

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

November 03, 2006

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2006**

**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: 000-24647**

**Dynavax Technologies Corporation**

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

**Delaware**

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

**33-0728374**

*(IRS Employer  
Identification No.)*

**2929 Seventh Street, Suite 100  
Berkeley, CA 94710-2753  
(510) 848-5100**

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

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒  
As of October 31, 2006, the registrant had outstanding 37,939,673 shares of common stock.

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**DYNAVAX TECHNOLOGIES CORPORATION**

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**FORWARD-LOOKING STATEMENTS**

*This Quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. Our forward-looking statements include discussions regarding our business and financing strategies, future research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the introduction of our products, uncertainty regarding our future operating results and prospects for profitability. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in*

*Item 1A Risk Factors and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.*

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

	<b>September 30, 2006 (unaudited)</b>	<b>December 31, 2005 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,951	\$ 8,725
Marketable securities	25,243	66,385
Investments held by Symphony Dynamo, Inc.	17,727	
Restricted cash	408	408
Accounts receivable	1,885	689
Prepaid expenses and other current assets	1,117	1,277
Total current assets	62,331	77,484
Property and equipment, net	4,918	2,197
Goodwill	2,312	
Other intangible assets, net	4,633	
Other assets	1,304	412
Total assets	\$ 75,498	\$ 80,093
<b>Liabilities, noncontrolling interest and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,108	\$ 952
Accrued liabilities	6,930	3,841
Deferred revenues	1,427	750
Total current liabilities	11,465	5,543
Deferred revenues, noncurrent	10,000	
Other long-term liabilities	135	187
Noncontrolling interest in Symphony Dynamo, Inc.	6,457	
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2006 and December 31, 2005		
Common stock: \$0.001 par value; 100,000 shares authorized at September 30, 2006 and December 31, 2005; 30,658 and 30,482 shares	31	30

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issued and outstanding at September 30, 2006 and December 31, 2005,  
respectively

Additional paid-in capital	198,809	192,840
Deferred stock compensation		(2,467)
Accumulated other comprehensive gain (loss):		
Unrealized gain (loss) on marketable securities available-for-sale	7	(144)
Cumulative translation adjustment	82	(5)
Accumulated other comprehensive gain (loss)	89	(149)
Accumulated deficit	(151,488)	(115,891)
Total stockholders' equity	47,441	74,363
Total liabilities, noncontrolling interest and stockholders' equity	\$ 75,498	\$ 80,093

*See accompanying notes.*

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**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Operations**  
(In thousands, except per share amounts)  
(Unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Revenues:				
Collaboration revenue	\$ 166	\$	\$ 166	\$ 12,199
Services and license revenue	692		916	
Grant revenue	734	404	1,327	1,856
Total revenues	1,592	404	2,409	14,055
Operating expenses:				
Research and development	12,781	6,797	30,135	19,945
General and administrative	4,656	2,319	10,639	7,132
Acquired in-process research and development			4,180	
Amortization of intangible assets	251		447	
Total operating expenses	17,688	9,116	45,401	27,077
Loss from operations	(16,096)	(8,712)	(42,992)	(13,022)
Interest and other income, net	673	428	2,093	1,229
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(15,423)	(8,284)	(40,899)	(11,793)
Loss attributed to noncontrolling interest in Symphony Dynamo, Inc.	3,271		5,302	
Net loss	\$ (12,152)	\$ (8,284)	\$ (35,597)	\$ (11,793)
Basic and diluted net loss per share	\$ (0.40)	\$ (0.33)	\$ (1.17)	\$ (0.48)
Shares used to compute basic and diluted net loss per share	30,605	24,751	30,551	24,740

*See accompanying notes.*

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

	<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>Operating activities</b>		
Net loss	\$ (35,597)	\$ (11,793)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	797	578
Loss attributed to noncontrolling interest in Symphony Dynamo, Inc.	(5,302)	
Acquired in-process research and development	4,180	
Amortization of intangible assets	447	
Gain on disposal of property and equipment	(50)	
Accretion and amortization on marketable securities	152	850
Realized loss on sale of marketable securities	23	
Interest accrued on notes receivable from stockholders		(16)
Stock-based compensation expense	2,366	961
Changes in operating assets and liabilities:		
Accounts receivable	(707)	2,070
Prepaid expenses and other current assets	160	(410)
Other assets	(507)	(10)
Accounts payable	1,933	868
Accrued liabilities	2,035	(461)
Deferred revenues	10,511	(7,000)
Net cash used in operating activities	(19,559)	(14,363)
<b>Investing activities</b>		
Purchases of investments held by Symphony Dynamo, Inc.	(17,727)	
Cash paid for acquisition, net of cash acquired	(14,045)	
Purchases of marketable securities	(19,627)	(39,203)
Maturities and sales of marketable securities	60,745	56,052
Purchases of property and equipment	(478)	(452)
Net cash provided by investing activities	8,868	16,397
<b>Financing activities</b>		
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Dynamo, Inc., net of fees	17,405	
Proceeds from employee stock purchase plan	114	115
Exercise of stock options	311	6
Repayment of notes receivable from stockholders		427
Net cash provided by financing activities	17,830	548

Effect of exchange rate on cash and cash equivalents	87	(4)
Net increase in cash and cash equivalents	7,226	2,578
Cash and cash equivalents at beginning of period	8,725	16,590
Cash and cash equivalents at end of period	\$ 15,951	\$ 19,168

**Supplemental disclosure of non-cash investing and financing activities**

Warrants issued in conjunction with the Symphony Dynamo, Inc. transaction	\$ 5,646	\$
Change in unrealized loss on marketable securities	\$ 151	\$ 6
Change in cumulative translation adjustment	\$ 87	\$ (4)
Disposal of fully depreciated property and equipment	\$ 255	\$
Exercise of stock options	\$	\$ 200
Repurchase of common stock for exercise of stock options	\$	\$ (200)

*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, or Dynavax or the Company, is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent allergies, infectious diseases, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

**Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which the Company considers 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. The condensed consolidated balance sheet at December 31, 2005 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2005 as filed with the Securities and Exchange Commission, or SEC, on March 16, 2006, as amended by Amendment No. 1 filed on August 4, 2006.

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries as well as a variable interest entity, Symphony Dynamo, Inc., for which we are the primary beneficiary as defined by Financial Accounting Standards Board, or FASB, Interpretation No. 46 (revised 2003),

Consolidation of Variable Interest Entities, or FIN 46R. All significant intercompany accounts and transactions have been eliminated. The Company operates in one business segment, which is the discovery and development of biopharmaceutical products.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

**Critical Accounting Policies**

The Company believes that there have been no significant changes in its critical accounting policies during the nine months ended September 30, 2006 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2005, except as discussed below.

***Revenue Recognition***

We recognize revenue from collaborative agreements, the performance of research and development and contract manufacturing services, royalty and license fees and grants. 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 collectibility is reasonably assured.

Revenues from collaboration and research and development service agreements are recognized as work is performed. Any upfront fees or amounts received in advance of performance are recorded as deferred revenue and recognized as earned over the estimated term of the performance obligation. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations and milestones has been nonrefundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer. Revenues from license fees and royalty payments are recognized when earned; up-front



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nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured.

Grant 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. Any amounts received in advance of performance are recorded as deferred revenue until earned.

### *Stock-Based Compensation*

On January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, Share-Based Payment, or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

### *Acquired In-process Research and Development*

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To assist in determining the value of the acquired in-process research and development, or in-process R&D, and certain other intangibles associated with the Rhein Biotech GmbH transaction discussed in Note 2, we obtained a third party valuation as of the acquisition date. We used the income approach and the cost approach to value in-process research and development. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for distribution to the investors in the asset. We perform a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. The cost approach is based on the theory that a prudent investor would pay no more than the cost of constructing a similar asset of like utility at prices applicable at the time of the appraisal. We estimate the costs involved in re-creating the technology using the historical cost and effort applied to the development of the technology prior to the valuation date. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process R&D and other intangibles is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

### *Goodwill and Other Intangible Assets*

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

### *Valuation of Long-lived Assets*

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

- significant changes in the strategy for our overall business;

significant underperformance relative to expected historical or projected future operating results;

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significant changes in the manner of our use of acquired assets;

significant negative industry or economic trends;

significant decline in our stock price for a sustained period; and

our market capitalization relative to net book value.

