

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

August 03, 2007

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 June 30, 2007

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 July 31, 2007, the registrant had outstanding 39,740,794 shares of common stock.

**INDEX**  
**DYNAVAX TECHNOLOGIES CORPORATION**

	<b>Page No.</b>
<b>PART I FINANCIAL STATEMENTS</b>	4
Item 1. Condensed Consolidated Financial Statements (Unaudited)	4
Condensed Consolidated Balance Sheets as of June 30, 2007 and December 31, 2006	4
Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2007 and 2006	5
Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2007 and 2006	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures about Market Risk	22
Item 4. Controls and Procedures	22
<b>PART II OTHER INFORMATION</b>	23
Item 1. Legal Proceedings	23
Item 1A. Risk Factors	23
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3. Defaults upon Senior Securities	31
Item 4. Submission of Matters to a Vote of Security Holders	32
Item 5. Other Information	32
Item 6. Exhibits	32
<b>SIGNATURES</b>	33

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

**FORWARD-LOOKING STATEMENTS**

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

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

	<b>June 30, 2007 (unaudited)</b>	<b>December 31, 2006 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,503	\$ 14,154
Marketable securities available-for-sale	40,977	58,677
Investments held by Symphony Dynamo, Inc.	35,098	13,363
Restricted cash	408	408
Accounts receivable	1,102	2,154
Inventory	248	257
Prepaid expenses and other current assets	1,760	673
 Total current assets	 86,096	 89,686
 Property and equipment, net	 6,040	 5,200
Goodwill	2,312	2,312
Other intangible assets, net	3,879	4,382
Other assets	155	1,310
 Total assets	 \$ 98,482	 \$ 102,890
 <b>Liabilities, noncontrolling interest and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 3,405	\$ 2,181
Accrued liabilities	9,636	10,742
Deferred revenues	548	778
 Total current liabilities	 13,589	 13,701
 Deferred revenues, noncurrent	 10,000	 10,000
Liability from Program Option exercised under the SDI collaboration	15,000	
Other long-term liabilities	82	117
 Noncontrolling interest in Symphony Dynamo, Inc.	 11,963	 2,016
 Commitments and contingencies		
 Stockholders equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at June 30, 2007 and December 31, 2006		

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Common stock: \$0.001 par value; 100,000 shares authorized at June 30, 2007 and December 31, 2006; 39,741 and 39,715 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	40	40
Additional paid-in capital	246,358	244,787
Accumulated other comprehensive income:		
Unrealized gain on marketable securities available-for-sale	35	28
Cumulative translation adjustment	152	144
Accumulated other comprehensive income	187	172
Accumulated deficit	(198,737)	(167,943)
Total stockholders' equity	47,848	77,056
Total liabilities, noncontrolling interest and stockholders' equity	\$ 98,482	\$ 102,890

See accompanying notes.

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Revenues:				
Collaboration revenue	\$ 752	\$	\$ 1,499	\$
Services and license revenue	461	224	570	224
Grant revenue	587	305	1,715	593
<b>Total revenues</b>	<b>1,800</b>	<b>529</b>	<b>3,784</b>	<b>817</b>
Operating expenses:				
Research and development	19,164	10,762	32,796	17,354
General and administrative	4,206	3,380	8,386	5,983
Acquired in-process research and development		4,180		4,180
Amortization of intangible assets	252	196	503	196
<b>Total operating expenses</b>	<b>23,622</b>	<b>18,518</b>	<b>41,685</b>	<b>27,713</b>
Loss from operations	(21,822)	(17,989)	(37,901)	(26,896)
Interest and other income, net	1,081	685	2,054	1,420
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(20,741)	(17,304)	(35,847)	(25,476)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	3,037	2,031	5,053	2,031
<b>Net loss</b>	<b>\$ (17,704)</b>	<b>\$ (15,273)</b>	<b>\$ (30,794)</b>	<b>\$ (23,445)</b>
Basic and diluted net loss per share	\$ (0.45)	\$ (0.50)	\$ (0.78)	\$ (0.77)
Shares used to compute basic and diluted net loss per share	39,741	30,536	39,734	30,524

