DYNAVAX TECHNOLOGIES CORP
Form 10-Q
October 31, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011 September 30, 2011

or

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

For the transition period from to .

Commission file number: 001-34207

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

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

2929 Seventh Street, Suite 100

Berkeley, CA 94710-2753

(510) 848-5100

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files). Yes x No ¨

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

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

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

As of October 27, 2011, the registrant had outstanding 126,808,747 shares of common stock.

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DYNAVAX TECHNOLOGIES CORPORATION

This Quarterly Report on Form 10-Q includes Dynavax and HEPLISAV which are trademarks of Dynavax Technologies Corporation. Other brands, names and trademarks mentioned in this Quarterly Report on Form 10-Q are property of their respective owners.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. Forward-looking statements are based on our beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. Our forward-looking statements include discussions regarding our business and financing strategies, research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development and potential regulatory approval of our products, 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 INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Dynavax Technologies Corporation

Condensed Consolidated Balance Sheets

(In thousands, except per share amounts)

	September 30, 2011 (Unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 19,072	$ 22,453
Marketable securities	34,149	49,701
Accounts receivable	783	1,001
Prepaid expenses and other current assets	1,393	1,360
Total current assets	55,397	74,515
Property and equipment, net	6,127	6,404
Goodwill	2,312	2,312
Restricted cash	659	652
Other intangible assets, net	0	299
Other assets	224	67
Total assets	$ 64,719	$ 84,249
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,313	$ 2,329
Accrued liabilities	7,316	10,159
Deferred revenues	1,429	1,429
Total current liabilities	10,058	13,917
Deferred revenues, noncurrent	4,583	5,655
Long-term note payable to Symphony Dynamo Holdings LLC (Holdings)	12,342	10,939
Long-term contingent liability to Holdings	877	843
Other long-term liabilities	630	784
Commitments and contingencies (Note 6)		
Stockholders equity:		
Preferred stock: $0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2011 and December 31, 2010	0	0
Common stock: $0.001 par value; 250,000 and 150,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 125,611 and 115,611 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	126	116
Additional paid-in capital	397,996	369,686
Accumulated other comprehensive loss:		
Unrealized loss on marketable securities available-for-sale	(6)	(17)
Cumulative translation adjustment	(612)	(729)

Total accumulated other comprehensive loss	(618)	(746)
Accumulated deficit	(361,275)	(316,945)
Total stockholders equity	36,229	52,111
Total liabilities and stockholders equity	$ 64,719	$ 84,249

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,	
	2011	2010	2011	2010
Revenues:				
Collaboration revenue	$ 369	$ 10,402	$ 7,098	$ 19,164
Grant revenue	658	1,218	2,437	2,697
Service and license revenue	147	29	652	323
Total revenues	1,174	11,649	10,187	22,184
Operating expenses:				
Research and development	11,777	14,204	39,706	40,729
General and administrative	4,217	3,951	13,025	12,694
Amortization of intangible assets	0	245	299	735
Total operating expenses	15,994	18,400	53,030	54,158
Loss from operations	(14,820)	(6,751)	(42,843)	(31,974)
Interest income	18	12	74	53
Interest expense	(485)	(399)	(1,462)	(1,229)
Other income (expense)	58	2,140	(99)	(9,036)
Net loss	$ (15,229)	$ (4,998)	$ (44,330)	$ (42,186)
Basic and diluted net loss per share	$ (0.12)	$ (0.06)	$ (0.37)	$ (0.57)
Shares used to compute basic and diluted net loss per share	124,069	86,826	119,244	74,519

See accompanying notes.

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Dynavax Technologies Corporation

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Operating activities		
Net loss	$ (44,330)	$ (42,186)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,009	1,114
Amortization of intangible assets	299	735
(Gain)/loss on disposal of assets	(8)	0
Non-cash interest associated with long-term note payable to Holdings	1,403	1,198
Fair value adjustments to the common stock, warrant and contingent liability issued to Holdings	34	8,917
Accretion and amortization of marketable securities	895	125
Stock-based compensation expense	3,934	1,552
Changes in operating assets and liabilities:		
Accounts receivable	218	(360)
Prepaid expenses and other current assets	(33)	(493)
Restricted cash and other assets	(164)	(2,054)
Accounts payable	(1,016)	381
Accrued liabilities and other long term liabilities	(2,997)	9,947
Deferred revenues	(1,072)	(12,360)
Net cash used in operating activities	(41,828)	(33,484)
Investing activities		
Purchases of marketable securities	(38,007)	(30,894)
Proceeds from maturities of marketable securities	52,675	11,750
Purchases of property and equipment, net	(578)	(133)
Proceeds from the sale of property and equipment	14	0
Net cash provided by (used in) investing activities	14,104	(19,277)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	24,078	44,124
Proceeds from employee stock purchase plan	132	72
Proceeds from exercise of stock options and delivery of restricted stock units	169	71
Proceeds from exercise of warrants	7	0
Net cash provided by financing activities	24,386	44,267
Effect of exchange rate on cash and cash equivalents	(43)	(17)
Net decrease in cash and cash equivalents	(3,381)	(8,511)
Cash and cash equivalents at beginning of period	22,453	36,720
Cash and cash equivalents at end of period	$ 19,072	$ 28,209

Supplemental disclosure of cash flow information				
Disposal of fully depreciated assets	$	845	$	0
Net change in unrealized losses on marketable securities, net	$	11	$	3

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

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine, autoimmune program partnered with GlaxoSmithKline (GSK) and hepatitis C and hepatitis B therapies; and a preclinical program partnered with AstraZeneca AB (AstraZeneca). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory and immunoregulatory sequences. 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 (GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2010 has been derived from audited financial statements at that date, but does not include all disclosures required by GAAP for complete financial statements.

The unaudited condensed consolidated financial statements and these notes should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2010 as filed with the Securities and Exchange Commission (the SEC).

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries, Rhein Biotech GmbH (Rhein or Dynavax Europe) and Symphony Dynamo, Inc. (SDI). All significant intercompany accounts and transactions have been eliminated. We have reclassified the prior year deferred rent balance from current accrued liabilities to other long-term liabilities in order to conform to the current year presentation. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

Liquidity and Financial Condition

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2011, we had cash, cash equivalents and marketable securities of $53.2 million, restricted cash of $0.7 million and working capital of $45.3 million. We currently estimate that we have sufficient cash resources to meet our anticipated cash needs through the next 12 months based on cash and cash equivalents and marketable securities on hand at September 30, 2011 and anticipated revenues and funding from existing agreements.