Determination of recoverability is based on an estimate of undiscounted cash flows resulting from the use of the asset and its eventual disposition.

*Consolidation of Variable Interest Entities*

Under FIN 46R, Consolidation of Variable Interest Entities, arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities, or VIEs. An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

Based on the provisions of FIN 46R, we have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Our consolidated financial statements include the accounts of Symphony Dynamo, Inc. discussed in Note 4.

**2. Acquisition of Rhein Biotech GmbH**

On April 21, 2006, the Company completed the acquisition of Rhein Biotech GmbH, or Rhein, from Rhein Biotech NV, a subsidiary of Berna Biotech AG, or Berna. As a result, the financial position and results of operations of Rhein have been included in our condensed consolidated financial statements as of September 30, 2006 and for the period from April 22, 2006 through September 30, 2006. Rhein, located in Düsseldorf, Germany, became a wholly-owned subsidiary which the Company refers to as Dynavax Europe. Through this acquisition, Dynavax gained ownership of a current Good Manufacturing Practice, or GMP,-certified vaccine manufacturing facility in the European Union, control over the production and supply of its hepatitis B surface antigen and potentially other antigens to support clinical and commercial programs, management and personnel with expertise in biopharmaceutical product development and production and a complementary pipeline of vaccine and antiviral products. Upon closing of the transaction, Dynavax's license and supply agreement with Berna for the supply of hepatitis B surface antigen used in the Company's HEPLISAV vaccine was terminated, eliminating Berna's option to commercialize HEPLISAV.

Under the terms of the transaction, the Company purchased all of the outstanding capital stock of Rhein, which included the satisfaction of outstanding debt and certain employee and acquisition costs for an aggregate purchase price of approximately \$14.6 million. The components of the purchase price are summarized in the following table (in thousands):

**Consideration and acquisition costs:**

Cash paid for common stock	\$ 7,925
Cash paid to satisfy outstanding debt	4,550
Employee costs	745
Acquisition costs	1,338
Total purchase price	\$ 14,558

Under the purchase method of accounting, the total purchase price is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of the acquisition. Certain purchase accounting adjustments were made in order to state the tangible assets acquired and liabilities

assumed at their estimated fair values and in accordance with the Company's accounting policies and U.S. generally accepted accounting principles. These adjustments primarily impacted deferred revenue and acquired property and equipment. The Company utilized a third party valuation expert to assess the fair value of the identifiable intangible assets acquired, as well as in-process research and development. The purchase price was allocated using information available at the time of acquisition. The Company may adjust the preliminary purchase price relating to goodwill,

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intangible assets and in-process R&D after obtaining more information regarding, among other things, asset valuations, liabilities assumed and revisions of preliminary estimates. The excess of purchase price over the aggregate fair values was recorded as goodwill.

The preliminary allocation of the total purchase price is as follows (in thousands):

**Allocation of purchase price:**

Cash and cash equivalents	\$ 513
Accounts receivable	489
Other current assets	385
Property, plant and equipment	3,092
Goodwill	2,312
Intangible assets	5,080
In-process research and development	4,180
Accounts payable	(273)
Deferred revenue	(166)
Other current liabilities	(1,054)
Total purchase price	\$ 14,558

Intangible assets consist primarily of manufacturing process, customer relationships, and developed technology. The manufacturing process derives from the methods for making proteins in *Hansenula* yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. The developed technology derives from a licensed hepatitis B vaccine product. 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 acquired as part of the acquisition (in thousands, except years):

	<b>Estimated Useful Life (in Years)</b>	<b>Amount</b>
<b>Intangible Assets</b>		
Manufacturing process	5	\$ 3,670
Customer relationships	5	1,230
Developed technology	7	180
Total		\$ 5,080

The following tables present details of the Company's total purchased intangible assets (in thousands):

<b>September 30, 2006</b>	<b>Gross</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Manufacturing process	\$ 3,670	\$ 326	\$ 3,344
Customer relationships	1,230	109	1,121
Developed technology	180	12	168
Total	\$ 5,080	\$ 447	\$ 4,633

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

**Year ending December 31,**

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2006 (remaining three months)	\$ 251
2007	1,006
2008	1,006
2009	1,006
2010	1,005
Thereafter	359
Total	\$ 4,633

The Company's methodology for allocating the purchase price to in-process R&D is determined through established valuation techniques in the biotechnology industry. In-process R&D is expensed upon acquisition because technological feasibility has not been established at that date and no future alternative uses exist. Total in-process R&D expense was \$4.2 million for the nine months ended September 30, 2006.

The unaudited financial information in the table below summarizes the combined results of operations of Dynavax and Rhein, on a proforma basis, as though the companies had been combined as of January 1, 2006 and 2005. The proforma financial information is

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presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of each of the periods presented. The proforma financial information for the nine months ended September 30, 2006 includes a charge for the write off of in-process R&D. The proforma financial information for all periods presented also includes the purchase accounting adjustments on Rhein's revenue, adjustments to depreciation on acquired property and equipment, and amortization charges from acquired intangible assets.

The following table summarizes the unaudited proforma financial information (in thousands, except per share amounts):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Revenues	\$ 1,592	\$ 1,096	\$ 3,095	\$ 16,278
Net loss	\$(12,152)	\$(9,550)	\$(37,885)	\$(15,457)
Basic and diluted earnings per share	\$ (0.40)	\$ (0.39)	\$ (1.24)	\$ (0.62)

**3. Collaborative Research and Development Agreements**

In September 2006, we entered into a 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, or COPD. The collaboration will use our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, Dynavax and AstraZeneca will collaborate to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca will be responsible for any development and worldwide commercialization of products arising out of the research program. Dynavax may also have the opportunity to co-promote in the United States products arising from the collaboration. The financial terms of the collaboration include an upfront fee of \$10 million plus research funding and preclinical milestones that could bring the total committed funding to \$27 million. The total potential deal value including future development milestones approximates \$136 million. Upon commercialization, Dynavax is also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$0.2 million for the quarter ended September 30, 2006. As of September 30, 2006, the Company recorded deferred revenue of \$10.6 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

In March 2005, the Company agreed to end its collaboration with UCB Farchim, S.A., or UCB, and regained full rights to its allergy program. During the second quarter of 2005, the Company received cash payments in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the collaboration. Collaboration revenue for the nine months ended September 30, 2005 included accelerated recognition of \$7.0 million in deferred revenue as the Company had no ongoing obligations under the collaboration. Collaboration revenue from UCB amounted to \$12.2 million during the nine months ended September 30, 2005.

In 2004, the Company was awarded \$0.5 million from the Alliance for Lupus Research to be received during 2005 and 2006 to fund research and development of new treatment approaches for lupus. For the nine months ended September 30, 2006 and 2005, the Company recognized revenue of approximately \$0.1 million and \$0.2 million, respectively, associated with the lupus grant.

In 2003, the Company was awarded government grants totaling \$8.3 million to be received over as long as three and one-half years, assuming annual review criteria are met, to fund research and development of certain biodefense programs. Revenue associated with these grants is recognized as the related expenses are incurred. For the three months ended September 30, 2006 and 2005, the Company recognized revenue of approximately \$0.6 million and \$0.3 million, respectively, associated with government grants for biodefense programs. For the nine months ended September 30, 2006 and 2005, the Company recognized revenue of approximately \$1.2 million and \$1.7 million, respectively.

**4. Symphony Dynamo, Inc.**

On April 18, 2006, the Company entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, Symphony Dynamo, Inc., or SDI, has agreed to invest \$50.0 million to fund the clinical development of these programs and we have licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We continue to be primarily responsible for the development of these programs.