*See accompanying notes.*

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

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Operating activities</b>		
Net loss	\$ (30,794)	\$ (23,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	712	227
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	(5,053)	(2,031)
Acquired in-process research and development		4,180
Amortization of intangible assets	503	196
Gain on disposal of property and equipment		(50)
Accretion and amortization on marketable securities	(1,239)	169
Realized loss on sale of marketable securities		23
Stock-based compensation expense	1,497	1,396
Changes in operating assets and liabilities:		
Accounts receivable	1,052	468
Prepaid expenses and other current assets	(1,087)	2
Inventory	9	
Other assets	1,155	(505)
Accounts payable	1,224	242
Accrued liabilities	(1,106)	1,300
Deferred revenues	(230)	(87)
Net cash used in operating activities	(33,357)	(17,915)
<b>Investing activities</b>		
Change in investments held by Symphony Dynamo, Inc.	(21,735)	(19,044)
Cash paid for acquisition, net of cash acquired		(14,045)
Purchases of marketable securities	(40,504)	(7,653)
Proceeds from sales of marketable securities		10,987
Proceeds from maturities of marketable securities	59,450	31,318
(Purchases) disposal of property and equipment, net	(1,587)	41
Net cash (used in) provided by investing activities	(4,376)	1,604
<b>Financing activities</b>		
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Dynamo, Inc., net of fees	30,000	17,405
Issuance cost associated with common stock offering	(19)	
Proceeds from employee stock purchase plan	71	57
Proceeds from exercise of stock options	22	149



Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Net cash provided by financing activities	30,074	17,611
Effect of exchange rate on cash and cash equivalents	8	65
Net (decrease) increase in cash and cash equivalents	(7,651)	1,365
Cash and cash equivalents at beginning of period	14,154	8,725
Cash and cash equivalents at end of period	\$ 6,503	\$ 10,090
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Disposal of fully depreciated property and equipment	\$ 24	\$
Warrants issued in conjunction with the Symphony Dynamo, Inc. transaction	\$	\$ 5,646
Liability from Program Option exercised under the SDI collaboration	\$ 15,000	\$

*See accompanying notes.*

**Dynavax Technologies Corporation**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

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

Dynavax Technologies Corporation 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 infectious diseases, allergies, 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 U.S. generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2006 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, 2006 as filed with the Securities and Exchange Commission, or SEC, on March 16, 2007.

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 intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

**Use of Estimates**

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

**Significant Accounting Policies**

We believe that there have been no significant changes in our critical accounting policies during the six months ended June 30, 2007 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2006.

**Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, which agreed to address the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may be applied to earlier periods. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and

financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Final Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of June 30, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to June 30, 2008.

## 2. Inventory

Inventories as of June 30, 2007 consist of the following (in thousands):

	<b>June 30, 2007</b>	<b>December 31, 2006</b>
Raw materials	\$ 184	\$ 194
Finished goods	64	63
Total	\$ 248	\$ 257

## 3. Intangible Assets

Intangible assets consist of manufacturing process, customer relationships, and developed technology acquired in connection with the acquisition of Rhein Biotech GmbH, or Rhein or Dynavax Europe, in April 2006. 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>June 30, 2007</b>	<b>Original Estimated Useful Life (in Years)</b>	<b>Gross</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Manufacturing process	5	\$ 3,670	\$ 876	\$ 2,794

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Customer relationships	5	1,230	294	936
Developed technology	7	180	31	149
Total		\$ 5,080	\$ 1,201	\$ 3,879

8

---

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

<b>Year ending December 31,</b>	
2007 (remaining six months)	\$ 503
2008	1,006
2009	1,006
2010	1,005
2011	325
Thereafter	34
<b>Total</b>	<b>\$ 3,879</b>

#### **4. Collaborative Research and Development Agreements**

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca AB, or AstraZeneca, for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We received an upfront payment of \$10 million upon signing the agreement and are eligible to receive research funding, preclinical milestones and future development milestones that in total could approximate \$136 million. Upon commercialization, we are also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$0.8 million and \$1.5 million for the three and six months ended June 30, 2007, respectively. As of June 30, 2007, our deferred revenue was \$10.5 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the first quarter of 2008. Revenue associated with these grants is recognized as the related expenses are incurred. For the six months ended June 30, 2007 and 2006, we recognized revenue of approximately \$1.7 million and \$0.5 million, respectively.

#### **5. 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, Symphony Dynamo, Inc., or SDI, agreed to fund up to \$50.0 million for the clinical development of these programs and we 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 \$30.0 million in April 2007. We are 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 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, and was recorded as a reduction in the noncontrolling interest in SDI and an increase in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option, defined as 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 our sole discretion. We also received an option to purchase either the hepatitis B or hepatitis C program, defined as the Program Option. We exercised the Program Option in April 2007 for the hepatitis B program. The exercise of the Program Option requires a payment obligation of \$15 million to Holdings upon the expiration of

the SDI collaboration in 2011 if the Purchase Option for all programs is not exercised at any time through the remaining term of the collaboration. The long-term liability for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If we do not exercise our exclusive right to purchase the remaining programs licensed under the agreement, the intellectual property rights to those programs at the end of the development period will remain with SDI. The long-term liability of \$15.0 million was offset against the noncontrolling interest in SDI.