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

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

Use of Estimates

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

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Significant Accounting Policies

We believe that there have been no substantive changes in our significant accounting policies during the nine months ended September 30, 2011 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010 other than the changes to our accounting policies related to revenue recognition as discussed below.

Revenue Recognition

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

On January 1, 2011, we adopted on a prospective basis Accounting Standards Update (ASU) 2009-13, Multiple-Deliverable Revenue Arrangements (ASU 2009-13), which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated. The adoption of the standard did not impact our financial position or results of operations as of and for the nine months ended September 30, 2011 as we did not enter into or materially modify any multiple-element arrangements during that period. The adoption of this standard may result in revenue recognition patterns for future agreements that are different from those recognized for our existing multiple-element arrangements.

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

On January 1, 2011, we elected to prospectively adopt ASU 2010-17, Milestone Method of Revenue Recognition (ASU 2010-17). Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a collaboration partner s performance. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there was substantial uncertainty whether any such milestones would be achieved at the time we entered into these agreements. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone. The election to adopt the milestone method did not impact our financial position or results of operations as of and for the nine months ended September 30, 2011.

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

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

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

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

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

Recent Accounting Pronouncements

Accounting Standards Update 2011-05

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income which was issued to enhance comparability between entities that report under U.S. GAAP and International Financial Reporting Standards (IFRS), and to provide a more consistent method of presenting non-owner transactions that affect an entity s equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. We do not expect that the adoption of this ASU will have any material impact on our results of operations or financial position.

Accounting Standards Update 2011-04

In May 2011, the FASB issued ASU No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. We are currently evaluating the impact, if any, that the adoption of this pronouncement may have on our results of operations or financial position.

2. Fair Value Measurements

FASB Accounting Standards Codification (ASC) 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value as follows:

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

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

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

September 30, 2011	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 13,169	$ 0	$ 0	$ 13,169
U.S. government agency securities	0	13,466	0	13,466
Corporate debt securities	0	24,231	0	24,231
Total assets	$ 13,169	$ 37,697	$ 0	$ 50,866
Liabilities:				
Long-term contingent liability to Symphony Dynamo Holdings LLC	$ 0	$ 0	$ 877	$ 877
Total liabilities	$ 0	$ 0	$ 877	$ 877

December 31, 2010	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 18,980	$ 0	$ 0	$ 18,980
U.S. government agency securities	0	49,039	0	49,039
Corporate debt securities	0	1,764	0	1,764
Total assets	$ 18,980	$ 50,803	$ 0	$ 69,783
Liabilities:				
Long-term contingent consideration liability to Holdings	$ 0	$ 0	$ 843	$ 843
Total liabilities	$ 0	$ 0	$ 843	$ 843

Assets

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

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

When determining if there are any other-than-temporary impairments of our investments, we evaluate: (i) whether the investment has been in a continuous realized loss position for over 12 months, (ii) the duration to maturity of our investments, (iii) our intention to hold the investments to maturity and if it is more likely than not that we will be required to sell the investment before recovery of the amortized cost basis, (iv) the credit rating of each investment, and (v) the type of investments made. Through September 30, 2011, we have not recognized any other-than-temporary losses on our investments. There were no sales of marketable securities during the quarters ended September 30, 2011 and 2010.

Liabilities

In connection with our acquisition of SDI in December 2009, we are obligated to make future contingent cash payments to the former Symphony Dynamo Holdings LLC (Holdings) shareholders related to certain payments received by us, if any, from future partnering agreements pertaining to our hepatitis C and cancer therapy programs. We estimated the fair value of this contingent liability using a discounted cash flow

model. The discounted cash flow model was derived from management s assumptions regarding the timing, amounts and probability of potential upfront and milestone payments for the development and/or commercialization of the hepatitis C program based on transactions for similar stage programs by other companies. These cash flows were discounted at a 14% rate at September 30, 2011.

Changes in the fair value of the contingent liability are recognized in Other income (expense) in the statement of operations in the period of the change. Certain events including, but not limited to, the timing and terms of any strategic partnership agreement

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related to the hepatitis C therapy program could have a material impact on the fair value of the contingent liability, and as a result, our results of operations and financial position. Based on our assumptions regarding our beta and risk free interest rate used in the discounted cash flow model, the change in fair value of the contingent liability resulted in other expense of $34 thousand for the nine months ended September 30, 2011.

The following table represents a reconciliation of the change in the fair value measurement of the contingent liability for the nine months ended September 30, 2011 (in thousands):

Contingent Liability to Holdings	Amount
Fair value measurement at December 31, 2010	$ 843
Adjustment to fair value measurement	34
Balance as of September 30, 2011	$ 877

3. Available-for-Sale Securities

The following is a summary of available-for-sale securities included in cash and cash equivalents and marketable securities as of September 30, 2011 and December 31, 2010 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
September 30, 2011				
Certificates of deposit and money market funds	$ 13,993	$ 0	$ 0	$ 13,993
U.S. government agency securities	13,467	0	(1)	13,466
Corporate debt securities	24,236	0	(5)	24,231
Total	$ 51,696	$ 0	$ (6)	$ 51,690
December 31, 2010				
Certificates of deposit and money market funds	$ 19,797	$ 0	$ 0	$ 19,797
U.S. Government agency securities	49,056	0	(17)	49,039
Corporate debt securities	1,764	0	0	1,764
Total	$ 70,617	$ 0	$ (17)	$ 70,600

There were no realized gains or losses from the sale of marketable securities in the quarters ended September 30, 2011 and 2010. As of September 30, 2011 and December 31, 2010, all of our investments have a stated maturity date that is within one year of the balance sheet date. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity.

4. Intangible Assets

Intangible assets consist primarily of a manufacturing process and customer relationships. The manufacturing process intangible 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, which were fully amortized at September 30, 2011 (in thousands, except years):

	Original Estimated Useful Life	Gross	Accumulated Amortization	Net

	(in Years)			
Manufacturing process	5	$ 3,670	$ (3,670)	$ 0
Customer relationships	5	1,230	(1,230)	0
Total	5	$ 4,900	$ (4,900)	$ 0

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5. Financing Agreements

On September 20, 2010, we entered into a Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $30.0 million of shares of our common stock (the Purchase Shares) over the 25-month term of the Purchase Agreement. Under the Purchase Agreement, we agreed to pay Aspire Capital a commitment fee equal to 4% of $30.0 million in consideration for Aspire Capital s obligation to purchase up to $30.0 million of our common stock. We paid this commitment fee of $1.2 million by the issuance of 600,000 shares of our common stock and this fee was recorded as a cost of raising capital and netted against the gross proceeds from the Purchase Agreement in September 2010. Upon execution of the Purchase Agreement, we sold 1,000,000 shares of common stock to Aspire Capital at a purchase price of $2.00 per share, for an aggregate purchase price of $2.0 million.

