

# DYNAVAX TECHNOLOGIES CORP

## **FORM 8-K** (Current report filing)

Filed 08/02/17 for the Period Ending 08/02/17

Address	2929 SEVENTH STREET SUITE 100 BERKELEY, CA 94710
Telephone	5108485100
CIK	0001029142
Symbol	DVAX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

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**Form 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): August 2, 2017**

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**Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

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**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)

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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))

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

On August 2, 2017, Dynavax Technologies Corporation (“Dynavax”) issued a press release announcing its financial results for the quarter ended June 30, 2017. 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 “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 August 2, 2017, titled “Dynavax Reports Second Quarter 2017 Financial Results”

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**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: August 2, 2017

By: /s/ DAVID JOHNSON

David Johnson  
Vice President

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**EXHIBIT INDEX**

**Exhibit  
No.**

**Description**

EX-99.1

Press Release, August 2, 2017, titled "Dynavax Reports Second Quarter 2017 Financial Results"



## DYNNAVAX REPORTS SECOND QUARTER 2017 FINANCIAL RESULTS

BERKELEY, CA – August 2, 2017 – Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the second quarter ended June 30, 2017. Cash, cash equivalents and marketable securities were \$127.0 million at June 30, 2017 compared to \$81.4 million at December 31, 2016. The increase was primarily due to net proceeds of \$88.2 million during the first half of 2017 from sales of common stock under an at-the-market sales agreement.

### Additional Financial Results

The net loss for the three months ended June 30, 2017 was \$20.3 million, or \$0.41 per share, compared to \$29.0 million, or \$0.75 per share, for the same period in 2016. The net loss for the six months ended June 30, 2017 was \$45.6 million, or \$1.00 per share, compared to \$56.0 million, or \$1.46 per share, for the same period in 2016.

Research and development expenses for the quarter and six months ended June 30, 2017 were \$14.8 million and \$31.2 million, respectively, compared to \$22.8 million and \$42.8 million for the same periods in 2016. The decrease in the 2017 periods reflect reduced compensation and related personnel costs as a result of the January 2017 restructuring and cost reduction initiative. Additionally, the 2017 periods reflect lower costs related to HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] clinical and manufacturing activity partially offset by increased costs relating to seeking regulatory approval for HEPLISAV-B and the ongoing development of SD-101 and earlier stage oncology programs.

General and administrative expenses for the quarter and six months ended June 30, 2017 were \$5.6 million and \$12.1 million, respectively, compared to \$9.2 million and \$17.3 million for the same periods in 2016. The decrease in the 2017 periods reflect reduced compensation and related personnel costs as a result of the January 2017 restructuring and cost reduction initiative. Additionally, the 2016 periods included costs related to hiring of consultants for administrative and commercial development services for an anticipated commercial launch of HEPLISAV-B.

### About HEPLISAV-B

HEPLISAV-B is an investigational adult hepatitis B vaccine that combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist to enhance the immune response. In Phase 3 trials, HEPLISAV-B showed higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise, all of which were similar to an existing vaccine.

HEPLISAV-B is administered in two doses over one-month. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. Results of a published Vaccine Safety Datalink study showed that only 54 percent of adults completed the three-dose hepatitis B vaccine series in one year.<sup>1</sup> Those who do not complete the series may not be adequately protected against hepatitis B.

Dynavax has worldwide commercial rights to HEPLISAV-B.

<sup>1</sup> Nelson, J. et al. American Journal of Public Health, "Compliance with Multiple-Dose Vaccine Schedules Among Older Children, Adolescents and Adults: Results from a Vaccine Safety Datalink Study." 2009. Vol. 99 No. S2.

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## About SD-101

SD-101 is Dynavax's proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. SD-101 is being studied for its multiple anti-tumor activities in innate immune cells and activation of plasmacytoid dendritic cells to stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as SD-101 enhance T and B cell responses and provide potent Type 1 interferon induction and maturation of plasmacytoid dendritic cells to antigen-presenting cells. SD-101 is being evaluated in several Phase 1/2 oncology studies to assess its safety and activity.

For information about SD-101 trials that are currently recruiting patients, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## About Dynavax

Dynavax is a clinical-stage immunology company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax is developing product candidates for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. Dynavax's lead product candidates are SD-101, an investigational cancer immunotherapeutic currently in Phase 1/2 studies, and HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information visit [www.dynavax.com](http://www.dynavax.com).

## Forward Looking Statements

This release contains forward-looking statements and estimates. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the FDA will approve HEPLISAV-B, notwithstanding the FDA Advisory Committee votes in favor of the efficacy and safety of HEPLISAV-B; whether additional studies or manufacturing process enhancements will be required, or other issues will arise that will delay the BLA review or negatively impact the review and decision whether to approve HEPLISAV-B; the nature and scope of the post-marketing pharmacovigilance plan for HEPLISAV-B; the final label claims and the nature of the label content for HEPLISAV-B; whether the ACIP will recommend use of HEPLISAV-B and the timing of receiving a recommendation; whether we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101; whether or not Dynavax and parties with whom we are collaborating may reach any future agreement on further studies or a more extensive collaboration beyond the clinical trials contemplated under the existing agreements; and other risks detailed in the "Risk Factors" section of our most recent periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available. Information on Dynavax's website at [www.dynavax.com](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

## Contact:

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**DYNAVAX TECHNOLOGIES CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Collaboration revenue	\$ -	\$ 1,683	\$ -	\$ 2,578
Grant revenue	105	88	253	127
Service and license revenue	-	876	-	884
<b>Total revenues</b>	<b>105</b>	<b>2,647</b>	<b>253</b>	<b>3,589</b>
<b>Operating expenses:</b>				
Research and development	14,814	22,750	31,159	42,817
General and administrative	5,612	9,151	12,084	17,320
Restructuring	-	-	2,783	-
<b>Total operating expenses</b>	<b>20,426</b>	<b>31,901</b>	<b>46,026</b>	<b>60,137</b>
<b>Loss from operations</b>	<b>(20,321)</b>	<b>(29,254)</b>	<b>(45,773)</b>	<b>(56,548)</b>
Interest income	235	220	380	445
Other income (expense), net	(232)	48	(212)	94
<b>Net loss</b>	<b>\$ (20,318)</b>	<b>\$ (28,986)</b>	<b>\$ (45,605)</b>	<b>\$ (56,009)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.41)</b>	<b>\$ (0.75)</b>	<b>\$ (1.00)</b>	<b>\$ (1.46)</b>
<b>Weighted average shares used to compute basic and diluted net loss per share</b>	<b>49,700</b>	<b>38,496</b>	<b>45,787</b>	<b>38,491</b>

**DYNAVAX TECHNOLOGIES CORPORATION**

**SELECTED BALANCE SHEET DATA**

(In thousands)

(Unaudited)

	<b>June 30,</b>	<b>December 31,</b>
	<b>2017</b>	<b>2016</b>
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 126,961	\$ 81,415
Property and equipment, net	16,751	17,174
Goodwill	2,140	1,971
Other assets	6,116	9,120
<b>Total assets</b>	<b>\$ 151,968</b>	<b>\$ 109,680</b>
<b>Liabilities and stockholders' equity</b>		
Other liabilities	11,441	20,479
<b>Total liabilities</b>	<b>11,441</b>	<b>20,479</b>
Stockholders' equity	140,527	89,201
<b>Total liabilities and stockholders' equity</b>	<b>\$ 151,968</b>	<b>\$ 109,680</b>