In accordance with Financial Standards Board Interpretation No. 46 (revised 2003), Consolidation of Variable Interest Entities, or 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 consolidated financial statements as of June 30, 2007 and for the period from April 18, 2006 through December 31, 2006. Accordingly, the investments held by SDI in the consolidated balance sheet include the \$50.0 million of funding, less funds spent to date on the development of the programs. The noncontrolling interest in SDI reflects \$50.0 million of funding reduced by (i) the structuring fee and other closing costs of \$2.6 million, (ii) the value assigned to the warrants issued to Holdings upon closing of \$5.6 million, (iii) the Program Option obligation of \$15.0 million, and (iv) SDI's losses through June 30, 2007. Reimbursable expenses incurred under the SDI programs were \$6.6 million for the six months ended June 30, 2007.

## 6. Commitments

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 in September 2009 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. 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 six months ended June 30, 2007 and June 30, 2006, was \$1.0 million and \$0.8 million, respectively. Deferred rent was \$0.2 million as of June 30, 2007.

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.

Future minimum payments under the non-cancelable portion of our operating leases at June 30, 2007, excluding payments from the sublease agreement, are as follows (in thousands):

<b>Year ending December 31,</b>	
2007 (remaining six months)	\$ 1,109
2008	2,255
2009	1,529
<b>Total</b>	<b>\$ 4,893</b>

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of June 30, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. 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, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be



contingent and have summarized all significant arrangements below.

10

---

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of June 30, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$11 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.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Such fees and milestone payments to the Regents could approximate \$1 million in 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. ( Green Cross ) entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to SUPERVAX, a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time. To date revenue from SUPERVAX has not been material.

### 7. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and stock options to purchase 6.2 million and 5.6 million shares of common stock as of June 30, 2007 and 2006, respectively, were excluded from the calculation of diluted net loss per share because the effect would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Numerator:				
Net loss	\$(17,704)	\$(15,273)	\$(30,794)	\$(23,445)
Denominator:				
Weighted-average common shares outstanding used for basic and diluted net loss per share	39,741	30,536	39,734	30,524

### 8. Comprehensive Loss

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

	Six Months Ended June 30,	
	2007	2006
Net loss	\$(30,794)	\$(23,445)
Increase in unrealized gain on marketable securities available-for-sale	7	72
Increase in cumulative translation adjustment	8	65
Comprehensive loss	\$(30,779)	\$(23,308)

**9. Stockholders Equity**

As of June 30, 2007, we have two share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan. The 1997 Equity Incentive Plan, or 1997 Plan, expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any

outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

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

	Employee Stock Options				Employee Stock Purchase Plan	
	Three Months Ended		Six Months Ended		Six Months Ended	
	June 30,		June 30,		June 30,	
	2007	2006	2007	2006	2007	2006
Weighted-average fair value	\$2.78	\$3.79	\$3.75	\$3.99	\$2.64	\$2.65
Risk-free interest rate	4.8%	5.1%	4.8%	4.8%	5.0%	4.7%
Expected life (in years)	4.0	5.8	4.6	5.7	1.2	1.2
Volatility	0.7	0.8	0.8	0.8	0.7	0.7
Expected dividends						

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Employee and director stock-based compensation expense	\$ 674	\$ 731	\$ 1,471	\$ 1,388
Other stock-based compensation expense	15	(1)	26	8
Total	\$ 689	\$ 730	\$ 1,497	\$ 1,396

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of June 30, 2007 the total unrecognized compensation cost related to non-vested options granted amounted to \$8.5 million, which is expected to be recognized over the options remaining weighted-average vesting period of 1.8 years.

Activity under the our stock option plans was as follows:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price
			Per Share
Balance at December 31, 2006	1,997,141	3,421,339	\$ 5.26
Options authorized	400,000		
Options granted	(925,685)	925,685	\$ 5.99
Options exercised		(5,666)	\$ 3.86

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

1997 Plan shares expired	(273,188)		
Options cancelled:			
Options forfeited (unvested).	190,984	(190,984)	\$ 5.91
Options expired (vested)	1,621	(1,621)	\$ 8.09
Balance at June 30, 2007	1,390,873	4,148,753	\$ 5.40

12

---

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 June 30, 2007:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding options (vested and expected to vest)	3,692,987	\$ 5.30	7.9	\$1,374,460
Options exercisable	1,624,568	\$ 4.49	6.7	\$1,260,978

#### Employee Stock Purchase Plan

As of June 30, 2007, 496,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees acquired 82,032 shares of our common stock under the Purchase Plan. At June 30, 2007, 413,770 shares of our common stock remained available for future purchases.