Pursuant to the Purchase Agreement, on any business day on which the closing sale price of our common stock exceeds $1.00 over the 25-month term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice directing Aspire Capital to purchase up to 150,000 Purchase Shares per business day (defined in the Purchase Agreement as any day on which the principal market is open for trading including any day on which the principal market is open for trading for a period of time less than the customary time). We and Aspire Capital may mutually agree to increase the number of shares that may be sold per business day to as much as an additional 1,000,000 Purchase Shares per business day. The purchase price per Purchase Share is the lower of (i) the lowest sale price for the common stock on the date of sale or (ii) the arithmetic average of the three lowest closing sale prices for the common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date of those securities. During the nine months ended September 30, 2011, we sold through Aspire Capital an aggregate of 9,800,000 shares of common stock for net proceeds of $24.1 million. In October 2011, we obtained the remaining $2.6 million available to us under the Purchase Agreement by the sale of 1,195,210 shares of common stock.

6. Commitments and Contingencies

We lease our facilities in Berkeley, California (the Berkeley Lease), and Düsseldorf, Germany (the Düsseldorf Lease), under operating leases that expire in September 2017 and March 2023, respectively. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease are divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. We entered into sublease agreements under the Düsseldorf Lease for a certain portion of the leased space. The sublease income is offset against our rent expense. Total net rent expense related to our operating leases, is as follows (in thousands):

	Nine Months Ended September 30,	
	2011	2010
Rent expense, net	$ 1,276	$ 1,820

Deferred rent was $0.6 million and $0.8 million as of September 30, 2011 and December 31, 2010, respectively.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2011, excluding payments from the sublease agreements, are as follows (in thousands):

Year ending December 31,	
2011 (remaining three months)	$ 451
2012	1,815
2013	1,835
2014	1,794
Thereafter	8,312
Total	$ 14,207

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, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2011 and December 31, 2010. Under the terms of the Berkeley

Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to $1.1 million, until such time as our projected cash and cash equivalents will exceed $20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20.0 million for a period of 12 consecutive months.

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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, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2011 and December 31, 2010.

As part of the consideration we transferred to Holdings for the acquisition of SDI, we are obligated to make contingent cash payments equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies. Using a discounted cash flow model, we estimated the fair value of the contingent liability to be $0.9 million as of September 30, 2011.

In connection with the exercise of our purchase of all of the outstanding equity of SDI on December 30, 2009, we issued a note to Holdings in the principal amount of $15 million. We estimated the fair value of the non-interest bearing note payable to Holdings using a net present value model using a discount rate of 17%. Imputed interest will be recorded as interest expense over the term of the loan. The principal amount of $15 million is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. If we elect to pay the note in shares of our common stock, the number of shares issued will be determined by our stock price at the date of payment.

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

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2011, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $15.7 million through 2015. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies.

7. Collaborative Research and Development Agreements

GlaxoSmithKline

In December 2008, we entered into a worldwide strategic alliance with GSK to discover, develop, and commercialize toll-like receptor (TLR) inhibitors for diseases such as lupus, psoriasis and rheumatoid arthritis. We agreed to conduct research and early clinical development in up to four programs. We are eligible to receive potential contingent development payments which we have determined to be substantive milestones. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances, and we are eligible to receive contingent option exercise payments. If GSK exercises its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales, if any, and have retained an option to co-develop and co-promote one product under this agreement.

We received an initial payment of $10 million. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. As of September 30, 2011, $6.0 million of the initial payment remains deferred. For the nine months ended September 30, 2011 and 2010, we recognized revenue of $1.1 million in each period related to the initial payment. During the nine months ended September 30, 2011, we received a milestone payment of $6.0 million for the initiation of a Phase 1 clinical trial which was recognized in full upon receipt.

In October 2011, our worldwide strategic alliance with GSK was expanded to develop a TLR8 inhibitor for the treatment of multiple autoimmune and inflammatory diseases. The addition of the TLR8 program entitled us to receive a $3.0 million milestone payment from GSK.

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AstraZeneca

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The research term of this agreement was extended through July 2010. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences (ISS). AstraZeneca has the right to sublicense its rights upon our prior consent.

We received an upfront payment of $10 million. Revenue from the upfront payment had been deferred until we amended certain indemnification obligations in our agreement with AstraZeneca which allowed for the upfront payment to be fully recognized as collaboration revenue in the third quarter of 2010. In 2008, we received a milestone payment of $4.5 million for the nomination of a candidate drug. Revenue from the milestone payment was deferred and recognized ratably over the estimated research period through July 2010. Revenue from the milestone payment was $0.8 million for the nine months ended September 30, 2010. Revenue from the performance of research services was $3.3 million for the nine months ended September 30, 2010 and immaterial for 2011.

In October 2011, we amended our agreement with AstraZeneca to allow us to manage the early clinical development on behalf of the collaboration of AZD 1419, a proprietary second-generation TLR-9 agonist for asthma. Development expenses will be funded by AstraZeneca and we will receive an initial payment of $3.0 million to begin the clinical program. Under the terms of the amended agreement, AstraZeneca will provide us with a total of approximately $20 million in payments to cover the cost of clinical development activities through Phase 2a. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a $20 million milestone payment, and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. Additionally, we are eligible to receive potential future development payments that amount to nearly $100 million, and upon commercialization, we are eligible to receive royalties based on product sales, if any. We have the option to co-promote in the United States products arising from the collaboration, if any.

National Institutes of Health and Other Funding

In September 2008, we were awarded a five-year $17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the 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 our program under Contract No. HHSN272200800038C. For the nine months ended September 30, 2011 and 2010, we recognized revenue of approximately $1.7 million and $2.1 million, respectively, related to this contract.

In August 2010, we were awarded a grant from the NIH s NIAID to take a systems biology approach to study the differences between individuals who do or do not respond to vaccination against the hepatitis B virus (HBV). This study will be one of several projects covered in a five-year, $17.6 million grant to the Baylor Institute of Immunology Research in Dallas as part of the Human Immune Phenotyping Centers program. For the nine months ended September 30, 2011 and 2010, we recognized revenue of approximately $0.5 million and $6 thousand, respectively, related to this grant.

In July 2010, we were awarded a $0.6 million grant from the NIH to explore the feasibility of developing a universal vaccine to prevent infection by human papilloma virus (HPV). For the nine months ended September 30, 2011 and 2010, we recognized revenue of approximately $0.2 million and $0.1 million, respectively, related to this grant.

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. For the nine months ended September 30, 2011 and 2010, we recognized revenue of approximately $0.1 million and $0.2 million, respectively, related to this grant.

