavax by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the Net income (loss) attributable to Dynavax by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive. Outstanding warrants and stock options to purchase 11.6 million and 10.7 million shares of common stock as of March 31, 2009 and 2008, respectively, were excluded from the calculation of diluted net income (loss) per share because the effect would have been anti-dilutive.

The following is a reconciliation of the numerator and denominator used in the basic and diluted net income (loss) per share computations (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Numerator:		
Net income (loss) attributable to Dynavax	\$ 5,101	\$ (12,429)
Denominator:		
Weighted-average common shares outstanding used for basic and diluted net income (loss) per share	39,889	39,785

**9. Comprehensive Income (Loss)**

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net income (loss) attributable to Dynavax	\$ 5,101	\$ (12,429)
Increase (decrease) in unrealized gain on marketable securities available-for-sale	(32)	44
Increase (decrease) in cumulative translation adjustment	(408)	60

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Comprehensive income (loss) attributable to Dynavax	\$ 4,661	\$ (12,325)
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### 10. Stockholders Equity

As of March 31, 2009, we have two share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan. The 1997 Equity Incentive Plan, or 1997 Plan, expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

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

	Employee Stock Options		Employee Stock Purchase Plan	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2009	2008	2009	2008
Weighted-average fair value	\$ 0.49	\$ 3.34	\$ 0.46	\$ 2.15
Risk-free interest rate	1.7%	2.8%	0.8%	2.0%
Expected life (in years)	4.0	4.7	1.3	1.3
Volatility	1.6	0.7	1.6	0.7
Expected dividends				

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

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

	Three Months Ended March 31,	
	2009	2008
Employee and director stock-based compensation expense	\$ 522	\$ 643
Other stock-based compensation expense	(3)	18
<b>Total</b>	<b>\$ 519</b>	<b>\$ 661</b>

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 15%. As of March 31, 2009 the total unrecognized compensation cost related to non-vested options granted amounted to \$5.5 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.8 years.

Activity under the stock option plans was as follows:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average
			Exercise Price Per Share
Balance at December 31, 2008	660,653	5,172,976	\$ 4.79
Options authorized	400,000		
Options granted	(1,059,400)	1,059,400	\$ 0.56
Options exercised			
1997 Plan shares exercised			
Options cancelled:			
Options forfeited (unvested)	56,693	(56,693)	\$ 3.83
Options expired (vested)	171,084	(171,084)	\$ 5.96
1997 Plan options expired			



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Balance at March 31, 2009	229,030	6,004,599	\$	4.02
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The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of March 31, 2009:

	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)	5,216,060	\$ 4.21	7.4	\$ 62,450
Options exercisable	2,744,452	\$ 5.16	6.1	\$

**Employee Stock Purchase Plan**

As of March 31, 2009, 496,000 shares were reserved and approved for issuance under the Employee Stock Purchase Plan (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 acquired 262,072 shares of our common stock under the Purchase Plan. At March 31, 2009, 233,928 shares of our common stock remained available for future purchases.

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### **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.*

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

#### **Overview**

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) product candidates. Based on our proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. We have partnerships with leading pharmaceutical companies such as GlaxoSmithKline (GSK), AstraZeneca, and Novartis Vaccines and Diagnostics, Inc. (Novartis) as well as funding from Symphony Dynamo, Inc. (SDI) and the National Institutes of Health (NIH).

Our diversified pipeline of product candidates includes:

HEPLISAV™, a Phase 3 hepatitis B vaccine;

SD-101, a Phase 1b hepatitis C therapy developed under our SDI funding agreement;

DV-601, a Phase 1b proprietary hepatitis B therapy;

Our Universal Flu vaccine, a preclinical vaccine under a supply and option agreement with Novartis;

AZD1419, a preclinical asthma therapy partnered with AstraZeneca; and

DV1079, a preclinical autoimmune and inflammatory disease therapy partnered with GSK

Our objective is to build a product-based business with a portfolio of products focused on serious unmet medical needs. Our diversified pipeline includes TLR agonists and inhibitors and targets infectious, respiratory, autoimmune, and inflammatory diseases. We discover novel TLR product candidates based on our proprietary technologies, including immunostimulatory sequences (ISS) and immunoregulatory sequences (IRS), which are short DNA sequences. ISS enhance the ability of the immune system to fight disease and control chronic inflammation by specifically targeting TLRs found on a specialized subset of immune cells to alter the innate immune response. IRS specifically inhibit TLRs associated with autoimmune and inflammatory diseases.