#### 10. Subsequent Events

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, or Deerfield, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loans for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, Dynavax has no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. Deerfield received 1.25 million warrants upon execution of the loan agreement at an exercise price of \$5.13 per share. Additional warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive a total of 5.55 million warrants during the term of the loan agreement.

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

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

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

#### Overview

Dynavax Technologies Corporation is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent infectious diseases, allergies, 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 product candidates include: HEPLISAV<sup>™</sup>, a hepatitis B vaccine in Phase 3; TOLAMBA<sup>™</sup>, a ragweed allergy immunotherapy; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca AB, or AstraZeneca. Our preclinical work on a vaccine for influenza is partially funded by the National Institute of Allergy and Infectious Diseases. Our colorectal cancer trials and our preclinical hepatitis C therapeutic program are funded by Symphony Dynamo, Inc., or SDI.

#### **HEPLISAV**

HEPLISAV, our product candidate for hepatitis B prophylaxis, is based on proprietary ISS that specifically targets TLR9 to stimulate an innate immune response. HEPLISAV combines ISS with HBV surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection. Previously reported clinical trials results have shown 100% seroprotection after two doses in subjects 18 to 39 years of age, and after three doses in difficult-to-immunize subjects 40 to 70 years of age.

Our ongoing multi-center Phase 3 pivotal trial known as PHAST (Phase 3 HepelisAv Short-regimen Trial), which began in Canada in late 2006 and in Germany in June 2007, enrolled over 2,400 subjects 11 to 55 years of age, and compares a two-dose regimen of HEPLISAV administered at 0 and 1 month to the conventional three dose regimen of Engerix-B<sup>®</sup> marketed by GlaxoSmithKline.

In June 2007, we initiated a safety and immunogenicity study in the U.S., a second clinical trial designed to support the licensure of HEPLISAV. In the U.S. study, consistent with the PHAST trial, subjects 11 to 55 years of age are receiving a two-dose regimen of HEPLISAV, at 0 and 1 month. The primary endpoint of this trial will be measured four weeks after the second dose.

In the second half of 2007, we plan to initiate a lot-to-lot consistency study comparing three consecutive lots of HEPLISAV containing Hepatitis B surface antigen manufactured at Dynavax Europe. Approximately 2,000 subjects are anticipated to be enrolled in this trial in the U.S., Canada and Germany. The data from the PHAST trial, U.S. safety study, and subsequent lot-to-lot consistency trials will contribute to a safety database of approximately 4,000 subjects to support a planned BLA submission by the end of 2008.

Also in the second half of 2007, we plan to initiate a Phase 2 trial in Canada in patients with end-stage renal disease (ESRD) to evaluate the safety and immunogenicity of two different doses of HEPLISAV. The trial will enroll adults 40 to 70 years of age who have progressive loss of renal function and are either pre-dialysis or hemodialysis patients. This is a difficult-to-immunize patient population for whom conventional hepatitis B vaccines have shown limited efficacy. We intend to focus our development activities and resources on maximizing the potential of the demonstrated superiority of HEPLISAV over conventional hepatitis B vaccine in adults, and its potential in patients with ESRD.

#### **Allergy Franchise**

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs.

#### **TOLAMBA**

TOLAMBA, our product candidate for the treatment of ragweed allergy, consists of ISS linked to the purified major allergen of ragweed, Amb a 1. TOLAMBA is designed to target the underlying cause of seasonal allergic rhinitis caused by ragweed. The linking of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy.

In the fourth quarter of 2007, we plan to initiate a 300-patient, randomized, placebo-controlled environmental exposure chamber study of TOLAMBA. Patients will be screened and selected by exposure to ragweed allergen in the chamber to identify those with confirmed severe ragweed allergic disease on the basis of symptomatic response in the chamber. Patients will be enrolled and randomized to placebo or TOLAMBA treatment, then treated and re-exposed in the chamber to determine the effect of the six-week, six-injection TOLAMBA regimen. Efficacy will be measured by the difference in total nasal symptom scores (TNSS) at baseline and after treatment as compared to placebo. We anticipate receiving data from the chamber study in the first half of 2008.





To date, TOLAMBA has been administered to over 1,100 patients, and has been safe and well-tolerated. A Phase 2 study conducted in 2001-2002 showed 55% reduction ( $p=0.03$ ) in TNSS in the first season which was maintained ( $p=0.02$ ) in the second season with no additional therapy. This was a single site study with well-characterized, severe allergic patients. The Phase 2 study conducted in 2004-2005 at 19 centers in the U.S. showed a 21% reduction in symptoms in the first year ( $p=0.04$ ) which was also maintained in the second year with no additional therapy ( $p=0.02$ ). However, the largest study of TOLAMBA (the DARTT study), conducted in 2006 in 738 patients at 30 U.S. sites, failed to enroll patients with measurable ragweed-allergic disease; therefore, the effect of the treatment could not be measured and the study did not achieve its primary endpoints.