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, options, restricted stock units and warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and equity awards to purchase 37.2 million and 32.9 million shares of common stock as of September 30, 2011 and 2010, respectively, were excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2011 and 2010 because the effect would have been anti-dilutive.

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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 net loss. Comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (15,229)	$ (4,998)	$ (44,330)	$ (42,186)
Decrease (increase) in unrealized loss on marketable securities available-for-sale	(8)	(7)	11	3
Decrease (increase) in cumulative translation adjustment	(438)	668	117	(384)
Comprehensive loss	$ (15,675)	$ (4,337)	$ (44,202)	$ (42,567)

10. Stockholders Equity

As of September 30, 2011, we had four share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program (the 2004 Plan); the 2004 Employee Stock Purchase Plan; 2010 Employment Inducement Stock Awards Plan (the 2010 Inducement Plan); and the 2011 Equity Incentive Plan (the 2011 Plan). The 1997 Equity Incentive Plan (the 1997 Plan) expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. In January 2011, our stockholders approved the 2011 Plan. The 2011 Plan provides for the issuance of up to 15,000,000 shares of our common stock to employees and non-employees of the Company and became effective on January 6, 2011. The 2011 Plan is administered by our Board of Directors (the Board), or a designated committee of the Board, and awards granted under the 2011 Plan have a term of 10 years unless earlier terminated by the Board. Upon the effectiveness of the 2011 Plan, no additional awards will be granted under either the 2004 Plan or the 2010 Inducement Plan. As of January 6, 2011, all shares currently subject to awards outstanding under the 1997 Plan, 2004 Plan or 2010 Inducement Plan that expire or are forfeited will be included in the reserve for the 2011 Plan to the extent such shares would otherwise return to such plans.

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

	Employee Stock Options				Employee Stock Purchase Plan	
	Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010	2011	2010
Weighted-average fair value per share	$ 2.36	$ 1.58	$ 2.76	$ 1.44	$ 2.19	$ 1.47
Risk-free interest rate	1.0%	1.1%	1.6%	1.8%	0.3%	0.4%
Expected life (in years)	4.0	4.0	4.0	4.0	1.2	0.9
Volatility	1.6	1.6	1.6	1.6	1.6	1.6
Expected dividends						

Expected volatility is based on historical volatility of our stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were grouped and considered separately for valuation purposes. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The dividend yield is 0% for all years and is based on our history and expectation of dividend payouts.

Compensation expense is based on awards ultimately expected to vest and reflects estimated forfeitures. For equity awards with time-based vesting, the fair value is amortized to expense on a straight-line basis over the vesting periods. For equity awards with performance-based vesting criteria, the fair value begins to be amortized to expense when the achievement of the vesting criteria becomes probable. As of

September 30, 2011, the total unrecognized compensation cost related to non-vested equity awards amounted to $9.4 million, which is expected to be recognized over the remaining weighted-average vesting period of two years and less than one year for options and restricted stock units, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Employee and director stock-based compensation expense	$ 1,286	$ 587	$ 3,933	$ 1,520
Other stock-based compensation expense	1	(1)	1	32
Total	$ 1,287	$ 586	$ 3,934	$ 1,552

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development expense	$ 528	$ 258	$ 1,571	$ 347
General and administrative expense	759	328	2,363	1,205
Total	$ 1,287	$ 586	$ 3,934	$ 1,552

Activity under the stock option plans was as follows:

	Options and Awards Available for Grant	Number of Options Outstanding	Weighted-Average Price Per Share
Balance at December 31, 2010	646,392	6,868,037	$ 3.05
2011 Plan options authorized	15,000,000	0	0
Options granted	(4,478,400)	4,478,400	$ 3.07
Options exercised	0	(54,000)	$ 1.38
Options cancelled:			
Options forfeited (unvested)	233,450	(233,450)	$ 1.82
Options expired (vested)	18,704	(18,704)	$ 5.36
Awards cancelled (unvested)	0	0	0
Balance at September 30, 2011	11,420,146	11,040,283	$ 3.09

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, 2011:

	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)	10,066,547	$ 3.13	7.39	$ 1,664,793
Options exercisable	4,120,930	$ 3.98	5.18	$ 736,655

Employee Stock Purchase Plan

As of September 30, 2011, our Employee Stock Purchase Plan (the Purchase Plan), has had the following activity to date:

	Number of Shares
Shares reserved and approved for issuance	996,000
Shares acquired	(558,140)
Shares remaining available for future purchases	437,860

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.

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The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Quarterly Report and the Consolidated Financial Statements and related Notes and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2010.

Overview

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

Our pipeline of product candidates includes: HEPLISAV; clinical-stage programs for our Universal Flu vaccine, autoimmune program partnered with GlaxoSmithKline (GSK) and hepatitis C and hepatitis B therapies; and a preclinical program partnered with AstraZeneca AB (AstraZeneca). We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. Our product candidates are based on the use of immunostimulatory and immunoregulatory sequences.

Recent Developments

HEPLISAV

In September 2011, we presented results for the entire study population of our Phase 3 trial of HEPLISAV (HBV-16) at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). HBV-16 was a multi-center, observer-blinded study to determine if the immunogenicity of two doses of HEPLISAV was non-inferior/superior to three doses of Engerix-B® by comparing seroprotection rates (SPR) at eight weeks post last dose in healthy adults over age 40. The data reported at ICAAC demonstrate HEPLISAV s ability to generate a faster, higher, and longer-lasting response as compared to Engerix-B®.

In October 2011, we presented additional data from HBV-16. The results of a prospective analysis of the diabetic subset population showed the superiority of HEPLISAV compared to Engerix-B at all measured time points. The modified intent to treat (MITT) analysis of adults with type II diabetes showed that HEPLISAV given as two doses over four weeks protected a significantly greater proportion of subjects in a shorter time and with longer-lasting protection than Engerix-B given as three doses over 24 weeks. The MITT subpopulations included all diabetic subjects that had received at least one dose of any of the four HEPLISAV lots or Engerix-B and had at least one post vaccination immunogenicity result. We also announced immunogenicity data for subpopulations known to be hypo-responsive (males, obese, and smokers) to currently licensed hepatitis B vaccines from HBV-16. The data demonstrate HEPLISAV s enhanced immune response and superiority as measured by peak SPRs for the subpopulations.

