DYNAVAX TECHNOLOGIES CORP
Form 10-Q
November 06, 2008
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2008

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Delaware	**33-0728374**
(State or other jurisdiction of incorporation or organization)	***(IRS Employer Identification No.)***

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

(Address, including Zip Code, and telephone number, including area code, of the registrant s principal executive offices)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer þ	Non-accelerated filer ¨ (Do not check if smaller reporting company)	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 þ

As of October 31, 2008, the registrant had outstanding 39,854,265 shares of common stock.

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DYNAVAX TECHNOLOGIES CORPORATION

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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 and Section 21E of the Securities Exchange Act of 1934 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.

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PART I. FINANCIAL STATEMENTS

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	September 30, 2008 (unaudited)	December 31, 2007 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 22,618	$ 14,293
Marketable securities available-for-sale	14,958	42,324
Investments held by Symphony Dynamo, Inc. (SDI)	26,685	31,631
Restricted cash	674	408
Accounts receivable	6,216	7,234
Prepaid expenses and other current assets	1,351	6,049
Total current assets	72,502	101,939
Property and equipment, net	10,241	7,314
Goodwill	2,312	2,312
Other intangible assets, net	2,504	3,239
Other assets		5,645
Total assets	$ 87,559	$ 120,449
Liabilities, noncontrolling interest and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,130	$ 4,418
Accrued liabilities	11,976	12,059
Deferred revenues	6,784	3,427
Total current liabilities	19,890	19,904
Deferred revenues, noncurrent	39,188	40,792
Liability from program option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	106	5,622
Noncontrolling interest in SDI	3,573	8,341
Commitments and contingencies		
Stockholders equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2008 and December 31, 2007		
Common stock: $0.001 par value; 100,000 shares authorized at September 30, 2008 and December 31, 2007; 39,854 and 39,765 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	40	40
Additional paid-in capital	261,862	258,266
Accumulated other comprehensive income:		
Unrealized gains on marketable securities available-for-sale	15	138
Cumulative translation adjustment	(273)	260

Accumulated other comprehensive income	(258)	398
Accumulated deficit	(251,842)	(227,914)
Total stockholders equity	9,802	30,790
Total liabilities, noncontrolling interest and stockholders equity	$ 87,559	$ 120,449

See accompanying notes.

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Dynavax Technologies Corporation

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Collaboration revenue	$ 7,960	$ 719	$ 21,435	$ 2,218
Grant revenue	581	133	2,027	1,848
Service and license revenue	316	162	1,687	732
Total revenues	8,857	1,014	25,149	4,798
Operating expenses:				
Research and development	10,456	14,909	38,522	47,705
General and administrative	3,913	5,029	11,904	13,414
Amortization of intangible assets	245	251	735	754
Total operating expenses	14,614	20,189	51,161	61,873
Loss from operations	(5,757)	(19,175)	(26,012)	(57,075)
Interest and other income	81	476	1,457	2,594
Loan forgiveness	5,000		5,000	
Interest expense	(6,457)	(23)	(9,141)	(88)
Loss including noncontrolling interest in SDI	(7,133)	(18,722)	(28,696)	(54,569)
Amount attributed to noncontrolling interest in SDI	1,713	1,621	4,768	6,674
Net loss	$ (5,420)	$ (17,101)	$ (23,928)	$ (47,895)
Basic and diluted net loss per share	$ (0.14)	$ (0.43)	$ (0.60)	$ (1.21)
Shares used to compute basic and diluted net loss per share	39,831	39,753	39,807	39,740

See accompanying notes.

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Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2008	2007
Operating activities		
Net loss	$ (23,928)	$ (47,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,361	1,091
Amount attributed to noncontrolling interest in SDI	(4,768)	(6,674)
Amortization of intangible assets	735	755
Loss on disposal of assets	25	
Accretion and amortization on marketable securities	(621)	(1,578)
Interest expense associated with Deerfield financing agreement	9,089	356
Loan forgiveness	(5,000)	
Stock-based compensation expense	2,488	2,482
Changes in operating assets and liabilities:		
Accounts receivable	1,018	1,580
Prepaid expenses and other current assets	1,173	(1,740)
Inventory		(6)
Other assets	(85)	1,365
Accounts payable	(3,288)	(230)
Accrued liabilities	(968)	30
Deferred revenues	1,753	3
Net cash used in operating activities	(21,016)	(50,461)
Investing activities		
Change in investments held by SDI	4,946	(19,441)
Purchases of marketable securities	(23,082)	(41,479)
Proceeds from sales of marketable securities	4,046	
Proceeds from maturities of marketable securities	46,900	80,450
Purchases of property and equipment, net	(4,328)	(2,314)
Net cash provided by investing activities	28,482	17,216
Financing activities		
Proceeds from the purchase of noncontrolling interest in SDI, net of fees		30,000
Proceeds from notes payable issued to Deerfield	2,000	3,500
Repayment of notes payable issued to Deerfield	(817)	
Proceeds from issuance of common stock, net of issuance costs		(19)
Proceeds from employee stock purchase plan	204	149
Proceeds from exercise of stock options	5	22
Net cash (used in) provided by financing activities	1,392	33,652
Effect of exchange rate on cash and cash equivalents	(533)	81

