

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

May 02, 2008

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**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2008

or

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

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

Commission file number: 000-50577

**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)*

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

As of April 30, 2008, the registrant had outstanding 39,805,740 shares of common stock.

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

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**FORWARD-LOOKING STATEMENTS**

*This Quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 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.*

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

	<b>March 31, 2008 (unaudited)</b>	<b>December 31, 2007 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,858	\$ 14,293
Marketable securities available-for-sale	27,828	42,324
Investments held by Symphony Dynamo, Inc. (SDI)	29,475	31,631
Restricted cash	661	408
Accounts receivable	6,140	7,234
Prepaid expenses and other current assets	5,205	6,049
<b>Total current assets</b>	<b>85,167</b>	<b>101,939</b>
Property and equipment, net	10,268	7,314
Goodwill	2,312	2,312
Other intangible assets, net	2,994	3,239
Other assets	4,591	5,645
<b>Total assets</b>	<b>\$ 105,332</b>	<b>\$ 120,449</b>
<b>Liabilities, noncontrolling interest and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,764	\$ 4,418
Accrued liabilities	10,267	12,059
Deferred revenues	3,516	3,427
<b>Total current liabilities</b>	<b>16,547</b>	<b>19,904</b>
Deferred revenues, noncurrent	40,127	40,792
Liability from program option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	7,616	5,622
Noncontrolling interest in SDI	6,775	8,341
Commitments and contingencies		
Stockholders equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at March 31, 2008 and December 31, 2007		
Common stock: \$0.001 par value; 100,000 shares authorized at March 31, 2008 and December 31, 2007; 39,806 and 39,765 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	40	40
Additional paid-in capital	259,068	258,266
Accumulated other comprehensive income:		
Unrealized gain on marketable securities available-for-sale	182	138
Cumulative translation adjustment	320	260

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Accumulated other comprehensive income	502	398
Accumulated deficit	(240,343)	(227,914)
<b>Total stockholders' equity</b>	<b>19,267</b>	<b>30,790</b>
Total liabilities, noncontrolling interest and stockholders' equity	\$ 105,332	\$ 120,449

See accompanying notes.

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

(In thousands, except per share amounts)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>		
Collaboration revenue	\$ 5,774	\$ 747
Grant revenue	324	1,128
Service and license revenue	216	109
<b>Total revenues</b>	<b>6,314</b>	<b>1,984</b>
<b>Operating expenses:</b>		
Research and development	15,120	13,632
General and administrative	4,571	4,180
Amortization of intangible assets	245	251
<b>Total operating expenses</b>	<b>19,936</b>	<b>18,063</b>
<b>Loss from operations</b>	<b>(13,622)</b>	<b>(16,079)</b>
Interest and other income, net	971	1,001
Interest expense	(1,344)	(28)
<b>Loss including noncontrolling interest in Symphony Dynamo, Inc.</b>	<b>(13,995)</b>	<b>(15,106)</b>
<b>Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.</b>	<b>1,566</b>	<b>2,016</b>
<b>Net loss</b>	<b>\$ (12,429)</b>	<b>\$ (13,090)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.31)</b>	<b>\$ (0.33)</b>
<b>Shares used to compute basic and diluted net loss per share</b>	<b>39,785</b>	<b>39,727</b>

*See accompanying notes.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (12,429)	\$ (13,090)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	438	342
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc. (SDI)	(1,566)	(2,016)
Amortization of intangible assets	245	251
Accretion and amortization on marketable securities	(331)	(688)
Interest associated with Deerfield financing agreement	1,323	
Stock-based compensation expense	661	808
Changes in operating assets and liabilities:		
Accounts receivable	1,094	936
Prepaid expenses and other current assets	844	(1,009)
Inventory		11
Other assets	(80)	1,157
Accounts payable	(1,654)	(617)
Accrued liabilities	(2,234)	(954)
Deferred revenues	(576)	(30)
Net cash used in operating activities	(14,265)	(14,899)
<b>Investing activities</b>		
Change in investments held by SDI	2,156	4,754
Purchases of marketable securities	(5,926)	(16,090)
Proceeds from sales of marketable securities	4,047	
Proceeds from maturities of marketable securities	16,750	25,699
Purchases of property and equipment, net	(3,398)	(711)
Net cash provided by investing activities	13,629	13,652
<b>Financing activities</b>		
Proceeds from notes payable issued to Deerfield	2,000	
Proceeds from issuance of common stock, net of issuance costs		(19)
Proceeds from employee stock purchase plan	136	71
Proceeds from exercise of stock options	5	22
Net cash provided by financing activities	2,141	74
Effect of exchange rate on cash and cash equivalents	60	(2)
Net increase in cash and cash equivalents	1,565	(1,175)
Cash and cash equivalents at beginning of period	14,293	14,154



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Cash and cash equivalents at end of period	\$ 15,858	\$ 12,979
<b>Supplemental disclosure of cash flow information</b>		
Disposal of fully depreciated property and equipment	\$	\$ 18

*See accompanying notes.*

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

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

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative 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. We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

**Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2007 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission, or SEC.

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

**Use of Estimates**

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

**Significant Accounting Policies**

There have been no significant changes in our critical accounting policies during the three months ended March 31, 2008 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007.

**Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 ( SFAS 160 ). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our consolidated results of operations and financial condition.



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In December 2007, the FASB ratified the final consensus in Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaboration Agreements*, which required certain income statement presentation of transactions with third parties and of payments between parties to the collaboration arrangement, along with disclosure about the nature of the arrangement. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated results of operations and financial condition.

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

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we adopted SFAS 157 in the first quarter of fiscal 2008. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, the Company has adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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

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

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

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

**2. Fair Value Measurements**

In accordance with SFAS 157, the following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and investments held by SDI measured at fair value on a recurring basis as of March 31, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money Market Funds	\$ 40,210	\$	\$	\$ 40,210
U.S. Treasury Bills	4,749			4,749
Corporate Debt Securities		27,828		27,828

Total		\$ 44,959	\$ 27,828	\$	\$ 72,787
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Intangible assets consist primarily of manufacturing process, customer relationships, and developed technology. The manufacturing process derives from the methods for making proteins in Hansenula yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at March 31, 2008 (in thousands, except years):

	<b>Original Estimated</b>			
	<b>Useful Life</b>	<b>Gross</b>	<b>Accumulated</b>	<b>Net</b>
	<b>(in Years)</b>		<b>Amortization</b>	
Manufacturing process	5	\$ 3,670	\$ 1,428	\$ 2,242
Customer relationships	5	1,230	478	752