Our strategies are focused on discovering novel compounds based on our proprietary technologies and developing our diversified pipeline of product candidates through partnerships with leading pharmaceutical companies or funding agreements. For our partnered products, we seek to leverage the experience and resources of our pharmaceutical partners to further the development and potentially commercialize these product candidates. For our other proprietary product candidates, we are developing these to evaluate the clinical potential with a goal of commercializing these products ourselves or through pharmaceutical partnerships.

#### **Recent Developments**

***HEPLISAV***

Our lead product candidate is HEPLISAV, a Phase 3 hepatitis B vaccine that has shown clinical benefits in our trials. Our 9 clinical trials conducted over the past 10 years have included approximately 2,500 individuals vaccinated with HEPLISAV. In August 2008, HEPLISAV met its primary endpoint in the largest clinical trial conducted to date, a Phase 3 trial known as PHAST (Phase 3 HeplisAv Short-regimen Trial).

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HEPLISAV is based on our proprietary ISS that specifically target TLR9 to stimulate an innate immune response. This vaccine combines our first generation 1018 ISS with hepatitis B surface antigen (HBsAg) manufactured in our Dynavax Europe facility in Düsseldorf, Germany. HEPLISAV is aimed at unmet needs in the vaccination of adults and end-stage renal disease (ESRD) patients by providing an increased response with fewer doses in a shorter period of time.

Clinical development was suspended in March 2008, when the U.S. Food and Drug Administration (FDA) placed a clinical hold on the two HEPLISAV Investigational New Drug (IND) Applications, one for healthy adults and one for ESRD patients. The FDA requested a review of the clinical and preclinical safety data related to HEPLISAV, including all available information about a single case of Wegener's granulomatosis, an uncommon form of vasculitis. In October 2008 and February 2009, the FDA requested additional information which the agency indicated may be helpful in its risk assessment of the two INDs and may assist in finding a development path forward for HEPLISAV for healthy adults and ESRD patients. We continue our dialogue with the FDA to determine the development path, if any, that may be practicable for removing the clinical hold in these two indications. We are currently unable to assess whether future development in these indications is possible and practicable or of potential commercial value to us. In any event, we would require significant additional capital and/or a commercial partner to successfully complete development and commercialization of HEPLISAV and accordingly, there can be no assurance that we would further develop HEPLISAV.

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

The Company believes that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2009 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2008, except as discussed below with regards to the Company's adoption of Statement of Financial Accounting Standards 160, Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51 (SFAS 160) effective January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. We adopted SFAS 160 as of January 1, 2009 and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI has been reclassified to equity.

Consolidated net income or loss has been adjusted to include the net income or loss attributed to the noncontrolling interest in SDI.

Consolidated comprehensive income or loss has been adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

The Company must disclose for each reporting period the amounts of consolidated income or loss attributed to the Company and the noncontrolling interest in SDI. In addition, for each reporting period the Company must present a reconciliation at the beginning and end of the period of the carrying amount of total equity and equity attributable to the Company and the noncontrolling interest in SDI.

### **Results of Operations**

#### *Revenues*

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



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

Revenues:	Three Months Ended March 31,		Increase From 2008 to 2009	
	2009	2008	\$	%
Collaboration revenue	\$ 17,692	\$ 5,774	\$ 11,918	206%
Grant revenue	1,139	324	815	252%
Services and license revenue	513	216	297	138%
Total revenues	\$ 19,344	\$ 6,314	\$ 13,030	206%

Total revenues for the quarter ended March 31, 2009 increased by \$13.0 million, or 206%, over the same period in 2008 primarily due to an increase in revenue recognized from our collaboration arrangement with Merck. Collaboration revenue in 2009 includes recognition of \$15.5 million of previously deferred revenue associated with the upfront payment from Merck, which was accelerated due to Merck's termination of the collaboration agreement in December 2008. Grant revenue increased by \$0.8 million, or 252%, over the same period in 2008 due primarily to revenues earned from the NIH contract we were awarded in September 2008. Services and license revenue of \$0.5 million was derived primarily from R&D services provided to customers of Dynavax Europe.

We anticipate that our revenues will increase in 2009 as compared to 2008. As a result of Merck's termination of the collaboration, we expect to recognize in fiscal 2009 approximately \$28.5 million of deferred revenue associated with the upfront payment from Merck on a ratable basis through the effective date of the termination, which is June 2009. In addition, Merck is obligated to make payments to us for the 180-day wind down period through June 2009.

*Research and Development*

Research and development expense consists of compensation and related personnel costs which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates, and cost of sales relating to service and license revenue.