Net increase in cash and cash equivalents	8,325	488
Cash and cash equivalents at beginning of period	14,293	14,154
Cash and cash equivalents at end of period	$ 22,618	$ 14,642
Supplemental disclosure of non-cash flow information		
Disposal of fully depreciated property and equipment	$	$ 26
Modification of warrants previously issued to Deerfield	$ 890	$
Warrants issued in conjunction with Deerfield financing agreement	$	$ 3,349
Liability from program option exercised under the SDI collaboration	$	$ 15,000

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 is a clinical-stage biopharmaceutical company that develops innovative products for the treatment of infectious diseases, respiratory diseases and cancer. Our novel Toll-like Receptor 9 (TLR9) agonist products are based on proprietary immunostimulatory sequences (ISS), which are short DNA sequences that stimulate the innate immune response. 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, 2007 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, 2007 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 subsidiaries 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

There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2008 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007 except as below:

Goodwill and Other Intangible Assets

Goodwill amounts are recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method of accounting. The valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. The Company operates in one segment and we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired as required by SFAS No. 142, Goodwill and Other Intangible Assets. We considered the decline in our stock price and market capitalization as compared to the Company s net carrying value and determined

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that no interim impairment analysis was deemed necessary as of the period ended September 30, 2008.

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (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. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our consolidated results of operations and financial condition.

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 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. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated results of operations and financial condition.

In March 2007, the FASB discussed EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities , which addressed the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity s expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus was not permitted. Accordingly, we adopted EITF 07-3 in the first quarter of fiscal 2008. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption.

In September 2006, the FASB issued SFAS 157, Fair Value Measurements. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we adopted SFAS 157 in the first quarter of fiscal 2008. 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. On October 10, 2008, the FASB issued FSP FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active , which clarifies the application of SFAS 157 in a market that is not active and provides examples to illustrate key considerations in determining the fair value of the financial asset when the market for that financial asset is not active. Therefore, we adopted the provisions of SFAS 157 and FSP FAS 157-3 with respect to our financial assets and liabilities only. 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

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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There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption of this pronouncement.

2. Fair Value Measurements

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 September 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money Market Funds	$ 45,618	$	$	$ 45,618
U.S. Government Agency Securities		3,490		3,490
Corporate Debt Securities		13,712		13,712
Total	$ 45,618	$ 17,202	$	$ 62,820

3. Intangible Assets

Intangible assets consist of the manufacturing process and customer relationships we acquired through Rhein Biotech GmbH (Rhein). 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 table presents details of the purchased intangible assets at September 30, 2008 (in thousands, except years):

September 30, 2008	Original Estimated Useful Life (in Years)	Gross	Accumulated Amortization	Net
Manufacturing process	5	$ 3,670	$ 1,794	$ 1,876
Customer relationships	5	1,230	602	628
Total	5	$ 4,900	$ 2,396	$ 2,504

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

Year ending December 31,	
2008 (remaining three months)	$ 244
2009	980
2010	980
2011	300
Total	$ 2,504

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);

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);

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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).

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 $84.2 million as of October 1, 2008, 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 September 30, 2008, the investments held by SDI were $26.7 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 September 30, 2008, the noncontrolling interest balance was $3.6 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 $4.8 million and $6.7 million for the nine months ended September 30, 2008 and 2007, respectively. In accordance with FIN 46R, we have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our consolidated statements of operations, and we will continue to deduct such losses until the carrying amount of the noncontrolling interest in the consolidated balance sheet is reduced to zero. We will be required to recognize losses incurred by SDI in our consolidated statements of operations after the noncontrolling interest balance has

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been exhausted.

