# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 8-K

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): 11/01/2012

## **Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

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

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(Address of principal executive offices, including zip code)

(510) 848-5100

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

	Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:					
[]	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)					
[]	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)					

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition

On November 1, 2012, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the third quarter ended September 30, 2012. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information with respect to item 2.02 in this current report and its accompanying exhibit shall not be deemed to "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this current report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange commission made by Dynavax, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 9.01. Financial Statements and Exhibits

- (d) Exhibits. The following exhibit is furnished herewith:
- 99.1 Press Release, dated November 1, 2012 titled "Dynavax Reports Third Quarter 2012 Financial Results."

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Dynavax Technologies Corporation** 

Date: November 02, 2012 By: /s/ Christine R. Larson

Christine R. Larson Vice President and Chief Financial Officer

## EXHIBIT INDEX

Exhibit No. Description

EX-99.1 DYNAVAX REPORTS THIRD QUARTER 2012 FINANCIAL RESULTS

**Contacts:** 

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Officer

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## DYNAVAX REPORTS THIRD QUARTER 2012 FINANCIAL RESULTS

BERKELEY, CA - November 1, 2012 - Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the third quarter ended September 30, 2012. The Company had \$148.3 million in cash, cash equivalents and marketable securities as of September 30, 2012.

Total revenues for the quarter ended September 30, 2012 were \$2.9 million compared to \$1.2 million for the quarter ended September 30, 2011, due primarily to higher collaboration and grant revenue recognized as a result of research and development reimbursable under Dynavax's partnerships with AstraZeneca and the National Institute of Allergy and Infectious Diseases.

Research and development expenses for the quarter ended September 30, 2012 were \$12.9 million compared to \$11.8 million for the quarter ended September 30, 2011. Increased research and development expenses in the third quarter of 2012 were primarily attributed to manufacturing and regulatory activities for HEPLISAV<sup>TM</sup>.

General and administrative expenses for the quarter ended September 30, 2012 were \$7.1 million compared to \$4.2 million for the quarter ended September 30, 2011. General and administrative expenses increased primarily due to growth in the organization and activities to prepare for and support the commercial launch of HEPLISAV in the United States.

## **Recent Developments**

Dynavax reported the following recent developments:

- In June 2012, we reported that the FDA has established February 24, 2013, as the Prescription Drug User Fee Act (PDUFA) action date for our HEPLISAV Biologics License Application, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age. In August 2012, the FDA informed the Company that its Vaccines and Related Biological Advisory Committee is scheduled to discuss HEPLISAV at its meeting on November 15, 2012.
- In July 2012, the American Medical Association Current Procedural Terminology (CPT) Panel established a CPT code for an adult two dose hepatitis B vaccination schedule. CPT codes are designed to communicate uniform information about medical services and procedures among physicians and payers for administrative and financial purposes. If approved, HEPLISAV will be reported using the new two dose code, differentiating it from a three dose hepatitis B vaccine schedule.
- In July 2012, we filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for HEPLISAV for use in adults 18 through 70 years of age and in patients with chronic kidney disease. The Company was subsequently notified in August 2012 by the EMA that its MAA was accepted for review. The EMA is a European Union agency responsible for the evaluation of medicinal products that allows companies to submit a single application for marketing authorization in all European Union and European Economic Area European Free Trade Association states.
- In October 2012, we and AstraZeneca agreed to advance AZD1419, a proprietary second generation TLR-9 agonist for asthma, towards a Phase 1 clinical trial, which entitles us to a development milestone payment of \$6 million.

#### **About HEPLISAV**

HEPLISAV is an investigational adult hepatitis B vaccine for which U.S. and European licensure applications have been accepted for review by the FDA and EMA. In Phase 3 trials, HEPLISAV demonstrated higher and earlier protection with fewer doses than currently licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known to enhance the immune response.

## **About Dynavax**

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is

HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide higher and earlier protection with fewer doses than currently licensed vaccines. For more information visit www.dynavax.com.

- tables to follow -

### DYNAVAX TECHNOLOGIES CORPORATION

### **CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

(Unaudited)

	Th	Three Months Ended		Nine Months Ended	
		September 30,	September 30,		
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>	
Revenues:					
Collaboration revenue	\$ 1,050	\$ 369	\$ 3,602	\$ 7,098	
Grant revenue	1,219	658	3,188	2,437	
Service and license revenue	<u>605</u>	<u>147</u>	<u>1,118</u>	<u>652</u>	
Total revenues	2,874	1,174	7,908	10,187	
Operating expenses:					
Research and development	12,850	11,777	36,631	39,706	
General and administrative	7,121	4,217	18,871	13,025	
Amortization of intangible assets	_	_	_	<u>299</u>	
Total operating expenses	<u>-</u> 19,971	<u>-</u> 15,994	<u>55,502</u>	<u>53,030</u>	
Loss from operations	(17,097)	(14,820)	(47,594)	(42,843)	
Interest income	91	18	208	74	
Interest expense	(589)	(485)	(1,765)	(1,462)	
Other income (expense)	<u>(196)</u>	<u>58</u>	<u>(255)</u>	<u>(99)</u>	
Net loss	<u>\$ (17,791)</u>	<u>\$ (15,229)</u> .	<u>\$ (49,406)</u>	<u>\$ (44,330)</u>	
Basic and diluted net loss per share	<u>\$ (0.10)</u>	<u>\$ (0.12)</u>	<u>\$ (0.30)</u>	<u>\$ (0.37)</u>	
Shares used to compute basic and diluted net loss per share	<u>177,870</u>	124,069	<u>167,039</u>	119,244	

DYNAVAX TECHNOLOGIES CORPORATION SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	September 30,	December 31,
	<u>2012</u>	<u>2011</u>
Assets		
Cash and cash equivalents and marketable securities	\$ 148,279	\$ 113,961
Property and equipment, net	6,948	6,163
Goodwill	2,408	2,312
Other assets	<u>7,187</u>	<u>11,666</u>
Total assets	<u>\$ 164,822</u>	<u>\$ 134,102</u>
Liabilities and stockholders' equity		
Deferred revenues	\$ 8,947	\$ 10,596
Short-term note payable	14,452	12,810
Other liabilities	<u>11,365</u>	<u>10,816</u>
Total liabilities	34,764	34,222
Stockholders' equity	<u>130,058</u>	<u>99,880</u>
Total liabilities and stockholders' equity	<u>\$ 164,822</u>	<u>\$ 134,102</u>

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