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

Research and development:	Three Months Ended March 31,		Increase (Decrease) from 2008 to 2009	
	2009	2008	\$	%
Compensation and related personnel costs	\$ 4,134	\$ 5,367	(1,233)	(23)%
Outside services	4,438	8,036	(3,598)	(45)%
Facility costs	1,741	1,537	204	13%
Non-cash stock-based compensation	19	180	(161)	(89)%
Total research and development	\$ 10,332	\$ 15,120	\$ (4,788)	(32)%

Research and development expense for the three months ended March 31, 2009 decreased by \$4.8 million, or 32%, compared to the same period in 2008. The decrease in outside services is primarily due to a reduction in clinical development costs associated with HEPLISAV and the discontinuation of development for the TOLAMBA ragweed allergy program in May 2008. The decrease in compensation and related personnel costs is primarily due to the decline in employee headcount to support the organization.

We anticipate that our research and development expense in fiscal 2009 will remain consistent with 2008, if HEPLISAV development resumes.

*General and Administrative*

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



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

	Three Months Ended		Increase (Decrease)	
	March 31,		from 2008 to 2009	
	2009	2008	\$	%
<b>General and administrative:</b>				
Compensation and related personnel costs	\$ 1,748	\$ 2,044	(296)	(14)%
Outside services	1,124	1,383	(259)	(19)%
Legal costs	823	359	464	129%
Facility costs	235	310	(75)	(24)%
Non-cash stock-based compensation	494	475	19	4%
<b>Total general and administrative</b>	<b>\$ 4,424</b>	<b>\$ 4,571</b>	<b>\$ (147)</b>	<b>(3)%</b>

General and administrative expense for the three months ended March 31, 2009 decreased by \$0.1 million, or 3%, compared to the same period in 2008. The decrease in compensation and related personnel costs and outside services is due to an overall decline in the number of administrative employees, consulting fees and other professional fees incurred in conjunction with various corporate activities. These reductions were offset by increases in legal costs related to patent activities.

We expect general and administrative expense to decline in 2009 as compared to 2008, resulting from continued efforts to reduce outside service costs.

*Amortization of Intangible Assets*

Intangible assets consist primarily of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was \$0.2 million for both the three months ended March 31, 2009 and 2008.

*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 income was \$0.1 million and \$0.7 million for the three months ended March 31, 2009 and 2008, respectively. Interest income decreased by \$0.6 million, or 84%, compared to the same period in 2008 due to lower investment balances and the decline in returns on our investment portfolio resulting from current market conditions.

Interest expense includes amortization of deferred transaction costs and commitment fees related to the Deerfield financing agreement and miscellaneous banking fees. Interest expense was \$15 thousand and \$1.3 million for the three months ended March 31, 2009 and 2008, respectively. Interest expense decreased by \$1.3 million, or 99%, compared to the same period in 2008 due to interest expense incurred from the commitment fees and warrants issued under the Deerfield financing agreement, which was terminated in August 2008.

Other income (expense) includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. We reported \$0.3 million of other expense and \$0.3 million of other income for the three months ended March 31, 2009 and 2008, respectively. The variance year over year resulted from the affect of Euro to U.S. Dollar exchange rates.

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

Pursuant to the agreements that we entered into with SDI in April 2006, and in accordance with FAS 160, we have attributed net income or loss to Dynavax and the noncontrolling interest in SDI in our consolidated statements of operations. For the three months ended March 31, 2009 and 2008, the losses attributed to the noncontrolling interest were \$1.0 million and \$1.6 million, respectively.

**Recent Accounting Pronouncements**

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1 (EITF 07-1), Accounting for Collaboration Agreements which required certain income statement presentation of transactions with third parties and of payments between

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parties to the collaboration arrangement, along with disclosure about the nature of the arrangement. We adopted EITF 07-1 and our adoption did not have a material effect on our consolidated results of operations and financial condition.

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In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development (IPR&D) to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

In February 2008, the FASB issued FASB Staff Position No. (FSP) FAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore effective January 1, 2009, we implemented Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157, for our nonfinancial assets and liabilities that are remeasured at fair value on a non-recurring basis. The adoption of SFAS 157 for our nonfinancial assets and liabilities that are remeasured at fair value on a non-recurring basis did not impact our financial position or results of operations.