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 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 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 warrants issued and their related assumptions under the Black-Scholes option valuation model are as follows (in thousands, except for Black-Scholes Assumptions):

			Black-Scholes Assumptions				
Warrant Issuance Date	Shares Issued	Expiration Date	Risk-Free Interest Rate	Expected Life (in years)	Volatility	Exercise Price per Share	Assigned Value using Black-Scholes
July 18, 2007	1,250	1/17/2013	4.9%	5.5	0.7	$ 5.13	$ 3,350
October 18, 2007	1,300	4/17/2013	4.2%	5.5	0.7	$ 5.75	3,700
December 27, 2007	1,000	6/26/2013	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 $7.2 million and $9.0 million of deferred transaction cost in interest expense for the three and nine months ended September 30, 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 quarter ended September 30, 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 quarter ended September 30, 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(1)

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.

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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 as of and for the quarter ended September 30, 2008 due to these modifications.

6. Commitments and Contingencies

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 in September 2009 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 September 30, 2008 and December 31, 2007. The Berkeley Lease incentive is amortized as an offset to rent expense over the lease term, through September 2014. Total net rent expense related to our operating leases for the nine months ended September 30, 2008 and 2007, was $1.9 million and $1.5 million, respectively. Deferred rent was $0.6 million as of September 30, 2008.

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 $55 thousand annually until August 2010. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2008, excluding payments from the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2008 (remaining three months)	$ 508
2009	2,439
2010	2,619
2011	2,676
2012	2,735
Thereafter	9,842
Total	$ 20,819

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 September 30, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2008 and December 31, 2007. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20 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 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20 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 September 30, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of September 30, 2008.

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 upfront 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 obtain services from research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2008, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $4 million through 2010. 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.

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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. Such fees and milestone payments to the Regents could approximate $1 million in 2008.

7. Collaborative Research and Development Agreements

Merck

In October 2007, we entered into a global license and development collaboration agreement with Merck & Co., Inc. (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 and are eligible to receive development cost reimbursement, future development and sales milestone payments up to $105 million, and royalties on global sales of HEPLISAV. Revenue from the initial payment is deferred and recognized ratably over estimated performance period of the collaboration agreement. For the three and nine months ended September 30, 2008, we recognized revenue of $0.6 million and $1.9 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 $4.7 million and $15.4 million for the three and nine months ended September 30, 2008, respectively. The two Investigational New Drug (IND) Applications for HEPLISAV are currently on clinical hold by the FDA.

Also in October 2007, we entered into a manufacturing agreement with Merck for the supply of hepatitis B surface antigen. Under the terms of the agreement, we are responsible for manufacturing the hepatitis B surface antigen component of HEPLISAV for Merck. We expect to produce hepatitis B surface antigen at Dynavax Europe s Düsseldorf, Germany facility using our proprietary technology developed there. If HEPLISAV is successful, we may be unable to meet our commercial supply obligations and support expected market demand without the construction of a new facility. This manufacturing obligation is for 10 years from the date of first major market launch of HEPLISAV. The October 2007 agreements with Merck are terminable upon prior written notice to us, following which all rights and licenses to Merck with respect to HEPLISAV will terminate and revert to Dynavax. Based on the current status of the program following the continuation of clinical hold by the FDA in October 2008, there can be no assurance that Merck will not terminate the existing HEPLISAV agreements.

AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca AB (AstraZeneca) for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. 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 a 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 September 30, 2008, we recognized revenue of $1.0 million related to the preclinical milestone. Collaboration revenue resulting from the performance of research services amounted to $0.9 million and $2.3 million for the three and nine months ended September 30, 2008, respectively. As of September 30, 2008, we recorded deferred revenue of $13.9 million associated with the preclinical milestone, upfront fee and amounts billed in advance for research services per the contract terms.

National Institutes of Health

In September 2008, we were awarded a five-year $17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the National Institutes of Health s (NIH) National Institute of Allergy and Infectious Diseases (NIAID) to develop novel vaccine adjuvant candidates that signal through receptors of the innate immune system. The

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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. No revenue was recognized during the quarter ended September 30, 2008 for this contract.

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 September 30, 2008, we recognized revenue of approximately $0.2 million.

In August 2007, we were awarded a two-year $3.25 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with this grant is recognized as the related expenses are incurred. For the nine months ended September 30, 2008 and 2007, we recognized revenue of approximately $1.4 million, and $1.8 million, respectively.

8. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and stock options to purchase 11.0 million and 7.5 million shares of common stock as of September 30, 2008 and 2007, respectively, were excluded from the calculation of diluted net 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 loss per share computations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Numerator:				
Net loss	$ (5,420)	$ (17,101)	$ (23,938)	$ (47,895)
Denominator:				
Weighted-average common shares outstanding used for basic and diluted net loss per share	39,831	39,753	39,807	39,740

9. Comprehensive Loss

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

	Nine Months Ended September 30,	
	2008	2007
Net loss	$ (23,938)	$ (47,895)
Decrease in unrealized gains on marketable securities available-for-sale	(123)	(5)
Increase (decrease) in cumulative translation adjustment	(533)	81
Comprehensive loss	$ (24,594)	$ (47,819)

10. Stockholders Equity

As of September 30, 2008, 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.