#### ***Peanut Allergy Immunotherapy***

Our peanut allergy program involves direct linkage of critical peanut allergens to a proprietary TLR9 agonist. This approach is designed to mask the IgE binding sites of the native allergen to ensure the safety of the intervention, and to induce an allergen-specific Th1 to Th2 immune shift, to reprogram the immune response in allergic patients. Our approach to peanut allergy provided protection in a mouse model of peanut induced anaphylaxis. Subject to successful completion of product selection and optimization activities and preclinical studies, we plan to initiate clinical studies in 2009.

#### ***Cat Allergy Immunotherapy***

Our cat allergy program, similar to our approach to peanut allergy, involves direct linkage of the major cat allergen to a proprietary TLR9 agonist. Subject to successful completion of product selection and optimization activities and preclinical studies, we plan to initiate clinical studies in 2009. We anticipate that the clinical development path for a disease-modifying cat allergy therapy to be focused on challenge studies, in which both patient selection and study timing can be tightly controlled.

#### ***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 therapy, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, SDI agreed to fund up to \$50.0 million for the clinical development of these programs and we 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 \$30.0 million in April 2007. We are 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 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, defined as the Purchase Option. 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 received an option to purchase either the hepatitis B or hepatitis C program, defined as the Program Option. Dynavax exercised the Program Option in April 2007 for the hepatitis B program. The exercise of the Program Option requires a payment obligation of \$15 million to Holdings upon the expiration of the SDI collaboration in 2011 if the purchase option for all programs is not exercised at any time through the remaining term of the collaboration. The long-term liability for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If we do not exercise our exclusive right to purchase the remaining programs licensed under the agreement, the intellectual property rights to those 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. In December 2006, we initiated a Phase 1 dose escalation clinical trial of our cancer product candidate in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. In addition, a Phase 2 study has been completed in non-Hodgkin's lymphoma (NHL) of

ISS in combination with Rituxan<sup>™</sup> (rituximab). In December 2006, we announced preliminary data from this Phase 2 study based on 23 patients with histologically confirmed CD20+, B-cell follicular NHL who had relapsed after at least one prior treatment regimen for lymphoma. This study showed a possible correlation between biomarker response to ISS and clinical outcomes; patients with high biomarker induction had a doubling of response rate and progression free survival versus patients with low biomarker induction. The combination of rituximab and our ISS was well-tolerated, and adverse events were minimal. We previously reported a Phase 1, dose-escalation trial of our ISS in combination with rituximab in 20 patients with NHL in which dose-dependent pharmacological activity was demonstrated without significant toxicity.

We anticipate that additional cancer product candidates will advance into clinical trials in solid tumors in 2007, and our hepatitis C therapeutic product candidate is also planned to enter the clinic in 2007.

***Hepatitis B Immunotherapy***

We are developing a novel therapy to treat chronic hepatitis B infection that combines hepatitis B surface antigen and hepatitis B core antigen. In March 2007, we initiated a Phase 1 study of this therapy in 20 healthy subjects, to evaluate the safety and immunogenicity of two dosing regimens. Results from this trial are anticipated in the second half of 2007.

***AstraZeneca Research Collaboration and License Agreement***

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 is using our proprietary second-generation TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration.

***Influenza Vaccine***

In the fourth quarter of 2006, we announced preclinical data that indicate our flu vaccine can improve the immunogenicity of standard flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with standard vaccine enhances the immune response of the standard vaccine, allows reduction of standard vaccine dosage, and provides extra layers of protection that are not strain-dependent. Our flu vaccine is based on our proprietary TLR9 agonist-based ISS technology. The preclinical work was funded in part by a research and development grant for a pandemic flu vaccine from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health.

***SUPERVAX***

In April 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, or Dynavax Europe. As a result, we acquired a hepatitis B vaccine called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection when administered on a two-dose schedule. SUPERVAX was launched in Argentina in December 2006 and is approved for marketing and sales through a third party partner. We intend to continue registration activities for SUPERVAX as a two-dose vaccine for adolescents for commercialization through partners in select countries outside of North America and Europe.

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

We believe that there have been no significant changes in our critical accounting policies during the six months ended June 30, 2007 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2006.