## **Liquidity and Capital Resources**

As of March 31, 2009, we had \$60.5 million in cash, cash equivalents and marketable securities and investments held by SDI. Our funds are currently invested in a variety of securities, including institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

Cash used in operating activities was \$8.0 million during the three months ended March 31, 2009 compared to \$14.3 million for the same period in 2008. The decrease in cash usage compared to the prior year was due primarily to our net income as compared to our net loss for the same period in 2008.

Cash provided by investing activities was \$3.2 million during the three months ended March 31, 2009 compared to \$13.6 million for the same period in 2008. The decrease was attributed to the decline in proceeds from sales and maturities of marketable securities, net of purchases.

Cash provided by financing activities was \$37 thousand during the three months ended March 31, 2009 compared to \$2.1 million for the same period in 2008. The decrease was primarily attributed to the termination of the Deerfield financing agreement.

We currently anticipate that our cash and marketable securities, collaboration agreements, and investments held by SDI will enable us to maintain our operations for at least the next twelve months. Because of the significant time it will take for any of our product candidates to complete clinical trials, achieve regulatory approval and generate significant revenue, we will require substantial additional capital resources. We may raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations.

Additional financing may not be available on acceptable terms, if at all and therefore may adversely affect our ability to operate as a going concern. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, fail to meet the diligence obligations under existing licenses or enter into collaborative agreements at an earlier stage of development on less favorable terms than we would otherwise choose.

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The following summarizes our significant contractual obligations as of March 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>More than 5 years</b>
Future minimum payments under our operating lease, excluding payments from the sublease agreement	\$ 18,945	\$ 1,877	\$ 7,828	\$ 4,687	\$ 4,553
Long-term liability from the program option exercised under the SDI collaboration	15,000		15,000		
<b>Total</b>	<b>\$ 33,945</b>	<b>\$ 1,877</b>	<b>\$ 22,828</b>	<b>\$ 4,687</b>	<b>\$ 4,553</b>

We lease our facilities in Berkeley, California (Berkeley Lease) and Düsseldorf, Germany (Düsseldorf Lease) under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$58 thousand in 2009 and \$40 thousand in 2010. The sublease rental income is offset against rent expense.

In April 2007, we exercised an option to repurchase our hepatitis B program from SDI. The exercise of the program option triggered a payment obligation of \$15 million which will be due upon the expiration of the SDI collaboration in 2011, if the purchase option for all programs is not exercised. The price for the program option is payable in cash only and will be fully creditable against the exercise price for any exercise of the purchase option.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of March 31, 2009 and December 31, 2008. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of March 31, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of March 31, 2009.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of March 31, 2009, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$8.2 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. As of March 31, 2009, such fees and milestone payments to the Regents could approximate \$1.3 million in 2009.

**Off-balance Sheet Arrangements**

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

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

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

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents 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 U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of March 31, 2009 was \$0.8 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

**(b) Changes in internal controls**

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

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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations. We do not believe any of the current claims or allegations are material to our current business or operations.

**ITEM 1A. RISK FACTORS**

*Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future products, timing of development activities, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.*

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$243.6 million as of March 31, 2009. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. Our current grants are scheduled to terminate in 2010, although we were awarded a five-year government contract totaling \$17 million in September 2008. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate revenue. The clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect and we continue our dialogue with the FDA to determine the development path, if any, that may be practicable for removing the clinical hold. Clinical trials for certain of our other product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

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

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

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

**If we are unable to secure additional funding, we will have to reduce or discontinue operations.**

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding in the current financing environment may not allow us to continue operations as currently planned. We may be unable to obtain additional capital on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations. For example, if we are permitted to further develop HEPLISAV following our current discussions with the FDA, we would require significant additional capital and/or a commercial partner to successfully complete development and commercialization of HEPLISAV and accordingly, there can be no assurance that we would further develop HEPLISAV.





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

None of our product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced product candidates. The clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources, and with respect to HEPLISAV, there can be no assurance that the removal of the clinical hold in one or both of the indications would be permitted or if permitted, that HEPLISAV could be developed, financed or commercialized in a timely manner or without significant additional studies and difficulties or delays in development.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. For example, in October 2008 the FDA communicated that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children, but advised us that there may be an acceptable risk versus potential benefit profile for ESRD patients. In February 2009, the FDA requested additional clinical and safety information which the agency indicated may be helpful in its risk assessment of the two INDs and may assist in finding a development path forward for HEPLISAV, not only in ESRD patients but also in healthy adults. There can be no assurance as to whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies or patient data. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations.