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In accordance with FIN 46R, we have determined that SDI is a variable interest entity for which we are the primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our condensed consolidated financial statements as of September 30, 2006 and for the period from April 18, 2006 through September 30, 2006. Accordingly, the investments held by SDI and noncontrolling interest in SDI in the condensed consolidated balance sheet include the initial \$20.0 million of funding, less funds spent to date on the development of the programs. The noncontrolling interest in SDI, which will continue to be reduced by SDI's losses, was also reduced initially by (i) the structuring fee and other closing costs of \$2.6 million, and (ii) the value assigned to the warrants issued to Holdings upon closing of \$5.6 million.

Collaboration funding for SDI programs was \$5.3 million for the period from April 18, 2006 through September 30, 2006. Collaboration funding, net of certain administrative expenses incurred and interest income earned by SDI, is reflected in the loss attributed to the noncontrolling interest in SDI.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of Dynavax common stock at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant issued upon closing was assigned a value of \$5.6 million using the Black-Scholes valuation model, which has been recorded as a reduction in the noncontrolling interest in SDI and an increase in additional paid in capital.

In consideration for the warrant, Dynavax received an exclusive purchase option, or the Purchase Option, to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at Dynavax's sole discretion. Dynavax also has an option to purchase either the hepatitis B or hepatitis C program, or the Program Option, during the first year of the agreement. The Program Option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If the Company does not exercise its exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

**5. Commitments**

The Company leases its facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and August 2009, respectively. The Berkeley Lease can be terminated at no cost to the Company in September 2009 but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the condensed consolidated balance sheets as of September 30, 2006 and December 31, 2005. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2009. Total net rent expense related to our operating leases for the nine months ended September 30, 2006 and 2005, was \$1.3 million and \$1.1 million, respectively. Deferred rent was \$0.2 million as of September 30, 2006.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to the Company totaling \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2006, excluding payments from the sublease agreement, are as follows (in thousands):

**Year ending December 31,**

2006	\$ 433
2007	1,755
2008	1,808

2009	1,230
	\$ 5,226

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, 2006 and is collateralized by a certificate of

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deposit which has been included in restricted cash in the condensed consolidated balance sheets as of September 30, 2006 and December 31, 2005. 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.

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, the Company 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, 2006, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$30 million through 2008. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

The Company entered into a series of exclusive license agreements with the Regents of the University of California in March 1997 and October 1998. These agreements provide the Company with certain technology and related patent rights and materials related to ISS, TNF-alpha inhibitors, vaccines using DNA and immunoregulatory sequences. Under the terms of the agreements, the Company pays annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies.

On April 21, 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to a hepatitis B vaccine. In exchange, Rhein will be required to pay Green Cross a certain profit share until Green Cross's development costs for the product are recouped and a certain profit share for a specified period of time.

In December 2004, Rhein entered into a joint venture agreement under which it is obligated to perform research and development services up to a maximum of 1.5 million Euro, or approximately \$2.0 million, related to the development of a vaccine for cytomegalovirus. As of September 30, 2006, the remaining obligation was approximately \$0.9 million.

**6. 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 potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase and incremental common shares issuable upon the exercise of stock options and warrants are considered to be potentially dilutive common shares and are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Numerator:				
Net loss	(12,152)	(8,284)	(35,597)	(11,793)
Denominator:				
Weighted-average common shares outstanding used for basic and diluted net loss per share	30,605	24,751	30,551	24,740



**Table of Contents****7. Stockholders Equity**

As of September 30, 2006, the Company had three share-based compensation plans: the 1997 Equity Incentive Plan; the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan.

Prior to January 1, 2006, the Company accounted for its share-based compensation plans under the recognition and measurement provisions of APB Opinion No. 25, Accounting for Stock Issued to Employees, or APB 25, and related interpretations, as permitted by FASB Statement No. 123, Accounting for Stock-Based Compensation, or FAS 123. On January 1, 2006, the Company adopted the fair value recognition provisions of FAS 123R using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

As a result of the adoption of FAS 123R, the Company reduced its deferred stock compensation balance and additional paid in capital previously associated with APB 25 accounting by \$2.5 million as of January 1, 2006. Also as a result of adopting FAS 123R, the Company's net loss for the three and nine months ended September 30, 2006 are higher by \$0.7 million and \$1.5 million, respectively, than if the Company had continued to account for share-based compensation under APB 25. Basic and diluted net loss per share for the three and nine months ended September 30, 2006 are higher by \$0.02 and \$0.05, respectively, than if the Company had continued to account for share-based compensation under APB 25.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of FAS 123 to options granted under the Company's share-based compensation plans during the three and nine months ended September 30, 2005 (in thousands, except per share amounts). For purposes of this proforma disclosure, the fair value of the options is estimated using the Black-Scholes option valuation model and amortized to expense on a straight-line basis over the vesting periods of the options.

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
Net loss, as reported	\$ (8,284)	\$ (11,793)
Add: Stock-based employee compensation expense included in net loss	307	975
Less: Stock-based employee compensation expense determined under the fair value based method	(739)	(2,156)
Net loss, proforma	\$ (8,716)	\$ (12,974)
Net loss per share:		
Basic and diluted net loss, as reported	\$ (0.33)	\$ (0.48)
Basic and diluted net loss, proforma	\$ (0.35)	\$ (0.52)

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

**Employee Stock**

	<b>Employee Stock Options</b>				<b>Purchase Plan</b>	
	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>		<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Weighted-average fair value	\$2.14	\$3.42	\$3.95	\$3.82	\$1.95	\$3.23
Risk-free interest rate	4.0%	4.1%	4.8%	3.7%	4.9%	3.7%
Expected life (in years)	4.0	4.0	5.7	4.0	1.2	1.7
Volatility	0.70	0.68	0.79	0.73	0.66	0.70
Expected dividends						

Expected volatility is based on historical volatility of the Company's stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were each found to have similar historical option exercise and

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termination behavior and thus were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Employee and director stock-based compensation expense	\$ 949	\$ 307	\$ 2,337	\$ 975
Non-employee stock-based compensation expense	21	1	29	(14)
Total	\$ 970	\$ 308	\$ 2,366	\$ 961

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized for the three and nine months ended September 30, 2006 was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of September 30, 2006, the total unrecognized compensation cost related to non-vested options granted amounted to \$7.1 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.5 years.

Activity under the our stock option plans was as follows:

	<b>Options Available for Grant</b>	<b>Number of Options Outstanding</b>	<b>Weighted-Average Exercise Price Per Share</b>
Balance at December 31, 2005	2,831,668	2,598,797	\$ 4.43
Options authorized	400,000		
Options granted	(1,423,730)	1,423,730	\$ 5.52
Options exercised		(148,568)	\$ 2.09
Options cancelled:			
Options forfeited (unvested)	635,118	(635,118)	\$ 5.23
Options expired (vested)	76,663	(76,663)	\$ 4.12
Balance at September 30, 2006	2,519,719	3,162,178	\$ 4.88

Total options exercised during the nine months ended September 30, 2006 and September 30, 2005 was 148,568 and 136,416, respectively. The total intrinsic value of the options exercised during the nine months ended September 30, 2006 and September 30, 2005 was approximately \$0.5 million and \$0.8 million, respectively. No income tax benefits were realized by the Company in the nine months ended September 30, 2006 or September 30, 2005, as the Company reported an operating loss.

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, 2006:

<b>Number of Shares</b>	<b>Weighted-Average Exercise Price Per Share</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
2,875,620	\$ 4.80	7.9	\$ 1,849,329

Outstanding options (vested and  
expected to vest)

Options exercisable	1,307,234	\$ 4.03	7.0	\$ 1,482,701
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#### **Employee Stock Purchase Plan**

As of September 30, 2006, 496,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, or any future stock dividend or other similar change in the Company's common stock or capital structure. During the nine months ended September 30, 2006, employees acquired 27,082 shares of our common stock under the Purchase Plan. At September 30, 2006, 434,226 shares of our common stock remained available for future purchases.

#### **8. Subsequent Events**

On October 10, 2006, the Company closed its underwritten public offering of 7,130,000 shares of its common stock, including the exercise of the underwriter's over-allotment option of 930,000 shares, at a price of \$4.40 per share. The offering was made under the

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Company's effective shelf registration statement filed in September 2006 and resulted in net proceeds to the Company of approximately \$29 million.