***Results of Operations***

*Revenues*

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

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

	Three Months Ended		Increase (Decrease) from 2007 to 2006		Six Months Ended		Increase (Decrease) from 2007 to 2006	
	June 30,				June 30,			
	2007	2006	\$	%	2007	2006	\$	%
<b>Revenues:</b>								
Collaboration revenue	\$ 752	\$	\$ 752	100%	\$ 1,499	\$	\$ 1,499	100%
Services and license revenue	461	224	237	106%	570	224	346	154%
Grant revenue	587	305	282	92%	1,715	593	1,122	189%
Total revenues	\$ 1,800	\$ 529	\$ 1,271	240%	\$ 3,784	\$ 817	\$ 2,967	363%

Total revenues for the six months ended June 30, 2007 were \$3.8 million, compared to \$0.8 million for the same period in 2006. Total revenues in 2007 consisted of collaboration revenue from AstraZeneca, services and license fees from R&D services provided to customers of Dynavax Europe, and grants primarily awarded by the National Institute of Allergy and Infectious Diseases.

We anticipate that our total revenues will continue to increase in 2007 as compared to 2006 due primarily to research funding under our collaboration with AstraZeneca.

#### *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):

	Three Months Ended		Increase (Decrease) from 2006 to 2007		Six Months Ended		Increase (Decrease) from 2006 to 2007	
	June 30,				June 30,			
	2007	2006	\$	%	2007	2006	\$	%
<b>Research and development:</b>								
Compensation and related personnel costs	\$ 5,186	\$ 3,069	\$ 2,117	69%	\$ 9,514	\$ 5,544	\$ 3,970	72%
Outside services	12,127	6,180	5,947	96%	19,802	9,046	10,756	119%
Facility costs	1,545	1,241	304	24%	2,959	2,208	751	34%
Non-cash stock-based compensation	306	272	34	13%	521	556	(35)	(6%)
Total research and development	\$ 19,164	\$ 10,762	\$ 8,402	78%	\$ 32,796	\$ 17,354	\$ 15,442	89%

Research and development expenses for the six months ended June 30, 2007 increased by \$15.4 million, or 89%, over the same period in 2006. The increase was primarily due to outside services which included a one-time \$5 million payment in June 2007 for a non-exclusive license to certain patents and patent applications for the purpose of commercializing HEPLISAV. The remaining growth in outside services was due to increased clinical trial and clinical material manufacturing costs related to HEPLISAV and expenses incurred to support SDI programs and Dynavax Europe operations. Compensation and related personnel costs increased in 2007 resulting from continued organizational growth to further develop our clinical candidates and the impact of Dynavax Europe.

We anticipate that our research and development expenses will increase significantly in 2007 as compared to 2006, primarily in connection with the advancement of HEPLISAV, TOLAMBA and our programs in cancer, hepatitis B

and hepatitis C therapies, asthma and flu.

*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):

	Three Months Ended		Increase (Decrease) from 2006 to 2007		Six Months Ended		Increase (Decrease) from 2006 to 2007	
	June 30,		\$	%	June 30,		\$	%
	2007	2006			2007	2006		
<b>General and administrative:</b>								
Compensation and related personnel costs	\$ 1,742	\$ 1,641	\$ 101	6%	\$ 3,529	\$ 2,805	\$ 724	26%
Outside services	1,181	784	397	51%	2,358	1,464	894	61%
Legal costs	753	348	405	116%	1,245	632	613	97%
Facility costs	150	149	1	1%	283	293	(10)	(3%)
Other						(50)	50	(100%)
Non-cash stock-based compensation	380	458	(78)	(17%)	971	839	132	16%
<b>Total general and administrative</b>	<b>\$ 4,206</b>	<b>\$ 3,380</b>	<b>\$ 826</b>	<b>24%</b>	<b>\$ 8,386</b>	<b>\$ 5,983</b>	<b>\$ 2,403</b>	<b>40%</b>

General and administrative expenses for the six months ended June 30, 2007 increased by \$2.4 million, or 40%, over the same period in 2006. The increase primarily reflects additional compensation and related personnel costs associated with overall organizational growth including the operations of Dynavax Europe. Outside services and legal costs increased in 2007 related to higher professional fees incurred in conjunction with various corporate development activities and expenses incurred to support SDI programs and Dynavax Europe operations.

We expect general and administrative expenses to increase modestly in 2007 as compared to 2006, resulting from continued organizational growth and expenses incurred to support the advancement of our clinical development programs and corporate development activities.