In late October 2011, we unblinded our Phase 3 primary endpoint immunogenicity data in subjects with chronic kidney disease (CKD) and reported that the data achieved statistical significance in demonstrating both the superiority and non-inferiority of HEPLISAV as compared to Engerix-B. A partial safety analysis also showed a similar safety profile for the two vaccines, with the incidence of post-injection reactions and adverse events similar in both the HEPLISAV and Engerix-B treatment groups. This Phase 3 multi-center trial evaluated 507 subjects, 18-75 years of age with CKD, as defined by a modified intent-to-treat analysis, and compared three doses of HEPLISAV given at months 0, 1 and 6 with eight doses of Engerix-B given as double-doses at months 0, 1, 2 and 6.

Also in October 2011, we reported on our regulatory approval submission strategy for HEPLISAV in the U.S. and Europe, stating that the U.S. Food and Drug Administration (the FDA) concurred with our plan to submit a Biologics License Application (BLA) for HEPLISAV for persons over 40 years of age. We plan to follow this with a supplemental BLA for licensure of a specific regimen for vaccinating CKD patients against hepatitis B infection at the time the initial application is approved. In addition, we noted that the European Medicines Agency (the EMA) advised that we could submit the primary endpoint immunogenicity data and associated safety data for the over-40 population as well as the CKD indication as part of our initial Marketing Authorization Application (the MAA) and that the outstanding CKD data can be submitted in the course of the MAA review. We expect to submit the first BLA in the first quarter of 2012 and plan to submit the MAA for European approval after the submission of our BLA in the U.S.

AstraZeneca

On October 4, 2011, we amended our agreement with AstraZeneca to allow us to manage the early clinical development on behalf of the collaboration of AZD 1419, a proprietary second-generation Toll-like Receptor-9 (TLR) agonist for asthma. Development expenses will be funded by AstraZeneca and Dynavax will receive an initial payment of $3.0 million to begin the clinical program.

Under the terms of the 2006 research collaboration and license agreement and as now amended, AstraZeneca will provide us with a total of approximately $20 million in payments to cover the cost of clinical development activities through Phase 2a. If AstraZeneca chooses to advance the program following completion of Phase 2a, we will receive a $20 million milestone payment, and AstraZeneca will retain its rights to develop the candidate therapy and to commercialize the resulting asthma product. Additional potential future development payments to us amount to nearly $100 million. We will receive royalties on worldwide sales of approved products and will have the opportunity to co-promote the product in the United States.

GlaxoSmithKline

In October 2011, our worldwide strategic alliance with GSK was expanded to develop a TLR8 inhibitor for the treatment of multiple autoimmune and inflammatory diseases. The addition of the TLR8 program entitled us to receive a $3.0 million milestone payment from GSK.

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Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, research and development activities, stock-based compensation, asset impairment, contingencies, and the valuation of certain liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2011 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010 other than the changes to our revenue recognition policy as discussed below.

Revenue Recognition

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

On January 1, 2011, we adopted on a prospective basis Accounting Standards Update (ASU) 2009-13, Multiple-Deliverable Revenue Arrangements (ASU 2009-13), which amends the criteria related to identifying separate units of accounting and provides guidance on whether multiple deliverables exist, how an arrangement should be separated and the consideration allocated. The adoption of the standard did not impact our financial position or results of operations as of and for the nine months ended September 30, 2011 as we did not enter into or materially modify any multiple-element arrangements during that period. The adoption of this standard may result in revenue recognition patterns for future agreements that are different from those recognized for our existing multiple-element arrangements.

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

On January 1, 2011, we elected to prospectively adopt ASU 2010-17, Milestone Method of Revenue Recognition (ASU 2010-17). Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone does not include events for which the occurrence is contingent solely on the passage of time or solely on a collaboration partner s performance. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones. Given the challenges inherent in developing biologic products, there was substantial uncertainty whether any such milestones would be achieved at the time we entered into these agreements. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone. The election to adopt the milestone method did not impact our financial position or results of operations as of and for the nine months ended September 30, 2011.

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

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

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

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

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

Results of Operations

Revenues

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2010 to 2011		Nine Months Ended September 30,		Increase (Decrease) from 2010 to 2011	
	2011	2010	$	%	2011	2010	$	%
Revenues:								
Collaboration revenue	$ 369	$ 10,402	$ (10,033)	(96%)	$ 7,098	$ 19,164	$ (12,066)	(63%)
Grant revenue	658	1,218	(560)	(46%)	2,437	2,697	(260)	(10%)
Service and license revenue	147	29	118	407%	652	323	329	102%
Total revenues	$ 1,174	$ 11,649	$ (10,475)	(90%)	$ 10,187	$ 22,184	$ (11,997)	(54%)

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Total revenues for the three and nine months ended September 30, 2011 decreased as compared to the same periods in 2010. The decrease was primarily due to the reduction in collaboration revenue from our asthma program and from our terminated collaboration with Merck. Collaboration revenue in the nine months ended September 30, 2010 included $4.0 million from Merck in satisfaction of its obligations for the wind down period following termination, $4.0 million from AstraZeneca for research services that completed in July 2010, and $10 million from the AstraZeneca upfront payment which had been deferred until we amended certain indemnification obligations in our agreement which allowed for the upfront payment to be fully recognized in the third quarter of 2010. The decrease was partially offset by a milestone payment of $6.0 million from GSK for the initiation of a Phase 1 clinical trial recognized in the second quarter of 2011.

Grant revenue for the three and nine months ended September 30, 2011 decreased due to expiration of the NIH grants for the development of a therapy for systemic lupus erythematosus (SLE) and preclinical development of oligonucleotide-based TLR inhibitors for use in inflammatory skin diseases.

Service and license revenue for the three months ended September 30, 2011 increased as compared to the same period in 2010 as a result of research and development service revenue for customers of Rhein Biotech GmbH (Rhein or Dynavax Europe). Service and license revenue for the nine months ended September 30, 2011 increased as compared to 2010 as a result of the timing of royalties received by Rhein and increased research and development service revenue for customers of Rhein.

Research and Development Expense

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2010 to 2011		Nine Months Ended September 30,		Increase (Decrease) from 2010 to 2011	
	2011	2010	$	%	2011	2010	$	%
Research and development:								
Compensation and related personnel costs	$ 4,862	$ 3,379	$ 1,483	44%	$ 14,063	$ 10,621	$ 3,442	32%
Outside services	4,959	8,824	(3,865)	(44%)	19,792	24,818	(5,026)	(20%)
Facility costs	1,429	1,743	(314)	(18%)	4,281	4,943	(662)	(13%)
Non-cash stock-based compensation	527	258	269	104%	1,570	347	1,223	352%
Total research and development	$ 11,777	$ 14,204	$ (2,427)	(17%)	$ 39,706	$ 40,729	$ (1,023)	(3%)

Research and development expense for the three and nine months ended September 30, 2011 decreased from the same periods in 2010 primarily due to a decline in outside services following the completion of certain clinical development activities for HEPLISAV. The decrease in research and development expense was partially offset by increases in compensation from additional headcount and non-cash stock-based compensation expense incurred for option grants with performance-based vesting criteria associated with the HEPLISAV program.