## **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 below and in Risk Factors as well as elsewhere in this document.*

*This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this quarterly report and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K.*

### **Overview**

Dynavax Technologies Corporation, or Dynavax or the Company, is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent allergies, infectious diseases, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

Our pipeline includes: TOLAMBA, a ragweed allergy immunotherapeutic, for which a major safety and efficacy trial, or DARTT, is currently underway, and that is in a supportive clinical trial in ragweed allergic children; HEPLISAV, a hepatitis B vaccine in a Phase 3 clinical trial; SUPERVAX, a hepatitis B vaccine; and a therapy for non-Hodgkin's lymphoma in a Phase 2 clinical trial. Our preclinical asthma and chronic obstructive pulmonary disease, or COPD, programs are partnered with AstraZeneca. Funding for our other preclinical programs in cancer, hepatitis B, and hepatitis C therapies and for influenza vaccine has been provided by Symphony Dynamo, Inc. and the National Institute of Allergy and Infectious Diseases.

### **Recent Developments**

#### ***TOLAMBA***

TOLAMBA (Amb a 1 ISS Conjugate, or AIC) is a novel injectable product candidate to treat ragweed allergy. In early 2006, we announced results from a two-year Phase 2/3 clinical trial of TOLAMBA showing that patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores and other efficacy endpoints compared to placebo-treated patients in the first and second year of the trial. The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo and local injection site tenderness was minor and transient.

Following a discussion with the U.S. Food & Drug Administration, or FDA, we initiated the Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT, and announced that enrollment in the DARTT exceeded expectations relative to the speed and number of study subjects. DARTT is a two-year, multi-center, well-controlled study in 738 ragweed allergic subjects, aged 18 to 55 years, randomized into three arms: prior dosing regimen, higher total dose regimen, and placebo. Subjects receive six injections over six weeks prior to the start of the 2006 ragweed season. Ragweed symptoms will be followed over the 2006 and 2007 ragweed seasons. The primary endpoint is reduction in total nasal symptom scores, or TNSS, in the higher total dose arm compared to placebo during the second (2007) ragweed season. The trial design includes a preliminary analysis anticipated to be conducted in early 2007 following completion of the 2006 ragweed season. We anticipate that data from the DARTT preliminary analysis, if positive, combined with the safety and efficacy data from the recently completed two year Phase 2/3 trial, and from an ongoing trial in ragweed allergic children, could provide sufficient patient data for determining the potential timeline to registration.

#### ***HEPLISAV***

HEPLISAV, our product candidate for hepatitis B prophylaxis, has completed a Phase 2 trial conducted in Singapore in adults (40 years of age and older) who are more difficult to immunize with conventional vaccines.

Results from the final analysis of this trial showed statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations

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when compared to GlaxoSmithKline's Engerix-B®. We intend to focus our development activities and resources on maximizing the potential of HEPLISAV's demonstrated superiority over conventional hepatitis B vaccine in both the younger (under 40 years of age) and older adult populations, and its potential in the worldwide dialysis market.

The Phase 3 trial in the older, more difficult to immunize population in Asia and the U.S.-based Phase 1 trial in patients with end-stage renal disease (pre-hemodialysis) are ongoing. We are in the process of planning additional trials designed to support registration activities. In the fourth quarter of 2006, we plan to initiate a pivotal Phase 3 safety and efficacy trial for HEPLISAV that will be conducted first in Canada and then expanded into the U.S. and Europe. In the first quarter of 2007, we anticipate initiating a Phase 2 trial in the end-stage renal disease (pre-hemodialysis) population that would be conducted in Europe and/or Canada.

### ***SUPERVAX***

In April 2006, we announced the acquisition of Rhein Biotech GmbH, which we refer to as Dynavax Europe. As a result, we acquired a hepatitis B vaccine product called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection when administered on a convenient, two-dose schedule. SUPERVAX is approved for marketing in Argentina and sales of the vaccine are expected in the fourth quarter of 2006 through a third party partner. We intend to continue development of and registration activities for SUPERVAX as a two-dose vaccine for commercialization in select countries.

### ***Non-Hodgkin's Lymphoma***

We are evaluating the potential of ISS to enhance the effect of monoclonal antibodies in cancer therapies. We have conducted an open-label Phase 1, dose-escalation trial of ISS in combination with Rituxan® (rituximab) in 20 patients with non-Hodgkin's lymphoma, or NHL. Results of this study showed dose-dependent pharmacological activity without significant toxicity. A follow-up Phase 2 trial of ISS with Rituxan in NHL is currently underway in 30 patients with histologically confirmed CD20+, B-cell follicular NHL who have received at least one previous treatment regimen for lymphoma. The primary objective is to assess the proportion of patients who are alive and without disease progression one year after initiating Rituxan therapy. Mechanistic studies will be performed to characterize the enhancement of antitumor activity by ISS.

### ***Symphony Dynamo, Inc.***

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, SDI has agreed to invest \$50.0 million to fund the clinical development of these programs and we have licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing, and which is obligated to fund an additional \$30.0 million in one year following closing. We continue to be primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, representing a 25% premium over the recent 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. In consideration for the warrant, we received an exclusive purchase option to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. The purchase option exercise price is payable in cash or a combination of cash and shares of our common stock, at our sole discretion. We also have an option to purchase either the hepatitis B or hepatitis C program during the first year of the agreement. The program option is exercisable at our sole discretion at a price which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the purchase option. If we do not exercise our exclusive right to purchase some or all of the programs licensed under the agreement, the intellectual property rights to the programs at the end of the development period will remain with SDI.

In cancer, we believe that the potent and multifaceted biological activities of ISS offer a number of distinct approaches to cancer therapy in a wide range of tumor types. We anticipate that our cancer product candidate will advance into clinical trials in solid tumors in the fourth quarter of 2006, and our hepatitis B and hepatitis C therapeutic

product candidates are currently planned to enter the clinic in 2007.

*AstraZeneca Research Collaboration and License Agreement*

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In September 2006, we entered into a 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, or COPD. The collaboration will use our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, Dynavax and AstraZeneca will collaborate to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca will be responsible for any development and worldwide commercialization of products arising out of the research program. Dynavax may also have the opportunity to co-promote in the United States products arising from the collaboration. The financial terms of the collaboration include an upfront fee of \$10 million plus research funding and preclinical milestones that could bring the total committed funding to \$27 million. The total potential deal value including future development milestones approximates \$136 million. Upon commercialization, Dynavax is also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$0.2 million for the quarter ended September 30, 2006. As of September 30, 2006, the Company recorded deferred revenue of \$10.6 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

### *Azimuth Opportunity Ltd.*

On August 31, 2006 we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd. Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of \$30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the 18-month term of the purchase agreement. From time to time over the term of the purchase agreement, and at our sole discretion, we may present Azimuth with draw down notices constituting offers to purchase our common stock. The per share purchase price for these shares is at a discount ranging from 5.2% to 7.0%. As of September 30, 2006, we have not completed any draw downs.

### *Sale of Common Stock*

On October 10, 2006, we sold 7,130,000 shares of common stock in an underwritten public offering, including the underwriter's over-allotment option, at a price of \$4.40 per share. The offering was made under the Company's effective shelf registration statement filed in September 2006 and resulted in net proceeds to the Company of approximately \$29 million.

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

We believe that there have been no significant changes in its critical accounting policies during the nine months ended September 30, 2006 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2005, except as discussed below.

### *Revenue Recognition*

We recognize revenue from collaborative agreements, the performance of research and development and contract manufacturing services, royalty and license fees and grants. 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 collectibility is reasonably assured.

Revenues from collaboration and research and development service agreements are recognized as work is performed. Any upfront fees or amounts received in advance of performance are recorded as deferred revenue and recognized as earned over the estimated term of the performance obligation. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenue recognized to date under these collaborations and milestones has been nonrefundable.

Revenues from the manufacturing and sale of vaccine and other materials are recognized upon meeting the criteria for substantial performance and acceptance by the customer. Revenues from license fees and royalty payments are recognized when earned; up-front nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured.