#### *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 \$0.5 million for the six months ended June 30, 2007.

#### *Interest and Other Income, Net*

Interest income is reported net of amortization on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. The following is a summary of our interest and other income, net (in thousands):

	Three Months Ended		Increase (Decrease) from 2006 to 2007		Six Months Ended		Increase (Decrease) from 2006 to 2007	
	June 30,		\$	%	June 30,		\$	%
	2007	2006			2007	2006		
<b>Interest and other income, net:</b>								
Interest income, net	\$ 1,078	\$ 675	\$ 403	60%	\$ 2,047	\$ 1,410	\$ 637	45%
Other income net	3	10	(7)	(70%)	7	10	(3)	(30%)
<b>Total interest and other income, net</b>	<b>\$ 1,081</b>	<b>\$ 685</b>	<b>\$ 396</b>	<b>58%</b>	<b>\$ 2,054</b>	<b>\$ 1,420</b>	<b>\$ 634</b>	<b>\$ 45%</b>

Interest and other income, net was \$2.1 million for the six months ended June 30, 2007 compared to \$1.4 million reported for the same period in 2006. The increase was primarily due to approximately \$0.5 million of interest earned on the investments held by SDI and the investment of proceeds from our equity offerings in the fourth quarter of 2006.

#### *Amount Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.*

Pursuant to the agreements that we entered into with SDI in April 2006 and in accordance with Financial Accounting Standards Board Interpretation No. 46 (revised 2003), Consolidation of Variable Interest Entities, or FIN 46R , the results of operations of SDI have been included in our consolidated financial statements from the date of formation. We have deducted the losses attributed to the noncontrolling interest from our condensed consolidated statement of operations to the extent that the offsetting amount of the noncontrolling interest in the condensed consolidated balance sheet is zero. For the six months ended June 30, 2007 the loss attributed to the noncontrolling interest was \$5.1 million.



### **Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which agreed to address the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may be applied to earlier periods. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities*, which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 159 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Final Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of June 30, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. income taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to June 30, 2008.

### **Liquidity and Capital Resources**

As of June 30, 2007, we had \$47.5 million in cash, cash equivalents and marketable securities and \$35.1 million in investments held by SDI. Our funds are currently invested in a variety of securities, including institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

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 \$222 million in net cash proceeds. To a lesser extent, we have financed our operations through amounts received under collaborative agreements and government grants. 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 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 of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. In the fourth quarter of 2006, we completed a follow-on offering raising approximately \$29.3 million from the sale of 7,130,000 shares of common stock. We use these proceeds to fund our current operations.

In August 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%. In December 2006, we completed a draw down on our equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of our common stock. \$15 million remains available on our equity line of credit.

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, or Deerfield, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loans for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, Dynavax has no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. Deerfield received 1.25 million warrants upon execution of the loan agreement at an exercise price of \$5.13 per share. Additional warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive a total of 5.55 million warrants during the term of the loan agreement..

Cash used in operating activities was \$33.4 million during the six months ended June 30, 2007 compared to \$17.9 million for the same period in 2006. The increase in cash usage over the prior year was due primarily to the increase in our net loss and the amount attributed to the noncontrolling interest in SDI.

Cash used in investing activities was \$4.4 million during the six months ended June 30, 2007 compared to cash provided of \$1.6 million for the same period in 2006. The decrease was attributed to a reduction in the net proceeds from sales and maturities of marketable securities.

Cash provided by financing activities was \$30.1 million during the six months ended June 30, 2007 compared to \$17.6 million for the same period in 2006. Cash provided by financing activities primarily included the proceeds from the purchase of noncontrolling interest by preferred shareholders in Symphony Dynamo, Inc.

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

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

**Contractual Obligations**

The following summarizes our significant contractual obligations as of June 30, 2007 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Less</b>		
		<b>than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>
Future minimum payments under our operating lease	\$ 4,893	\$ 2,228	\$ 2,665	\$
Long-term liability from the Program Option exercised under the SDI collaboration	15,000			15,000
<b>Total</b>	<b>\$ 19,893</b>	<b>\$ 2,228</b>	<b>\$ 2,665</b>	<b>\$ 15,000</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 us in September 2009 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

In April 2007 we exercised an option to repurchase our hepatitis B program from Symphony Dynamo. The exercise of the Program Option triggers a payment obligation of \$15 million upon the expiration of the SDI collaboration if the Purchase Option for all programs is not exercised. The price for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of June 30, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. 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, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of June 30, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$11 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.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Such fees and milestone payments to the Regents could approximate \$1 million in 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to SUPERVAX, a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time. To date SUPERVAX revenue has not

been material.

***Off-balance Sheet Arrangements***

We do not have any off-balance sheet arrangements as defined by rules recently enacted by the SEC and Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have a current or future effect on our financial position. As

described above, SDI is not an off-balance sheet arrangement as it is considered a variable interest entity and included in our financial statements.

### **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. to support the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of June 30, 2007 was \$0.2 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

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

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

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

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS.