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

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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 September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007	2008	2007
Weighted-average fair value per share	$ 0.91	$ 2.51	$ 2.60	$ 3.57	$ 0.93	$ 1.96
Risk-free interest rate	2.7%	4.5%	2.8%	4.8%	2.4%	4.6%
Expected life (in years)	4.0	4.0	4.4	4.5	1.3	1.2
Volatility	0.8	0.7	0.7	0.8	0.8	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 each found to have similar historical option exercise and termination behavior and thus 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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Employee and director stock-based compensation expense	$ 1,051	$ 971	$ 2,469	$ 2,442
Other stock-based compensation expense	1	13	19	40
Total	$ 1,052	$ 984	$ 2,488	$ 2,482

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 11%. As of September 30, 2008 the total unrecognized compensation cost related to non-vested options granted amounted to $7.1 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.6 years.

Activity under the our stock option plans was as follows:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price Per Share
Balance at December 31, 2007	1,257,171	4,282,455	$ 5.36
Options authorized	400,000		
Options granted	(1,663,200)	1,663,200	$ 4.53
Options exercised			
1997 Plan shares exercised		(1,833)	$ 2.59
Options cancelled:			
Options forfeited (unvested)	429,798	(429,798)	$ 5.62
Options expired (vested)	63,550	(64,382)	$ 6.96
Balance at September 30, 2008	487,319	5,449,642	$ 5.07

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of September 30, 2008:

	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)	4,984,223	$ 5.04	7.5	
Options exercisable	2,509,880	$ 4.91	6.2	

Employee Stock Purchase Plan

As of September 30, 2008, 496,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment

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for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees acquired 193,868 shares of our common stock under the Purchase Plan. At September 30, 2008, 302,132 shares of our common stock remained available for future purchases.

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 is a clinical-stage biopharmaceutical company that develops innovative products for the treatment of infectious diseases, respiratory diseases and cancer. Our novel Toll-like Receptor 9 (TLR9) agonist products are based on proprietary immunostimulatory sequences (ISS), which are short DNA sequences that stimulate the innate immune response.

Our clinical product candidates include: HEPLISAV™, a hepatitis B vaccine partnered with Merck & Co., Inc. (Merck); a therapy for hepatitis B; and therapies for cancer and hepatitis C funded by Symphony Dynamo, Inc. (SDI). Our preclinical pipeline includes an asthma and COPD drug candidate partnered with AstraZeneca and a Universal Flu vaccine.

Recent Developments

HEPLISAV

HEPLISAV, our product candidate for hepatitis B prophylaxis, is based on proprietary ISS that specifically targets TLR9 to stimulate an innate immune response. HEPLISAV combines ISS with hepatitis B surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection. The multi-center PHAST (Phase 3 HeplisAv Short-regimen Trial) trial evaluated 2,427 subjects from 11 to 55 years of age in Canada and Germany. This phase 3 trial met its primary endpoint and evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month, compared to a three-dose regimen of Engerix-B administered at 0, 1, and 6 months. The primary endpoint was the proportion of subjects who developed protective antibody to hepatitis B after vaccination. Immunogenicity results from this trial demonstrated that subjects receiving HEPLISAV were seroprotected with fewer doses and at an earlier time point than subjects receiving Engerix-B. HEPLISAV is being jointly developed by Dynavax and Merck for use in adults and in patients with end stage renal disease.

In March 2008, the U.S. FDA placed the two Investigational New Drug (IND) Applications for HEPLISAV on clinical hold and requested a review of clinical and preclinical safety data for HEPLISAV, including all available information about a single case of Wegener s granulomatosis previously reported.

In September 2008, we submitted a response to the FDA s request for information. The response submitted to the FDA contained a thorough review of both clinical and preclinical safety data for HEPLISAV. Clinical data from 2,500 subjects who received HEPLISAV in a total of 9 clinical trials conducted over a period of nearly 10 years were provided, including data from the PHAST trial the largest clinical trial of HEPLISAV to date. In the response, we confirmed that two Serious Adverse Events (SAE) of systemic vasculitis were observed in the PHAST trial, one in the HEPLISAV group and one in the Engerix-B(R) control group. Specifically, one of the 1,819 subjects who received HEPLISAV was diagnosed as having Wegener s granulomatosis, a form of vasculitis associated with positive cytoplasmic-staining anti-neutrophil cytoplasmic antibody (c-ANCA). This individual did not have detectable c-ANCA prior to vaccination and remained negative throughout the course of HEPLISAV vaccination. The individual became positive for c-ANCA two months after the second dose of HEPLISAV. In the Engerix-B group, one of the 608 subjects