Grant 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. Any amounts received in advance of

performance are recorded as deferred revenue until earned.

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### *Stock-Based Compensation*

On January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards 123R, Share-Based Payment, or FAS 123R, using the modified-prospective transition method. Under this transition method, compensation cost includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of FAS 123 and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of FAS 123R. Results for prior periods have not been restated.

As a result of the adoption of FAS 123R, the Company reduced its deferred stock compensation balance and additional paid in capital by \$2.5 million as of January 1, 2006. As of September 30, 2006, the total unrecognized compensation cost related to non-vested options granted amounted to \$7.1 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.5 years.

Determining the appropriate fair value model and calculating the fair value of stock-based awards at the grant date requires judgment, including estimating forfeiture rates, stock price volatility and expected option life. The fair value of each option is amortized on a straight-line basis over the option's vesting period, assuming an annual forfeiture rate of 11%. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model, which requires the input of highly subjective assumptions including the expected life of the option and expected stock price volatility. 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, were grouped and considered separately for valuation purposes, which resulted in an expected life of 6.25 years. Non-executive level employees were found to have similar historical option exercise and termination behavior resulting in an expected life of 4 years. Expected volatility is based on historical volatility of the Company's stock and comparable peer data over the life of the options granted to executive and non-executive level employees.

### *Acquired In-process Research and Development*

We allocate the purchase price of acquisitions based on the estimated fair value of the assets acquired and liabilities assumed. To assist in determining the value of the acquired in-process research and development and certain other intangibles associated with the Rhein Biotech GmbH transaction discussed in Note 2 to the condensed consolidated financial statements, we obtained a third party valuation as of the acquisition date. We used the income approach and the cost approach to value in-process research and development. The income approach is based on the premise that the value of an asset is the present value of the future earning capacity that is available for distribution to the investors in the asset. We perform a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. Given the high risk associated with the development of new drugs, we adjust the revenue and expense forecasts to reflect the probability and risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the estimated fair value assigned to the in-process research and development and other intangibles is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available.

### *Goodwill and Other Intangible Assets*

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

### *Valuation of Long-lived Assets*

Long-lived assets to be held and used, including property and equipment and identified intangible assets, are reviewed for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Factors we consider important that could indicate the need for an impairment review include the following:

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significant changes in the strategy for our overall business;

significant underperformance relative to expected historical or projected future operating results;

significant changes in the manner of our use of acquired assets;

significant negative industry or economic trends;

significant decline in our stock price for a sustained period; and

our market capitalization relative to net book value.

Determination of recoverability is based on an estimate of undiscounted cash flows resulting from the use of the asset and its eventual disposition. Measurement of impairment charges for long-lived assets that management expects to hold and use are based on the fair value of such assets.

***Consolidation of Variable Interest Entities***

Under FIN 46R, Consolidation of Variable Interest Entities, arrangements that are not controlled through voting or similar rights are accounted for as variable interest entities, or VIEs. An enterprise is required to consolidate a VIE if it is the primary beneficiary of the VIE. The enterprise that is deemed to absorb a majority of the expected losses or receive a majority of expected residual returns of the VIE is considered the primary beneficiary.

Based on the provisions of FIN 46R, we have concluded that under certain circumstances when we enter into agreements that contain an option to purchase assets or equity securities from an entity, or enter into an arrangement with a financial partner for the formation of joint ventures which engage in research and development projects, a VIE may be created. For each VIE created, we compute expected losses and residual returns based on the probability of future cash flows. If we are determined to be the primary beneficiary of the VIE, the assets, liabilities and operations of the VIE will be consolidated with our financial statements. Our consolidated financial statements include the accounts of Symphony Dynamo, Inc. discussed in Note 4.

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

Revenues consist of amounts earned from collaborations, services, license fees and grants. Collaboration revenue includes revenue recognized under our collaboration agreements with AstraZeneca in 2006 and UCB in 2005. Services and license fees include research and development and contract manufacturing services, license fees, royalty payments, and sales of Supravax formulated bulk vaccine to a third party distributor. Grant revenue includes amounts earned under government and private agency grants.

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

	<b>Three Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>		<b>Nine Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>	
	<b>September 30, 2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>	<b>September 30, 2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
Revenues:								
Collaboration revenue	\$ 166	\$	\$ 166	%	\$ 166	\$ 12,199	\$ (12,033)	(99)%
Services and license revenue	692		692	%	916		916	%
Grant revenue	734	404	330	82%	1,327	1,856	(529)	(29)%
Total revenues	\$ 1,592	\$ 404	\$ 1,188	294%	\$ 2,409	\$ 14,055	\$ (11,646)	(83)%

Total revenues for the nine months ended September 30, 2006 were \$2.4 million, compared to \$14.1 million for the same period in 2005. Total revenues in 2006 consisted of collaboration revenue from AstraZeneca, services and license fees from Dynavax Europe which included approximately \$0.1 million in sales of Supervax formulated bulk vaccine to a third party distributor, and grants primarily awarded by the National Institute of Allergy and Infectious Diseases. Collaboration revenue for the nine months ended September 30, 2005 included accelerated recognition of \$7.0 million in deferred revenue following the end of our collaboration with UCB in March 2005.

**Table of Contents***Research and Development*

Research and development expenses consist of compensation and related personnel costs which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates, and the costs of selling Supervax formulated bulk vaccine. We expense our research and development costs as they are incurred.

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

	<b>Three Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>		<b>Nine Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>	
	<b>September 30,</b>				<b>September 30,</b>			
<b>Research and development:</b>	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
Compensation and related personnel costs	\$ 3,711	\$ 2,143	\$ 1,568	73%	\$ 9,256	\$ 6,427	\$ 2,829	44%
Outside services	7,410	3,590	3,820	106%	16,456	10,416	6,040	58%
Facility costs	1,415	922	493	53%	3,622	2,678	944	35%
Non-cash stock-based compensation	244	142	102	72%	800	424	376	89%
Total research and development	\$ 12,781	\$ 6,797	\$ 5,983	88%	\$ 30,135	\$ 19,945	\$ 10,189	51%

Research and development expenses for the third quarter 2006 increased by \$6.0 million, or 88%, over the same period in 2005. Research and development expenses for the nine month period increased by \$10.2 million, or 51%, over the same period in 2005. The change in both the quarter and nine month period was primarily due to increased clinical trial and clinical material manufacturing costs related to our lead product candidates TOLAMBA and HEPLISAV and expenses incurred to support SDI programs and Dynavax Europe operations. Outside services during the period included approximately \$0.1 million of cost associated with Supervax formulated bulk vaccine. Compensation and related personnel costs increased in 2006 resulting from continued organizational growth to further develop our clinical candidates and the impact of Dynavax Europe. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

We anticipate that our research and development expenses will increase significantly in 2006 as compared to 2005, primarily in connection with the advancement of our clinical programs in ragweed allergy and hepatitis B vaccines and our preclinical programs in cancer, hepatitis B and hepatitis C therapies and asthma.

*General and Administrative*

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

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

	<b>Three Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>		<b>Nine Months Ended</b>		<b>Increase (Decrease) from 2006 to 2005</b>	
	<b>September 30,</b>				<b>September 30,</b>			

<b>General and administrative:</b>	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
Compensation and related personnel costs	\$ 1,937	\$ 1,071	\$ 866	81%	\$ 4,743	\$ 3,259	\$ 1,484	46%
Outside services	1,215	695	519	75%	2,678	2,025	653	32%
Legal costs	625	258	367	142%	1,257	935	322	34%
Facility costs	154	128	26	20%	446	376	70	19%
Gain on disposal of property and equipment				%	(50)		(50)	(100)%
Non-cash stock-based compensation	725	166	559	337%	1,565	537	1,028	191%
Total general and administrative	\$ 4,656	\$ 2,319	\$ 2,337	101%	\$ 10,639	\$ 7,132	\$ 3,507	49%

General and administrative expenses for the third quarter 2006 increased by \$2.3 million, or 101%, over the same period in 2005. General and administrative expenses for the nine month period increased by \$3.5 million, or 49%, over the same period in 2005. The change in both the quarter and nine month period primarily reflects additional compensation and related personnel costs associated with overall organizational growth including the impact of Dynavax Europe. Outside services and legal costs increased in 2006 related to higher accounting and professional fees incurred in conjunction with various corporate development activities. In addition, we incurred higher stock-based compensation charges resulting from our adoption of FAS 123R effective January 1, 2006.