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

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

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$198.7 million as of June 30, 2007. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors and are scheduled to terminate in 2007. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate significant revenue. Clinical trials for certain of our product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

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

- obtaining regulatory approvals for our product candidates; and

- entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations or raise additional capital on less favorable terms.

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

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding may not allow us to continue operations as currently planned. We 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 on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations.

#### **The success of our TLR9 product candidates depends on achieving successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.**

None of our TLR9 product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced TLR9 product

candidates. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval.

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

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

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

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

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

result in significant additional costs;

potentially diminish any competitive advantages for those products;

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

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

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

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

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

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





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

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

Our most advanced product candidates in clinical trials are based on our 1018 ISS compound, and 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 ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

**We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, which could preclude us from manufacturing our product candidates on commercially reasonable terms.**

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

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

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

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. We may enter into manufacturing agreements with one or more commercial-scale contract manufacturers to produce additional supplies of HEPLISAV as required for new clinical trials and commercialization, or we may have to establish internal commercial-scale manufacturing capability for HEPLISAV, incurring increased capital and operating costs, delays in the commercial development of HEPLISAV and higher manufacturing costs than we have experienced to date.

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

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our clinical trials would delay our ability to commercialize our products and could have a material adverse effect on our business and operations.

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



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

We intend to 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.

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

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

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

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

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

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

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical

trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

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

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

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;

- compliance with varying international regulatory requirements, laws and treaties;

- securing international distribution, marketing and sales capabilities;

- adequate protection of our intellectual property rights;

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

- adverse tax consequences;

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

- geopolitical risks.

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

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

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

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

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

property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

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

able to commercialize HEPLISAV in the United States while these patents are issued, 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 if a license is available at all. A license may require us to pay substantial fees or royalties, require us to grant a cross-license to our technology or may not be available to us on acceptable terms, if at all. In addition, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

Another of our potential competitors, Coley, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, that may be asserted against our ISS products. In June 2007, we entered into an agreement with Coley under which we received a non-exclusive license to certain Coley patents and patent applications for the purpose of commercializing HEPLISAV. We may need to obtain a license to one or more of these patent claims held by Coley by paying fees or royalties or offering rights to our own proprietary technologies in order to commercialize one or more of our other formulations of ISS in the U.S. Such a license may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

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

Our success depends on our ability to:

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

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

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

The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the United States. 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 receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;

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

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



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

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

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

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

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

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

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

In 2006, we 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 are 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. In April 2007, we exercised our option for the hepatitis B program. The exercise of this program option triggers a payment obligation of \$15 million to Holdings upon the expiration of the SDI collaboration in 2011 if the purchase option for all programs is not exercised.

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.

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

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. This coverage may not be adequate or may not

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

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

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

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

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

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

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

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

- progress or results of any of our clinical trials or regulatory efforts, in particular any announcements regarding the progress or results of our planned trials;

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

- our ability to raise additional capital to fund our operations;

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

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

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

- our ability to enter into collaborations;

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

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

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

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

30

---

volume of trading in our common stock

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 financial and accounting systems, procedures or controls as we grow our business and organization and to satisfy new reporting requirements.**

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. Specifically, we have integrated the operations, technologies, products and personnel of Dynavax Europe into our operations and Dynavax Europe's operations will be required to be included in our assessment of internal controls over financial reporting under Section 404 by the end of 2007. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent auditors are unable to issue an unqualified attestation as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

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

None.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.



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

The Company held its Annual Meeting of Shareholders on June 13, 2007. The proposals voted on by the Company's shareholders and the voting results were as follows:

**Proposal 1: Election of Class I Directors**

The election of directors was approved as follows:

	<b>For</b>	<b>Withhold</b>
Dino Dina, M.D	34,417,951	1,118,010
Dennis Carson, M.D.	34,440,967	1,094,994
Denise M. Gilbert, Ph.D.	34,458,184	1,077,777

**Proposal 2: Ratification of Appointment of Independent Registered Public Accounting Firm**

Ernst & Young LLP was ratified as the Company's independent registered public accounting firm for fiscal year 2007 as follows:

<b>For</b>	<b>Against</b>	<b>Abstain</b>
34,862,566	50,947	622,448

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

**Exhibit  
Number**

**Document**

- 10.32 License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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.





**SIGNATURES**

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

DYNAVAX TECHNOLOGIES CORPORATION

Date: August 3, 2007

By: /s/ DINO DINA, M.D.

Dino Dina, M.D.  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: August 3, 2007

By: /s/ DEBORAH A. SMELTZER

Deborah A. Smeltzer  
Vice President, Operations and Chief Financial Officer  
(Principal Financial Officer)