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developed systemic vasculitis associated with perinuclear-staining antineutrophil cytoplasmic antibody, or p-ANCA, four months after the second dose of Engerix-B. Safety results showed the profile of 2 doses of HEPLISAV appeared similar to 3 doses of Engerix-B, with the exception that subjects who received HEPLISAV had a higher risk of developing injection site swelling, redness, and pain compared to those who received Engerix-B. The incidence of Adverse Events (AE) was 81.9 percent for the HEPLISAV group, compared to 81.4 percent for the Engerix-B group. The incidence of SAEs was 1.5 percent for the HEPLISAV group, compared to 2.1 percent for the Engerix-B group.

In October 2008, we received communication from the FDA regarding our response. The FDA stated that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The FDA also advised us that there may be an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from us and Merck before considering further pursuit of clinical studies in that patient population. We and Merck are evaluating the FDA s response in considering next steps, including the feasibility of developing the product for adults outside the U.S and globally for patients with renal failure. In the meantime, the clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect. There can be no assurance as to whether HEPLISAV can be developed further or that successful clinical development can occur in a timely manner or without additional studies or patient data. In addition, Merck may terminate the agreement for further development of HEPLISAV upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA may be released.

Influenza Vaccine

We are developing a Universal Flu vaccine designed specifically to overcome the limitations of standard seasonal and pandemic vaccines. Our approach combines a proprietary second-generation TLR9 agonist with two conserved influenza antigens nucleoprotein (NP) and the extracellular domain of matrix protein 2 (M2e) and a trivalent influenza vaccine. Our vaccine is designed to be differentiated from other influenza vaccines by providing both an adjuvant effect to enhance the immunogenicity of the seasonal vaccine and cross-strain protection via conserved influenza antigens.

In July 2008, we announced an agreement with Novartis for the supply and development, and possible commercialization, of our Universal Flu vaccine in collaboration with Novartis. Under the agreement, Novartis agreed to provide us with a supply of trivalent influenza vaccine, an essential component of our Universal Flu vaccine, for both clinical trial use and vaccine sales. Novartis received an exclusive option to negotiate a Joint Development and Commercialization Agreement with Dynavax. We agreed to conduct early-stage development through a defined proof-of-concept. If Novartis exercises the right to negotiate a further agreement for development and commercialization, we would retain co-commercialization rights in the U.S. and receive product royalties outside of the U.S. Should the option not be exercised, Novartis remains committed to providing commercial supply of trivalent influenza vaccine with pre-agreed commercial terms and we retain the right to independently continue with late-stage development and commercialization.

Immunoregulatory Sequences

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 that affects over a million people in the U.S., disproportionately affecting women of childbearing age. SLE is difficult to treat, and the few effective therapies have significant toxicities and side effects. The abnormal activation of two types of immune system cells, B lymphocytes and plasmacytoid dendritic cells (PDC) are important in the pathogenesis of the disease. The chronic activation of both cell types appears due to stimulation by DNA and RNA acting through the innate immune receptors, TLR7 and TLR9. We have developed a series of synthetic oligonucleotides, termed immunoregulatory sequence, or IRS, with sequence motifs strongly inhibitory for both TLR7 and TLR9 signaling. In earlier work we characterized the specificity of IRS and provided rationale for the treatment of lupus based on animal model and human in vitro experiments. We have developed an optimized and stabilized IRS molecule which we consider to be appropriate for clinical development. This grant comprises several related activities to advance the IRS program toward filing of an IND application for clinical trials.

Adjuvant Development

In September 2008, we were awarded a five-year $17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the National Institutes of Health s (NIH) 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.

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Critical Accounting Policies and the Use of Estimates

There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2008 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007 except as below:

Goodwill and Other Intangible Assets

Goodwill amounts are recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method of accounting. The valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. The Company operates in one segment and we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired as required by SFAS No. 142, Goodwill and Other Intangible Assets. We considered the decline in our stock price and market capitalization as compared to the Company s net carrying value and determined that no interim impairment analysis was deemed necessary as of the period ended September 30, 2008.

Results of Operations

Revenues

Revenues consist of amounts earned from collaborations, government and private agency grants, services and license fees. Services and license fees include research and development and contract manufacturing services, license fees and royalty payments.