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We expect general and administrative expenses to increase significantly in 2006 as compared to 2005, resulting from continued organizational growth and expenses incurred to support the advancement of our clinical development programs and corporate development activities.

*Acquired In-process Research and Development*

Following our April 2006 acquisition of Dynavax Europe, we recorded the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. As a result, we recorded net tangible assets of \$3.0 million, goodwill of \$2.3 million, other intangible assets of \$5.1 million, and expense associated with the acquired in-process research and development of \$4.2 million, representing the fair value of research projects that had not yet reached technological feasibility and that have no alternative future use.

*Amortization of Intangible Assets*

Intangible assets resulting from our April 2006 acquisition of Dynavax Europe consist primarily of manufacturing process, customer relationships, and developed technology. Amortization of intangible assets was \$0.4 million for the nine months ended September 30, 2006.

*Interest and Other Income, Net*

Interest and other income, net is comprised of interest income; amortization on marketable securities; and realized gains and losses on investments and foreign currency translation. The following is a summary of our interest and other income, net (in thousands):

	<b>Three Months Ended</b>		<b>Increase (Decrease)</b>		<b>Nine Months Ended</b>		<b>Increase (Decrease)</b>	
	<b>September 30,</b>		<b>from 2006 to 2005</b>		<b>September 30,</b>		<b>from 2006 to 2005</b>	
	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>%</b>
Interest and other income, net	\$673	\$428	\$245	57%	\$2,093	\$1,229	\$864	70%

Interest and other income, net of \$2.1 million for the nine months ended September 30, 2006 compared to \$1.2 million reported for the same period in 2005. The increase was primarily due to approximately \$0.4 million of interest earned on the investments held by SDI and the investment of proceeds from our follow-on equity offering in the fourth quarter of 2005.

*Non-controlling Interest in Symphony Dynamo, Inc.*

Pursuant to the agreements that we entered into with SDI in April 2006, the results of operations of SDI have been included in our condensed consolidated financial statements from the date of formation. Collaboration funding for SDI programs was \$5.3 million for the period from April 18, 2006 through September 30, 2006. Collaboration funding, net of certain administrative expenses incurred and interest income earned by SDI, is reflected in the loss attributed to the noncontrolling interest in SDI.

**Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of shares of our common stock, shares of our convertible preferred stock, and ordinary shares in a subsidiary, which have yielded a total of approximately \$177.9 million in net cash proceeds and, to a lesser extent, through amounts received under collaborative agreements and government grants for biodefense programs. We have also financed certain of our research and development activities under our agreements with SDI. We completed an initial public offering in February 2004, raising net proceeds during fiscal 2004 of approximately \$46.5 million from the sale of 6,900,000 shares of common stock. In the fourth quarter of 2005, we completed an underwritten public offering that resulted in net proceeds to the Company of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. As of September 30, 2006, we had \$41.2 million in cash, cash equivalents and marketable securities and \$17.7 million in investments held by SDI. These amounts did not include proceeds from our October 2006 sale of 7,130,000 shares of common stock in an underwritten public offering that resulted in net proceeds to the Company of approximately \$29 million. Our funds are currently invested in a variety of securities, including highly liquid institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

Cash used in operating activities of \$19.6 million during the nine months ended September 30, 2006 compared to \$14.4 million for the same period in 2005. The increase in cash usage over the prior year was due primarily to the increase in our net loss from

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operations and the increase in working capital, offset by the receipt of \$10.0 million in upfront fees from our collaboration with AstraZeneca. Cash provided by investing activities of \$8.9 million during the nine months ended September 30, 2006 compared to \$16.4 million for the same period in 2005. The increase was attributed to sales of marketable securities, net of \$14.0 million in cash paid to acquire Dynavax Europe and \$17.7 million in purchases of investments held by SDI. Cash provided by financing activities was \$17.8 million during the nine months ended September 30, 2006 compared to \$0.5 million for the same period in 2005, resulting primarily from proceeds from investments in SDI.

On August 31, 2006 we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd. Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of \$30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the 18-month term of the purchase agreement. From time to time over the term of the purchase agreement, and at our sole discretion, we may present Azimuth with draw down notices constituting offers to purchase our common stock. The per share purchase price for these shares is at a discount ranging from 5.2% to 7.0%. As of September 30, 2006, we have not completed any draw downs.

On October 10, 2006, the Company closed an underwritten public offering of 7,130,000 shares of its common stock, including the exercise of the underwriter's over-allotment option of 930,000 shares, at a price of \$4.40 per share. The offering was made under the Company's effective shelf registration statement filed in September 2006 and resulted in net proceeds to the Company of approximately \$29 million.

Excluding the potential impact of any equity funding, business collaborations or other transactions that may be entered into, we expect our cash, cash equivalents and marketable securities at December 31, 2006 to decline from 2005, primarily due to cash used for operations. We expect net cash used in operating activities to increase significantly in 2006 as compared to prior years related to the advancement of our clinical development programs.

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

Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions that are outside of our control. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern.

***Contractual Obligations***

The following summarizes our significant contractual obligations as of September 30, 2006 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	Total	Payments Due by Period		
		Less than 1 Year	1-3 Years	4 Years
<b>Contractual Obligations:</b>				
Future minimum payments under our operating lease	\$ 5,226	\$ 433	\$ 3,563	\$ 1,230
<b>Total</b>	<b>\$ 5,226</b>	<b>\$ 433</b>	<b>\$ 3,563</b>	<b>\$ 1,230</b>

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and August 2009, respectively. The Berkeley Lease can be terminated at no cost to the Company in September 2009 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

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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, 2006 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2006 and December 31, 2005. 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.

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, the Company 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, 2006, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$30 million through 2008. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

We entered into a series of exclusive license agreements with the Regents of the University of California in March 1997 and October 1998. These agreements provide us with certain technology and related patent rights and materials related to ISS, TNF-alpha inhibitors, vaccines using DNA and immunoregulatory sequences. Under the terms of the agreements, 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.

On April 21, 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to a hepatitis B vaccine. In exchange, Rhein will be required to pay Green Cross a certain profit share until Green Cross's development costs for the product are recouped and a certain profit share for a specified period of time.

In December 2004, Rhein entered into a joint venture agreement under which it is obligated to perform research and development services up to a maximum of 1.5 million Euro, or approximately \$2.0 million, related to the development of a vaccine for cytomegalovirus. As of September 30, 2006, the remaining obligation was approximately \$0.9 million.

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

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and 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 minimal exposure to foreign exchange rate fluctuations.

### **ITEM 4. CONTROLS AND PROCEDURES**

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



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The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and CFO concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or Exchange Act, as of the end of period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

**(b) Changes in internal controls**

No changes in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1A. RISK FACTORS.**

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

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

We have experienced significant operating losses in each year since our inception. To date, our revenue has resulted from collaboration agreements, services and license fees from Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors and will terminate in 2007. We anticipate that we will incur substantial additional operating losses for the foreseeable future. These losses have been, and will continue to be, principally the result of the various costs associated with our research and development activities. We expect our losses to increase primarily as a consequence of our continuing product development efforts.

We do not have any products that generate revenue. Clinical trials for TOLAMBA and HEPLISAV are ongoing. These and our other product candidates may never be commercialized, and we may never generate product-related revenue. Our ability to generate product revenue depends upon:

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

- obtaining regulatory approvals for our product candidates;

- entering into collaborative relationships on commercially reasonable terms for the development, manufacturing, sales and marketing of our product candidates, and then successfully managing these relationships; and

- obtaining commercial acceptance of our products, in particular TOLAMBA and HEPLISAV.

If we are unable to generate revenues or achieve profitability, we may be required to significantly reduce or discontinue our operations or raise additional capital under adverse circumstances.