General and Administrative Expense

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

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

	Three Months Ended September 30,		Increase (Decrease) from 2010 to 2011		Nine Months Ended September 30,		Increase (Decrease) from 2010 to 2011	
	2011	2010	$	%	2011	2010	$	%
General and administrative:								
Compensation and related personnel costs	$ 1,898	$ 1,619	$ 279	17%	$ 5,516	$ 4,750	$ 766	16%
Outside services	1,051	1,082	(31)	(3%)	3,104	3,068	36	1%
Legal costs	344	649	(305)	(47%)	1,507	2,958	(1,451)	(49%)
Facility costs	190	269	(79)	(29%)	589	724	(135)	(19%)
Non-cash stock-based compensation	734	332	402	121%	2,309	1,194	1,115	93%
Total general and administrative	$ 4,217	$ 3,951	$ 266	7%	$ 13,025	$ 12,694	$ 331	3%

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General and administrative expense for the three and nine months ended September 30, 2011 was relatively consistent with 2010. Compensation costs and non-cash stock-based compensation increased due to growth in the number of administrative employees to support the overall organization and expense incurred for option grants with performance-based vesting criteria. These increases were partially offset by reductions in legal costs related to patent activities and facility costs.

Amortization of Intangible Assets

Intangible assets consist of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and were being amortized over five years from the date of acquisition. Amortization of intangible assets was $0.3 million and $0.7 million for the nine months ended September 30, 2011 and 2010, respectively. The intangible assets were fully amortized at September 30, 2011.

Interest Income, Interest Expense, and Other Income (Expense)

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

	Three Months Ended September 30,		Increase (Decrease) from 2010 to 2011		Nine Months Ended September 30,		Increase (Decrease) from 2010 to 2011	
	2011	2010	$	%	2011	2010	$	%
Interest Income	$ 18	$ 12	$ 6	50%	$ 74	$ 53	$ 21	40%
Interest Expense	(485)	(399)	86	22%	(1,462)	(1,229)	233	19%
Other Income (Expense)	58	2,140	(2,082)	(97%)	(99)	(9,036)	(8,937)	(99%)

Interest expense for the three and nine months ended September 30, 2011 increased over the same periods in 2010 due to interest accreted on the note payable to Holdings.

Other income (expense) for the three and nine months ended September 30, 2011 was comprised of the change in fair value of the contingent liability to Holdings and foreign currency translation adjustments.

Other income (expense) for the three and nine months ended September 30, 2010 primarily included the fair value of the shares and incremental fair value of the warrants provided to Symphony Capital Partners, L.P. and certain of its affiliates (together, Symphony) in April 2010, as measured upon issuance and remeasured at June 30, 2010, which resulted in non-operating expense of $11.1 million, offset by a gain of $2.1 million for the change in fair value of the long-term contingent liability in the three months ended September 30, 2010. Other income (expense) for each period also included the change in fair value of the contingent liability to Holdings and foreign currency translation adjustments.

Recent Accounting Pronouncements

Accounting Standards Update 2011-05

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income which was issued to enhance comparability between entities that report under U.S. GAAP and International Financial Reporting Standards (IFRS), and to provide a more consistent method of presenting non-owner transactions that affect an entity s equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. We do not expect that the adoption of this ASU will have any material impact on our results of operations or financial position.

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Accounting Standards Update 2011-04

In May 2011, the FASB issued ASU No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. We are currently evaluating the impact, if any, that the adoption of this pronouncement may have on our results of operations or financial position.

Liquidity and Capital Resources

As of September 30, 2011, we had $53.2 million in cash, cash equivalents and marketable securities. Our funds are currently invested in short-term money market funds, U.S. government agency securities and corporate obligations.

Cash used in operating activities was $41.8 million during the nine months ended September 30, 2011 compared to $33.5 million for the same period in 2010. The increase in cash usage compared to the prior year was due primarily to the net loss and payments of liabilities.

Cash provided by investing activities was $14.1 million during the nine months ended September 30, 2011 compared to cash used in investing activities of $19.3 million for the same period in 2010. The increase was attributed to the net proceeds from maturities of marketable securities.

Cash provided by financing activities was $24.4 million during the nine months ended September 30, 2011 compared to cash provided of $44.3 million for the same period in 2010. During the nine months ended September 30, 2011, we sold 9,800,000 shares of common stock under our Purchase Agreement with Aspire Capital for net proceeds of $24.1 million. In October 2011, we obtained the remaining $2.6 million available to us under the Purchase Agreement by the sale of 1,195,210 shares of common stock. During the first half of 2010, we completed a public offering which resulted in net proceeds of $41.1 million.

We expect to continue to spend substantial funds in connection with development and manufacturing of our product candidates, particularly HEPLISAV; various human clinical trials for our product candidates; and protection of our intellectual property. In order to continue development of our product candidates, particularly HEPLISAV, we will need to raise additional funds. This may occur through future public or private financings and/or strategic alliance and licensing arrangements. Sufficient funding may not be available on acceptable terms or at all. Additionally equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we would need to delay, reduce the scope of, or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

We currently estimate that we will have sufficient cash resources to meet our cash needs through the next 12 months based on cash and cash equivalents and marketable securities on hand at September 30, 2011 anticipated revenues and funding from existing agreements. We note that our independent registered public accounting firm included in their audit opinion on our consolidated financial statements for the fiscal year ended December 31, 2010, a statement with respect to substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

Contractual Obligations

The following summarizes our significant contractual obligations as of September 30, 2011 and the effect those obligations are expected to have on our liquidity and cash flows 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 leases, excluding payments from sublease agreements	$ 14,207	$ 451	$ 5,444	$ 3,698	$ 4,614
Long-term note payable to Symphony Dynamo Holdings	15,000		15,000		

Total	$ 29,207	$ 451	$ 20,444	$ 3,698	$ 4,614

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

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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, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2011 and December 31, 2010. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below $20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to $1.1 million, until such time as our projected cash and cash equivalents will exceed $20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above $20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of $0.3 million. The letter of credit remained outstanding as of September 30, 2011 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of September 30, 2011 and December 31, 2010.

In connection with the exercise of our purchase of all of the outstanding equity of SDI on December 30, 2009, we issued a note to Holdings in the principal amount of $15 million. We estimated the fair value of the non-interest bearing note payable to Holdings using a net present value model using a discount rate of 17%. Imputed interest will be recorded as interest expense over the term of the loan. The principal amount of $15 million is due on December 31, 2012 and is payable in cash, our common stock or a combination thereof at our discretion. If we elect to pay the note in shares of our common stock, the number of shares issued will be determined by our stock price at the date of payment.