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

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

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA. Any extension, suspension, termination or unanticipated delays of our clinical trials could:

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

result in significant additional costs;

potentially diminish any competitive advantages for those products;

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

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

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



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

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

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, we or our contract manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

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

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

Our most advanced product candidate in clinical trials is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay or discontinue all of our clinical trials. For example, since March 2008, HEPLISAV has been and remains on clinical hold following a SAE that occurred in the PHAST clinical trial. As most of our clinical product candidates contain ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

### **We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.**

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

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

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

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The clinical hold on



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the two U.S. IND Applications for HEPLISAV has remained in effect since March 2008. There can be no assurance as to whether HEPLISAV can be further developed. Moreover, if HEPLISAV can not be successfully developed, we will have to re-purpose our Düsseldorf facility toward alternative manufacturing or research activities that may not fully utilize the facility's capacity, resulting in continued operating costs that may not be offset by corresponding revenues.

**We 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 or terminated. Any extension, delay or termination of our clinical trials would delay our ability to commercialize our products and could have a material adverse effect on our business and operations.

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

Even if we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community. 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 successfully market any approved product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

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

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV. We also intend to enter into collaborative relationships to provide funding to support our research and development programs. The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

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

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

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**We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop and commercialize our product candidates and achieve our objectives.**

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

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

We may introduce certain of our product candidates in various markets outside the 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;

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

adverse tax consequences;

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

regional and geopolitical risks.

If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

**We rely on our licenses from the Regents of the University of California. Impairment of these licenses or our inability to maintain them would severely harm our business.**

Our current research and development efforts depend upon our license arrangements with the Regents of the University of California, or UC. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate our agreements or convert exclusive to

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non-exclusive licenses. In addition, our license agreements with UC may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology.

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**If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of 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 scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. We are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institute Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside the 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 and/or GSK or the Institute Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV or any similar product candidate in the United States, 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. In addition, 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. 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, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, that may be asserted against our ISS products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies in order to commercialize one or more of our formulations of ISS in the U.S. other than with respect to HEPLISAV. Such a license 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 United States 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.



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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;

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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.

**We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some or all of the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise our option prior to the expiration of the development period, and even if we decide to exercise, we may not have the financial resources to exercise our option in a timely manner.**

In April 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapies (Development Programs) to Symphony Dynamo, Inc. (SDI) in consideration for a commitment from Symphony Capital Partners, LP and certain of its affiliates (Symphony) to provide \$50 million of capital to advance the Development Programs. As part of the arrangement, we received an exclusive purchase option (Purchase Option) to acquire all of the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices ranging from \$89.4 million as of March 31, 2009, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The intellectual property rights to the remaining cancer and hepatitis C therapy programs not purchased through the exercise of the Purchase Option will remain with SDI.

We and SDI jointly manage the Development Programs and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our Purchase Option. If we do not exercise the Purchase Option prior to its expiration, then our rights in and with respect to the Development Programs will terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement.

If we elect to exercise the Purchase Option, we will be required to make a payment of at least \$89.4 million, increasing thereafter quarterly, which at our discretion may be paid partially in shares of our common stock. As a result, in order to exercise the Purchase Option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the Purchase Option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the Purchase Option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.



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### **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 product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors. 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. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

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

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

### **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;

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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 enter into and maintain collaborations;

maintenance of our existing exclusive licensing agreements with the Regents of the University of California;

changes in government regulations, general economic conditions, industry announcements;

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

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

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

volume of trading in our common stock

One or more of these factors could cause a substantial decline in the price of our common stock. In October 2008, we experienced a decline in our market capitalization of nearly 80% based on the FDA's communication to us regarding the continuation of a clinical hold on two U.S. IND Applications for HEPLISAV. In November 2008, we transferred our listing of Dynavax shares to The Nasdaq Capital Market from The Nasdaq Global Market. We may be delisted from the Nasdaq Capital Market if our share price or market value of publicly held shares does not meet certain thresholds. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

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

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

authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;

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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 the Company's Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to

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the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of the Common Shares or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

**We will continue to implement additional financial and accounting systems, procedures or controls as our business and organization changes and to satisfy new reporting requirements.**

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls in order to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent auditors are unable to issue an unqualified attestation as to the effectiveness of our internal controls over financial reporting, 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.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Document</b>
10.40	Amendment No. 2, dated February 3, 2009, to the Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and Dynavax Technologies.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of 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 Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.



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We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

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**SIGNATURES**

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: April 30, 2009

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

Date: April 30, 2009

By: /s/ DEBORAH A. SMELTZER  
Deborah A. Smeltzer  
Vice President, Operations and Chief Financial Officer  
(Principal Financial Officer)