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

	Three Months Ended September 30,		Increase (Decrease) from 2007 to 2008		Nine Months Ended September 30,		Increase (Decrease) from 2007 to 2008	
Revenues:	**2008**	**2007**	**$**	**%**	**2008**	**2007**	**$**	**%**
Collaboration revenue	$ 7,960	$ 719	$ 7,241	1,007%	$ 21,435	$ 2,218	$ 19,217	866%
Grant revenue	581	133	448	337%	2,027	1,848	179	10%
Service and license revenue	316	162	154	95%	1,687	732	955	130%
Total revenues	$ 8,857	$ 1,014	$ 7,843	773%	$ 25,149	$ 4,798	$ 20,351	424%

Total revenues for the nine months ended September 30, 2008 were $25.1 million, compared to $4.8 million for the same period in 2007 primarily due to an increase in revenue recognized from our collaboration agreement with Merck. Service and license revenue of $1.7 million for the nine months ended September 30, 2008 increased primarily due to royalties received from customers of Dynavax Europe in the first half of 2008.

As a result of the clinical hold on the two U.S. IND Applications for HEPLISAV, we and Merck are currently evaluating next steps with respect to further clinical development of HEPLISAV which will impact the timing of Merck-related revenues, including the recognition of the upfront payment and future development cost reimbursement. However, we anticipate that our fourth quarter collaboration revenue will contribute to a significant increase in total 2008 revenues as compared to 2007.

Research and Development

Research and development expenses consist 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. We expense our research and development costs as they are incurred.

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

Research and development:	Three Months Ended September 30, 2008	2007	Increase (Decrease) from 2007 to 2008 $	%	Nine Months Ended September 30, 2008	2007	Increase (Decrease) from 2007 to 2008 $	%
Compensation and related personnel costs	$ 4,519	$ 4,756	$ (237)	(5)%	$ 14,546	$ 14,270	$ 276	2%
Outside services	3,715	8,153	(4,438)	(54)%	17,823	27,955	(10,132)	(36)%
Facility costs	1,745	1,730	15	1%	5,106	4,689	417	9%
Non-cash stock-based compensation	477	270	207	77%	1,047	791	256	32%
Total research and development	$ 10,456	$ 14,909	$ (4,453)	(30)%	$ 38,522	$ 47,705	$ (9,183)	(19)%

Research and development expenses for the nine months ended September 30, 2008 decreased by $9.2 million, or 19%, compared to the same period in 2007. The decrease is due primarily to a reduction in outside services. In 2007, outside services included a one-time $5 million payment for a non-exclusive license to certain patents and patent applications for the purpose of commercializing HEPLISAV. The remaining decline in outside services resulted primarily from a reduction in clinical trial, clinical material, and preclinical costs.

We anticipate that our research and development expenses will decrease in the fourth quarter of 2008 as compared to 2007 due to a reduction in HEPLISAV clinical development costs resulting from the clinical hold.

General and Administrative

General and administrative expenses 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, net of patent cost recoveries; allocated facility costs; and non-cash stock-based compensation.

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

General and administrative:	Three Months Ended September 30, 2008	2007	Increase (Decrease) from 2007 to 2008 $	%	Nine Months Ended September 30, 2008	2007	Increase (Decrease) from 2007 to 2008 $	%
Compensation and related personnel costs	$ 1,684	$ 1,850	$ (166)	(9)%	$ 5,528	$ 5,378	$ 150	3%
Outside services	994	1,057	(63)	(6)%	3,182	3,415	(233)	(7)%
Legal costs	414	1,245	(831)	(67)%	1,036	2,490	(1,454)	(58)%
Facility costs	256	167	89	53%	739	450	289	64%
Non-cash stock-based compensation	565	710	(145)	(20)%	1,419	1,681	(262)	(16)%
Total general and administrative	$ 3,913	$ 5,029	$ (1,116)	(22)%	$ 11,904	$ 13,414	$ (1,510)	(11)%

General and administrative expenses for the nine months ended September 30, 2008 decreased by $1.5 million, or 11%, compared to the same period in 2007. The decrease primarily reflects lower legal costs and a reduction in professional fees associated with various corporate activities.

We expect general and administrative expenses to decline in 2008 as compared to 2007, resulting from continued efforts to reduce costs.

Amortization of Intangible Assets

Intangible assets consist primarily of the manufacturing process and customer relationships we acquired through Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was $0.7 million and $0.8 million for the

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nine months ended September 30, 2008 and 2007, respectively.