As part of the consideration transferred from Dynavax to Holdings for the acquisition of SDI, we are obligated to make contingent cash payments equal to 50% of the first $50 million from any upfront, pre-commercialization milestone or similar payments received by us from any agreement with any third party with respect to the development and/or commercialization of the cancer and hepatitis C therapies. Using a discounted cash flow model, we estimated the fair value of the contingent liability to be $0.9 million as of September 30, 2011.

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

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2011, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately $15.7 million through 2015. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract through the notice period.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies, if any.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined by rules enacted by the Securities and Exchange Commission and accordingly, no such arrangements are likely to have a current or future effect on our financial position.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

Foreign Currency Risk. We have certain investments outside the U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of

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September 30, 2011 was a negative $0.6 million primarily related to translation of Dynavax Europe assets, liabilities and operating results from Euros to U.S. dollars. To date, the effect of our exposure to these exchange rate fluctuations has not been material, and we do not expect it to become material in the foreseeable future. We do not hedge our foreign currency exposures and have not used derivative financial instruments for speculation or trading purposes.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

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

(b) Changes in internal controls

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

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks Related to our Finances and Capital Requirements

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $361.3 million as of September 30, 2011. To date, our revenue has resulted from collaboration agreements, services and license fees from our customers and customers of Rhein Biotech GmbH (Rhein or Dynavax Europe), and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities.

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

Clinical trials for certain of our product candidates other than HEPLISAV are ongoing, and our other product candidates may never be commercialized or achieve profitability. Our ability to generate revenue depends upon demonstrating in clinical trials that our product candidates are safe and effective, obtaining regulatory approvals for our product candidates and entering into and maintaining successful collaborative relationships.

We expect to continue to incur substantial operating losses as we complete our Phase 3 clinical trials of HEPLISAV in support of regulatory filings, add infrastructure and operations to support commercialization of HEPLISAV, and potentially begin new research and development programs. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our product candidate, HEPLISAV. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize HEPLISAV, we may never be able to commercialize any future product candidates.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms. Additionally, if we continue to incur substantial additional net losses without additional equity funding, we will continue to deplete our stockholders equity, and if such equity balance falls below the listing requirement threshold of $2.5 million for the NASDAQ Capital Market, we may be delisted.

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

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

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

various human clinical trials for our product candidates; and

protection of our intellectual property.

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We currently estimate that we have will sufficient resources to meet our anticipated cash needs through the next 12 months based on cash and cash equivalents and marketable securities on hand at September 30, 2011 and anticipated revenues and funding from existing agreements.

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

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

Our independent registered public accounting firm included in their audit opinion on our consolidated financial statements for the year ended December 31, 2010 a statement with respect to substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

Risks Related to our Business

The success of our product candidates depends on timely achievement of successful clinical results and adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use and regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the U.S. Food and Drug Administration (FDA) and by foreign regulatory agencies. Our success is primarily dependent on our ability to timely enroll patients in clinical trials, achieve successful clinical results, provide adequate evidence of a product manufactured by a well-controlled process that is safe and effective for its intended use and obtain regulatory approvals for our most advanced product candidates. Approval processes in the United States and in other countries are uncertain, can take many years and require the expenditure of substantial resources.

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

Failure to timely and successfully complete clinical trials, show that our products are safe and effective and timely file and receive approval for our BLA would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product may restrict to whom we and our partners may market the product or in the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

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

HEPLISAV and most of our earlier stage programs rely on immunostimulatory sequences (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.

HEPLISAV is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. For example, from March 2008 until September 2009, the two investigational new drug (IND) applications for HEPLISAV were placed on clinical hold by the FDA following a serious adverse event that occurred in one of our clinical trials. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease but the other IND application for HEPLISAV remains on clinical hold. In addition, most of our clinical product candidates contain ISS, and if a common safety risk across therapeutic areas were identified, it 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 have no commercialization experience, and the time and resources to develop sales, marketing and distribution capabilities for HEPLISAV is significant. If we fail to achieve and sustain commercial success for HEPLISAV, our business would be harmed.

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

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to expand and sustain qualified manufacturing capacity to meet demand, in particular if there is significant increase in demand due to the recommendation to vaccinate persons with diabetes if we should obtain approval to market to those patients;
- our inability to determine appropriate pricing and reimbursement strategies for HEPLISAV in the potential patient populations that may use HEPLISAV, particularly in the diabetes market; and

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

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

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

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

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

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

result in significant additional costs;

potentially diminish any competitive advantages for those products;

potentially limit the markets for those products;

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

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

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

We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials which they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our products and could have a material adverse effect on our business and operations.

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

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

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

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We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations. We may not be able to comply with these and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates and could result in significant expense. Moreover, if our HEPLISAV clinical trials are sufficient for approval and depending on the level of market acceptance of the product, we likely would not have the capacity in our existing facility to meet all of our commercial supply needs in the future. For example, the recent ACIP recommendation that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age could significantly increase the market demand for HEPLISAV. Our current manufacturing capacity could supply up to approximately 2 million doses of HEPLISAV annually, which may not be sufficient to meet demand. Our ability to expand manufacturing capacity by improving utilization in our existing facility, improve upon our current production yields or by using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity plans, we may experience a shortage in our ability to timely supply HEPLISAV and our clinical candidates, which could have a material adverse effect on the success of HEPLISAV and our other product candidates.

If HEPLISAV cannot be successfully developed or is not commercially viable, we will have to use the Düsseldorf facility for alternative manufacturing or research activities that may not fully utilize the facility s capacity, resulting in continued operating costs that may not be offset by corresponding revenues.

We may also consider other alternatives for the Düsseldorf facility, including its sale or closure, which would result in certain costs of disposal or discontinuation of operations. Discontinuation of operations in Düsseldorf would be complex, expensive, time-consuming and difficult to execute without significant additional costs due to, among other things, international legal and tax considerations related to those operations. As a result, we may not realize cost savings associated with a potential closure of the Düsseldorf operations, 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.

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

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

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

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.

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

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

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- regional and geopolitical risks.