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

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop our product candidates, potentially commercialize them and generate revenues, we will require substantial additional capital resources in order to continue our operations, and any such funding may not allow us to continue operations as currently planned. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations, and any change in plans may increase these outlays and expenditures. We may be unable to obtain additional capital from financing sources or from agreements with collaborators on acceptable terms, or at all. If at any time sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate some or all of our research, preclinical or clinical programs or discontinue our operations.

**All of our product candidates are unproven, and our success depends on our product candidates being approved through uncertain and time-consuming regulatory processes. Failure to prove our products safe and effective in clinical trials and obtain regulatory approvals could require us to discontinue operations.**

None of our product candidates has been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our



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success is primarily dependent on our ability to obtain regulatory approval for TOLAMBA and HEPLISAV. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources. Product development failure can occur at any stage of clinical trials and as a result of many factors, many of which are not under our control.

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 TOLAMBA, we may be restricted from initiating further trials for TOLAMBA. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval in their jurisdictions.

Many new drug candidates, including many drug candidates that have completed Phase 3 clinical trials, have shown promising results in early clinical trials and subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our ability to eventually generate revenues and could require us to reduce the scope of or discontinue our operations.

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

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects or inadequate supply of the product candidate. In addition, our ability to conduct clinical trials for some of our product candidates, notably TOLAMBA, is limited due to the seasonal nature of ragweed allergy. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the target population is available for testing, which could result in a delay of an entire year. Our registration and commercial timelines will depend on results of the current and planned clinical trials and further discussions with the FDA. Consequently, we may experience additional delays in obtaining regulatory approval for these product candidates.

In particular for TOLAMBA or HEPLISAV, any extension, suspension, termination or unanticipated delays of our clinical trials could:

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

- result in significant additional costs;

- potentially diminish any competitive advantages for those products;

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

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

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

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

We may be exposed to future litigation by third parties based on claims that our product candidates, proprietary technologies or the licenses on which we rely, infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. If we become

involved in any litigation, interference or other administrative 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 relative to HEPLISAV, Merck & Co., Inc., or Merck, and GlaxoSmithKline Plc, or GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen. In addition, the Institute Pasteur also owns or has exclusive

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licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside of the United States, they remain in force in the United States and are likely to be in force when we commercialize HEPLISAV or a similar product in the United States. To the extent we were to commercialize HEPLISAV in the United States, Merck and/or GSK or the Institute Pasteur may bring claims against us.

If we are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against us, for example, as may arise to the extent we were to commercialize HEPLISAV or any similar product candidate in the United States, we could be required to pay substantial damages and we may be unable to commercialize our product candidates or use our proprietary technologies unless we obtain a license from these or other third parties. A license may require us to pay substantial royalties, require us to grant a cross-license to our technology or may not be available to us on acceptable terms or on any terms. In addition, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time. Any of these outcomes may require us to change our business strategy and could reduce the value of our business.

Another of our potential competitors, Coley Pharmaceutical Group, or Coley, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO. If these claims are held to be valid, Coley may seek to enforce its rights under these claims, including, for example, by suing us for patent infringement. Consequently, we may need to obtain a license to one or more of these claims held by Coley by paying cash, granting royalties on sales of our products or offering rights to our own proprietary technologies in order to commercialize one or more of our formulations of ISS in the U.S., including TOLAMBA and HEPLISAV. Such a license may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize products.

In December 2003, the PTO declared an interference to resolve first-to-invent disputes between a patent application filed by the Regents of the University of California, which is exclusively licensed to us, and an issued U.S. patent owned by Coley relating to immunostimulatory DNA sequences. The declaration of interference named the Regents of the University of California as senior party, indicating that a patent application filed by the Regents of the University of California and licensed to us was filed prior to a patent application owned by Coley that led to an issued U.S. patent. The interference provides the first forum to challenge the validity and priority of certain of Coley's patents. On March 10, 2005, the PTO issued a decision in the interference which did not address the merits of the case, but dismissed it on technical legal grounds based on the timing of Dynavax's filing of its claims and request for interference. Dynavax appealed this decision to the U.S. Federal Circuit court which on July 17, 2006, upheld the decision of the PTO. Dynavax has filed a motion for reconsideration and rehearing en banc which was denied in October 2006. Based on this recent denial, the Company is currently reviewing its potential alternatives.

**If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review, which may be costly and subject us to various enforcement actions.**

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, resulting in limitations on our labeling indications or marketing claims, or withdrawn completely if problems occur after commercialization. Thus, even if we receive FDA and other regulatory approvals, our product candidates may later exhibit qualities that limit or prevent their widespread use or that force us to withdraw those products from the market.

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

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in

warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

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**Our product candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.**

Our product candidates in clinical trials are based on our 1018 ISS compound, and substantially all of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay or discontinue all of our clinical trials. In addition, as all of our clinical product candidates contain 1018 ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

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

We have granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapeutics to Symphony Dynamo, Inc., or SDI, in consideration for a commitment from Symphony Capital Partners, LP and its co-investors to provide \$50 million of committed capital to advance these programs. As part of the arrangement, we received an option granting us the exclusive right, but not the obligation, to acquire certain or all of the programs at specified points in time at specified prices during the term of the five-year development period. The development programs under the arrangement will be jointly managed by SDI and us, and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our option. If we do not exercise the purchase option prior to its expiration, then our rights in and with respect to the SDI programs will terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement.

If we elect to exercise the purchase option, we will be required to make a substantial payment, which at our election may be paid partially in shares of our common stock. As a result, in order to exercise the option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders. In addition, the exercise of the purchase option will likely require us to record a significant charge to earnings and may adversely impact future operating results.

**A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may be unsuccessful in establishing and managing collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.**

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

one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

**We rely on third parties to supply materials and perform functions necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or manufacturers, or failure to replace them may delay our clinical trials and**

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**research and development efforts and may result in additional costs, which would preclude us from producing our product candidates on commercially reasonable terms.**

We rely on a number of third parties for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the 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 our control, resulting in higher cost or delays in our product development efforts.

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

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

In addition, we do not currently have a contract manufacturer for TOLAMBA or sufficient TOLAMBA to supply our potential commercial needs. We intend to enter into manufacturing agreements with one or more commercial-scale contract manufacturers to produce additional supplies of TOLAMBA as required for new clinical trials and commercialization. If we are unable to complete such agreements, we may be unable to commence and complete our clinical trials in a timely fashion, and we would have to establish an internal commercial scale manufacturing capability for TOLAMBA, incurring increased capital and operating costs, delays in the commercial development of TOLAMBA and higher manufacturing costs than we have experienced to date.

**We have or intend to contract with one or more third parties to conduct our clinical trials for TOLAMBA and HEPLISAV. If these third parties do not carry out 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 TOLAMBA or HEPLISAV.**

We rely on third parties to conduct our planned clinical trials for TOLAMBA or HEPLISAV. If these third parties do not carry out their contractual duties or obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to failure to adhere to our clinical protocols or for other reasons, our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our trials would delay our ability to commercialize TOLAMBA or HEPLISAV and 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.**

If we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our product candidates may not gain market acceptance among physicians, patients, health care payors and the medical community. The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise constrain our marketing claims, reducing our or our collaborators ability to market the benefits of our products to particular patient populations. If we are unable to successfully market any approved product candidates, or are limited in our marketing efforts by regulatory limits on labeling indications or marketing claims, our ability to generate revenues could be significantly impaired.

In particular, treatment with TOLAMBA, if approved, will require a series of injections, and we expect that some of the patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider using our product. We believe that market acceptance of TOLAMBA will also depend on our ability to offer competitive pricing, increased efficacy and improved ease of use as compared to existing or potential new allergy treatments.

We may seek partners for purposes of commercialization of HEPLISAV in selected markets worldwide. Marketing challenges vary by market and could limit or delay acceptance in any particular country. We believe that market acceptance of HEPLISAV will depend on our ability to offer increased efficacy and improved ease of use as compared to existing or potential new hepatitis B vaccine products.