Interest and Other Income, Loan Forgiveness and Interest Expense

Interest income is reported net of amortization on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. Interest expense includes amortization of deferred transaction costs and commitment fees related to the Deerfield financing arrangement. The following is a summary of our interest and other income, net and interest expense (in thousands, except for percentages):

	Three Months Ended September 30,		Increase (Decrease) from 2007 to 2008		Nine Months Ended September 30,		Increase (Decrease) from 2007 to 2008	
	2008	2007	$	%	2008	2007	$	%
Interest and other income	$ 81	$ 476	$ (395)	(83)%	$ 1,457	$ 2,594	$ (1,137)	(44)%
Loan forgiveness	5,000		5,000		5,000		5,000	
Interest expense	(6,457)	(23)	6,434	27,973%	(9,141)	(88)	9,053	10,288%

Interest and other income for the nine months ended September 30, 2008 decreased by $1.1 million, or 44%, compared to the same period in 2007 due primarily to lower investment balances and the decline in returns on our investment portfolio resulting from current market conditions.

Loan forgiveness represents a $5.0 million portion of the loan from Deerfield that was forgiven upon termination of the loan agreement.

Interest expense for the nine months ended September 30, 2008 increased by $9.1 million compared to the same period in 2007 due to interest expense incurred from the termination of the loan agreement with Deerfield and amendments to warrants issued to Deerfield.

Amount 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 FIN 46R, the results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006. In accordance with FIN 46R, we have deducted the losses attributed to the noncontrolling interest in the determination of net loss in our condensed consolidated statement of operations, and we will continue to deduct such losses until the carrying amount of the noncontrolling interest in the condensed consolidated balance sheet is reduced to zero. For the nine months ended September 30, 2008 and 2007 the losses attributed to the noncontrolling interest were $4.8 million and $6.7 million, respectively.

Recent Accounting Pronouncements

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. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our consolidated results of operations and financial condition.

In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 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. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated results of operations and financial condition.

In March 2007, the FASB discussed EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or

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Services to Be Used in Future Research and Development Activities , which addressed the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity s expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Early adoption of the provision of the consensus was not permitted. Accordingly, we adopted EITF 07-3 in the first quarter of fiscal 2008. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption.

In September 2006, the FASB issued SFAS 157, Fair Value Measurements. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we adopted SFAS 157 in the first quarter of fiscal 2008. In February 2008, the FASB issued FASB Staff Position (FSP) No. 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. On October 10, 2008, the FASB issued FSP FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active , which clarifies the application of SFAS 157 in a market that is not active and provides examples to illustrate key considerations in determining the fair value of the financial asset when the market for that financial asset is not active. Therefore, we adopted the provisions of SFAS 157 and FSP FAS 157-3 with respect to our financial assets and liabilities only. 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

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.

There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption of this pronouncement.

Liquidity and Capital Resources

As of September 30, 2008, we had $64.3 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 $21.0 million during the nine months ended September 30, 2008 compared to $50.5 million for the same period in 2007. The decrease in cash usage over the prior year was primarily due to an increase in revenue recognized from our collaboration agreements with Merck and AstraZeneca and a reduction in operating expenses and the amount attributed to the noncontrolling interest in SDI.

Cash provided by investing activities was $28.5 million during the nine months ended September 30, 2008 compared to cash provided of $17.2 million for the same period in 2007. The increase was attributed to the net proceeds from sales and maturities of marketable securities.

Cash provided by financing activities was $1.4 million during the nine months ended September 30, 2008 compared to cash provided of $33.7 million for the same period in 2007. Cash provided by financing activities in 2008 primarily included the proceeds from the Deerfield financing agreement. Cash provided by financing activities in 2007 primarily included the proceeds from the

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purchase of noncontrolling interest in SDI received in April 2007.

In August 2006, we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd (Azimuth). Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of $30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the term of the purchase agreement. $15 million remains available on our equity line of credit through the extended term of the agreement, which is December 31, 2008.

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.

The U.S. capital markets have recently experienced unprecedented challenges for issuers attempting to raise capital and the risk of a global recession compounds this situation such that 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 which may also result in failure to meet the diligence obligations under existing licenses or enter into collaborative arrangements at an earlier stage of development on less favorable terms than we would otherwise choose.

Contractual Obligations

The following summarizes our significant contractual obligations as of September 30, 2008 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 years
Future minimum payments under our operating lease, excluding payments from the sublease agreement	$ 20,819	$ 508	$ 7,734	$ 5,515	$ 7,062
Long-term liability from the program option exercised under the SDI collaboration	15,000		15,000		
Total	$ 35,819	$ 508	$ 22,734	$ 5,515	$ 7,062

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 September 2009 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 $55 thousand annually until August 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 subsequent 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 September 30, 2008 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2008 and December 31, 2007. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20 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 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20 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 September 30, 2008 and is collateralized by a certificate of deposit which has been included in

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restricted cash in the consolidated balance sheet as of September 30, 2008.