To date, we have not filed for marketing approval for any of our product candidates outside the United States. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

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

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

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

the indication for which the product is approved and its approved labeling;

the presence of other competing approved therapies;

the potential advantages of the product over existing and future treatment methods;

the relative convenience and ease of administration of the product;

the strength of our sales, marketing and distribution support;

the price and cost-effectiveness of the product; and

sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. For example, in connection with the removal of the clinical hold on HEPLISAV in September 2009 and related discussions with the FDA, it is expected that further development of HEPLISAV in the United States initially will be limited to individuals who are less responsive to current licensed vaccines, including adults over 40 years of age and individuals with chronic kidney disease. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV where existing products are approved for our target indications. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and

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services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments.

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

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV. Failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union, may significantly impair the potential for this product and our ability to successfully develop, manufacture and commercialize HEPLISAV as a product candidate. We also will need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;
- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future event payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals, successfully manufacture, and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

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

our partners may not comply with applicable government regulatory requirements.

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

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

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

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Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. 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, general and administrative support, 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. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific, manufacturing, sales, marketing, general and administrative and management personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives. 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.

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

Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer, Dr. Dino Dina, or our President, Dr. J. Tyler Martin. We currently have no key person insurance on any of our employees.

We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product s safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management s attention from our business and could result in significant financial liability.

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

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

Risks Related to our Intellectual Property

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

Our current research and development efforts depend upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual

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property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments in order to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are not able to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In addition, we must make timely payments or meet diligence obligations in order to maintain any such licenses in effect. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party s patents, which may not be possible or could require substantial funds and time.

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

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

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

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV or any similar product candidate, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

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

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the 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.

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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.

Risks Related to an Investment in our Common Stock

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

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

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

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

our ability to raise additional capital to fund our operations;

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

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

our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;

our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;

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

issuance of new or changed securities analysts reports or recommendations;

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

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

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the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility. We may in the future be the target of such litigation. Securities litigation could result in substantial costs, and divert management s attention and resources, which could harm our business, operating results and financial condition.

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

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

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

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

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

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

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

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

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

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

price of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 30, 2011, we had 125,611,037 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

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We also have filed registration statements on Form S-3 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under the Purchase Agreement, the warrants issued as part of our public offering closed in April 2010, the warrants issued to Symphony Dynamo Holdings LLC (Holdings) in connection with our acquisition of SDI in December 2009, and warrants issued to Deerfield Management in connection with the July 2007 Loan Agreement.

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

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

Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, Symphony) currently collectively control approximately 9,031,431 shares of our common stock and warrants to purchase approximately 4,515,717 shares of our common stock. Based on the number of shares of our common stock that are outstanding as of September 30, 2011, Symphony owns approximately 7% of our total outstanding shares of our common stock. If Symphony exercises all of the warrants held by it and assuming no other issuances of our common stock, Symphony would own approximately 10.4% of our total outstanding shares of common stock as of September 30, 2011. In addition, Holdings, an affiliate of Symphony, holds a promissory note in the principal amount of $15 million, which may be satisfied in cash, Dynavax common stock or a combination of cash and Dynavax common stock, at our election. Finally, under the terms of the Standstill and Corporate Governance Letter Agreement we entered into with Holdings on December 30, 2009, for as long as Holdings and its affiliates, which include Symphony, beneficially own 10% or more of our outstanding common stock, we agreed to use our commercially reasonable efforts to cause to be elected and remain as directors on our Board of Directors one individual designated by Holdings and a second individual who shall be an independent third party designated by Holdings and reasonably acceptable to us. Holdings designated Mark Kessel, a partner of Symphony Capital LLC, as its designee and Mr. Kessel has been appointed to our Board of Directors. On July 22, 2010, the Board of Directors nominated Daniel L. Kisner, M.D. to the Board of Directors as the independent third party designee. As a result, Symphony, Holdings and their affiliates will be able to exercise substantial influence over the direction of the Company.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Document
3.1[(1)]	Sixth Amended and Restated Certificate of Incorporation
3.2[(2)]	Amended and Restated Bylaws
3.3[(3)]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4[(4)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5[(5)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2[(6)]	Registration Rights Agreement
4.3[(6)]	Form of Warrant
4.4[(7)]	Form of Specimen Common Stock Certificate
4.5[(3)]	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC
4.6[(3)]	Form of Rights Certificate
4.7[(8)]	Form of Restricted Stock Unit Award Agreement.
4.8[(9)]	Form of Amended Warrant
4.9[(10)]	Form of Warrant
4.10[(11)]	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
10.30	Agreement dated September 1, 2006, by and between the Company and AstraZeneca AB.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Quarterly Report on Form 10-Q for the period ended September 30, 2005, as filed with the SEC on November 14, 2005.

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

(4) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 4, 2010.

(5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 5, 2011.

(6) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

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(7) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

(8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC.

(9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K, as filed with the SEC on March 16, 2010.

(10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 13, 2010.

(11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on September 20, 2010.

* Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.

Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Commission.

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EXHIBIT INDEX

Exhibit Number	Document
3.1[(1)]	Sixth Amended and Restated Certificate of Incorporation
3.2[(2)]	Amended and Restated Bylaws
3.3[(3)]	Form of Certificate of Designation of Series A Junior Participating Preferred Stock
3.4[(4)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.5[(5)]	Certificate of Amendment of Amended and Restated Certificate of Incorporation
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5 above.
4.2[(6)]	Registration Rights Agreement
4.3[(6)]	Form of Warrant
4.4[(7)]	Form of Specimen Common Stock Certificate
4.5[(3)]	Rights Agreement dated as of November 5, 2008, by and between Dynavax Technologies Corporation and Mellon Investor Services LLC
4.6[(3)]	Form of Rights Certificate
4.7[(8)]	Form of Restricted Stock Unit Award Agreement.
4.8[(9)]	Form of Amended Warrant
4.9[(10)]	Form of Warrant
4.10[(11)]	Registration Rights Agreement dated as of September 20, 2010, by and between Dynavax Technologies Corporation and Aspire Capital Fund, LLC.
10.30	Agreement dated September 1, 2006, by and between the Company and AstraZeneca AB.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(2) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, as filed with the SEC on November 14, 2005.

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

(4)

Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 4, 2010.

(5) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on January 5, 2011.

(6) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-145836) on Form S-3 filed on August 31, 2007.

(7) Incorporated by reference to Dynavax Technologies Corporation s Registration Statement (File No. 333-109965) on Form S-1 filed on January 16, 2004.

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(8) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC.

(9) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Annual Report on Form 10-K, as filed with the SEC on March 16, 2010.

(10) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on April 13, 2010.

(11) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax Technologies Corporation s Current Report on Form 8-K, as filed with the SEC on September 20, 2010.

* Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, are deemed not filed for purposes of section 18 of the Exchange Act and otherwise are not subject to liability under these sections.

Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Commission.

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SIGNATURES

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: October 31, 2011

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

Date: October 31, 2011

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