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**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 generate revenues from the sales of any approved product candidates in excess of the costs of producing the product candidates will depend in part on the availability of reimbursement from third party payors. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty therefore exists as to coverage and reimbursement levels for newly approved health care products, including pharmaceuticals. 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 the considerable capital resources we have spent and will continue to spend on product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investment in product development. If it becomes apparent, due to changes in coverage or pricing of pharmaceuticals in our market or a lack of reimbursement, that it will be difficult, if not impossible, for us to generate revenues in excess of costs, we will need to alter our business strategy significantly. This could result in significant unanticipated costs, harm our future prospects and reduce our stock price.

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

TOLAMBA, if approved, will compete directly with conventional allergy shots and indirectly with antihistamines, corticosteroids and anti-leukotriene agents, used to treat seasonal allergy symptoms, including those produced by GSK, Merck, Novartis, Schering-Plough and AstraZeneca Plc. Since our TOLAMBA ragweed allergy treatment would require a series of injections, we expect that some patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider our product.

HEPLISAV, if approved, will compete with existing vaccines produced by GSK and Merck, among others.

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

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

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

**We intend to 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 HEPLISAV and therapeutic product candidates.**

We plan to introduce HEPLISAV initially 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. We may also conduct operations in other foreign jurisdictions.

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;

- securing international distribution, marketing and sales capabilities;

- adequate protection of our intellectual property rights;

- difficulties and costs associated with complying with a wide variety of complex international laws and treaties;

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

- adverse tax consequences;

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

- geopolitical risks.

If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of HEPLISAV and therapeutic product candidates, as well as other product candidates that we may choose to commercialize internationally, which would impair our ability to generate revenues.

**We recently acquired Rhein Biotech GmbH and any difficulties from integrating the Rhein's business into ours could disrupt our business and harm our financial condition.**

In April 2006, we acquired Rhein Biotech GmbH. Through this acquisition, Dynavax gained ownership of a European Union (EU) GMP-certified vaccine manufacturing facility in Düsseldorf, Germany, certain vaccine and other commercial programs, a management team and personnel with specialized expertise in process development and vaccine manufacturing.



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Integrating Rhein's operations, technology and personnel with our operations and personnel is a complex process. The successful integration of Dynavax and Rhein will require, among other things, ongoing coordination of various integration efforts, relating to our personnel system, technologies and commercial programs. We may not be able to rapidly or efficiently integrate Rhein's business and technology into ours and the expected benefits of the combination may not materialize. Our ability to successfully integrate Rhein involves numerous risks, including:

- difficulties in integrating the operations, technologies, products and personnel of Rhein;

- difficulties in successfully utilizing Rhein's manufacturing capabilities to produce materials for our existing product candidates in lieu of purchasing such materials from third party vendors;

- diversion of management's attention from normal daily operations of the business;

- potential difficulties in integrating different projects;

- difficulties in entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;

- insufficient revenues to offset increased expenses associated with the acquisition; and

- potential loss of key employees of Rhein.

The Rhein acquisition may also cause us to:

- assume liabilities some of which may be unknown at the time of such acquisitions;

- record certain intangible assets in conjunction with our accounting for the transaction in the second quarter of 2006 that may be subject to immediate write-off, ongoing impairment testing, or potential periodic impairment charges, or may cause us to incur future amortization expenses; or

- become subject to unknown litigation.

Moreover, we will be required to include Rhein as part our Sarbanes-Oxley compliance requirements beginning in 2007. There can be no assurance that we will be able to successfully integrate Rhein and its technology and personnel into our business.

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

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials.

However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

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

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited product liability insurance coverage in the amount of \$1 million for each occurrence for

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

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

Our success depends on our ability to:

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting United States and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the United States, legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty, given that several of our product candidates may initially address market opportunities outside the United States. For example, we expect to market HEPLISAV, if approved, in various foreign countries with high incidences of hepatitis B, including Canada, Europe and selected markets in Asia, 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 might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

we might not have been the first to file patent applications for these inventions;

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection;

our issued patents may not provide a basis for commercially viable products 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 companies, universities or research institutions may harm our ability to do business;

other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and

other companies, universities or research institutions 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 leak of confidential data into 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.

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

Our success depends upon our license arrangements with the Regents of the University of California, or UC. These licenses are critical to our research and product development efforts. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the invention and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate any of these licensing agreements or convert them to non-exclusive licenses. In addition, our license agreements with UC may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology.

**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, in particular any announcements regarding the progress or results of our planned trials for TOLAMBA and HEPLISAV;

- progress of regulatory approval of our product candidates, in particular TOLAMBA and HEPLISAV, and compliance with ongoing regulatory requirements;

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

- market acceptance of our product candidates;

- our ability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;

- 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 form strategic partnerships or joint ventures;

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

- changes in government regulations;

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

- general economic conditions and other external factors;

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

volume of trading liquidity in our common stock

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One or more of these factors could cause a 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 is especially relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

### **Anti-takeover provisions of our certificate of incorporation, bylaws and Delaware law 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.

In addition, we are 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 five years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

### **We will continue to implement additional finance and accounting systems, procedures or controls as we grow our business and organization and to satisfy new reporting requirements.**

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. Specifically, with the Rhein acquisition, we now have foreign operations that will not later than 2007 be required to meet the Section 404 requirements as part of our operations. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control reporting. If we are unable to maintain an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our internal controls over financial reporting and the reliability of our financial statements, which could harm our business and could impact the market price of our common stock.

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

On April 18, 2006, pursuant to agreements with Symphony Capital LP discussed in Note 4 to the Condensed Consolidated Financial Statements included in this Form 10-Q, we issued to Symphony Holdings LLC a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. We filed a registration statement on Form S-3 (File No. 333-134688) on June 1, 2006 covering the resale of share of common stock subject to purchase pursuant to the warrants, and the warrants were

issued pursuant to Rule 506 promulgated under Regulation D.

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**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Document</b>
3.1(1)	Sixth Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
10.19(2)	2004 Non-employee Director Option Program (Revised) and 2005 Non-employee Director Cash Compensation Program, effective April 14, 2005 and amended February 23, 2006.
10.20(3)	Summary of Düsseldorf Lease Agreement as of August 14, 1990, as amended.
10.21(3)	Definitive Commercial Agreement, dated April 21, 2006, among Dynavax Technologies Corporation, Rhein Biotech NV and Rhein Biotech GmbH.
10.22(3)	Exclusive License Agreement, dated April 21, 2006, between Green Cross Vaccine Corp. and Rhein Biotech GmbH.
10.23(3)	Share Sale and Purchase Agreement, dated March 27, 2006, between Dynavax Technologies Corporation and Rhein Biotech N.V.
10.24(3)	License and Supply Agreement, dated February 28, 2002, between Corixa Corporation and Rhein Biotech N.V.
10.25(3)	Purchase Option Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.26(3)	Registration Rights Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.27(3)	Warrant Purchase Agreement, dated as of April 18, 2006, between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC.
10.28(3)	Amended and Restated Research and Development Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.29(3)	Novated and Restated Technology License Agreement, dated as of April 18, 2006, among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.
10.30	Research Collaboration and License Agreement, dated September 1, 2006, by and between AstraZeneca AB and Dynavax Technologies Corporation.

21.1(3)	List of Subsidiaries.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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**Exhibit  
Number**

**Document**

- |      |   |
|------|---|
| 32.1 | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
- 
- (1) Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax'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's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed with the SEC (Commission File No. 000-50577).
- (3) Incorporated by reference from such document filed with the

SEC as an  
exhibit to  
Dynavax's  
Quarterly  
Report on Form  
10-Q for the  
quarter ended  
June 30, 2006,  
as filed with the  
SEC  
(Commission  
File No. 000-  
50577).

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

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**SIGNATURES**

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

**DYNAVAX TECHNOLOGIES  
CORPORATION**

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

Date: November 3, 2006

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

Date: November 3, 2006

By: /s/ TIMOTHY G. HENN  
Timothy G. Henn  
Vice President, Finance and  
Administration and Chief Accounting  
Officer (Principal Accounting Officer)

Date: November 3, 2006