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 upfront 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 obtain services from research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2008, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $4 million through 2010. 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. Such fees and milestone payments to the Regents could approximate $1 million in 2008.

Off-balance Sheet Arrangements

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.

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 market value of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. 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 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. to support 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 September 30, 2008 was $0.3 million primarily related to translation of Dynavax Europe activities from Euros 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, or Exchange Act, as of the end of period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are

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met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

(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.

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 $251.8 million as of September 30, 2008. 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 2009, although we recently received a five-year government contract totaling $17 million. 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. Clinical trials for certain of our 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 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.

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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.

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. The FDA also advised us that there may be an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from us and Merck before considering further pursuit of clinical studies in that patient population. Pending further investigation and resolution satisfactory to the FDA and foreign regulatory authorities, 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. In addition, Merck may terminate the agreement for further development of HEPLISAV upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA may be released. Without support for this program from a development partner, we may not be able to continue further development of HEPLISAV.

Many new drug candidates, including many drug candidates that have completed Phase 3 clinical trials, have shown promising results in early clinical trials and subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. 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 an entire year.

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.

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

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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 candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, 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 candidates in clinical trials are 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, HEPLISAV is on clinical hold due to a communication from the FDA stating that the balance of risk versus potential benefit no longer favors continued clinical evaluation of this product in healthy adults and children in view of adverse events 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 and for fulfilling our manufacturing obligations under our collaboration with Merck. 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 or breach of our obligations under our Merck collaboration.

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 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, which is part of our

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collaboration with Merck. We are obligated to manufacture, on behalf of Merck, HEPLISAV for clinical development and commercial quantities of hepatitis B surface antigen. Accordingly, we will have to allocate the entire capacity of our Düsseldorf facility to meet our obligations under the Merck collaboration. Moreover, if the collaboration is successful, in order to meet our commercial supply obligations to Merck, we may need to establish commercial-scale manufacturing capability for HEPLISAV, which could involve significant capital investment and increased operating costs as well as additional risks associated with the construction, validation and operation of a new commercial manufacturing facility as well as the continued operation of our existing facility. There can be no assurance that we can successfully meet our supply obligations to Merck and maintain our internal product candidate timelines and, if we undertake the establishment of a new commercial manufacturing facility, that we can finance the capital costs and increased expenses that we would need to undertake in order to meet our supply obligations to Merck until or if HEPLISAV achieves commercial success. There also can be no assurance that the cost of meeting our supply obligation to Merck will be covered by the negotiated supply price.

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. 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, 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.

In October 2007, we entered into a collaborative arrangement with Merck to further develop and commercialize HEPLISAV. Pursuant to the terms of the collaboration, we are obligated to complete ongoing clinical studies, manufacture and supply on behalf of Merck, and conduct technology transfer with respect to our existing HEPLISAV development program. Although we will be reimbursed for specified development efforts and the delivery of clinical material to Merck in the further development and commercialization of HEPLISAV, Merck controls the development and commercialization plans and timelines for the product. In October 2008, we received communication from the FDA stating that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The FDA also advised us that there may be an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from us and Merck before considering further pursuit of clinical studies in that patient population. We and Merck are evaluating the FDA s response in considering next steps. In the meantime, the clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect. As a result of the clinical hold, there can be no assurance as to whether HEPLISAV can be developed further, or even if further

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development is permitted, that successful clinical development can occur in a timely manner or without additional studies or patient data.

Merck may terminate the arrangement upon written notice to us, and there can be no assurance that Merck will continue the collaboration regardless of whether or not the clinical hold by the FDA is released. Moreover, even if the collaboration continues, we may not successfully and timely fulfill our obligations under the collaboration, Merck may develop or market a potentially competitive product, or HEPLISAV, even if successfully developed, may not achieve commercial success sufficient for us to achieve all of the milestones and royalties contemplated under the collaborative arrangement. If Merck terminates the arrangement, 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.

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, respiratory diseases 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.

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;

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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 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.

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.

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

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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.

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

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

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

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 therapeutics (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 $84.2 million as of October 1, 2008, 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

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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 $84.2 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.

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.

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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;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to 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; 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 continuance of the clinical hold on two U.S. IND Applications for HEPLISAV. We may be delisted from the NASDAQ Global Market if our share price or market value of publicly held shares does not meet certain thresholds by January 2009. 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 is especially 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;

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

providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and

establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our recently adopted share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by the Company s Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at $0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of the Common Shares or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our Board of Directors.

We 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.

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ITEM 6. EXHIBITS

Exhibit Number	Document
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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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: November 6, 2008

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

Date: November 6, 2008

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