

DYNAVAX TECHNOLOGIES CORP

FORM 8-K (Current report filing)

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

**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): May 8, 2017

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))

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.

Item 2.02. Results of Operations and Financial Condition

On May 8, 2017, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended March 31, 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 May 8, 2017, titled "Dynavax Reports First Quarter 2017 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: May 8, 2017

By: /s/ DAVID JOHNSON

David Johnson
Vice President

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, dated May 8, 2017, titled "Dynavax Reports First Quarter 2017 Financial Results"



DYNAVAX REPORTS FIRST QUARTER 2017 FINANCIAL RESULTS

BERKELEY, CA – May 8, 2017 – Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the first quarter ended March 31, 2017. Cash, cash equivalents and marketable securities were \$85.4 million at March 31, 2017 compared to \$81.4 million at December 31, 2016. The increase was primarily due to net proceeds of \$29.5 million during the first quarter of 2017 from sales of common stock under an at-the-market sales agreement (ATM). The net loss for the quarter ended March 31, 2017 was \$25.3 million, or \$0.60 per share, compared to \$27.0 million, or \$0.70 per share, for the quarter ended March 31, 2016. Subsequent to March 31, 2017, additional net proceeds under the ATM Agreement were \$18.9 million through May 3, 2017.

“In January we reduced operating cost, limited further investment in HEPLISAV-B [Hepatitis B Vaccine, (Recombinant) Adjuvanted] until after we have received approval, and focused our efforts on immuno-oncology,” said Michael Ostrach, chief financial officer of Dynavax. “We expect HEPLISAV-B costs prior to any FDA decision to be approximately \$1 million per month and all other operating costs to support continued development of our oncology business for the remaining three quarters of 2017 to be approximately \$45 million. During the first quarter we maintained a strong financial position by reducing costs and financing our operations through use of the ATM. This has enabled us to advance HEPLISAV-B to a regulatory decision and continue to generate clinical results from our immuno-oncology portfolio to deliver value in both areas of our business during 2017. We have an abstract accepted for presentation in early June at the 2017 ASCO Annual Meeting reporting on our Phase 1b/2 study of SD-101 in combination with pembrolizumab in patients with metastatic melanoma and the Prescription Drug User Fee Act date for HEPLISAV-B is August 10, 2017.”

Research and development expenses were \$16.3 million for the first quarter of 2017 compared to \$20.1 million for the same period in 2016. This decrease was primarily due to lower costs related to HEPLISAV-B clinical activity and reduced personnel cost 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 were \$6.5 million for the first quarter of 2017 compared to \$8.2 million for the same period in 2016. The current quarter reflects reduced compensation and related personnel costs as a result of the January 2017 restructuring and cost reduction initiative. Additionally, the first quarter of 2016 included costs related to hiring of consultants for administrative and commercial development services for the anticipated commercial launch of HEPLISAV-B.

As part of the January 2017 restructuring, the company suspended manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B during the regulatory review period and reduced its global workforce by approximately 40%. During the first quarter of 2017 we recorded charges of \$2.8 million related to severance, other termination benefits and outplacement services.

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.

About HEPLISAV-B

HEPLISAV-B™ [Hepatitis B Vaccine, (Recombinant) Adjuvanted] 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.¹ Those who do not complete the series may not be adequately protected against hepatitis B.

Dynavax has worldwide commercial rights to HEPLISAV-B.

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.

¹ 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.

Forward Looking Statements

This release contains forward-looking statements and estimates, including statements regarding estimated operating costs and anticipated cost reductions. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether anticipated operating costs projections will be achieved; whether HEPLISAV-B will be approved by the FDA; whether or not FDA will require additional clinical trials; the outcome of the scheduled Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and whether it will impact the timing of FDA review or negatively impact the review and approval of the HEPLISAV-B Biologics License Application (BLA); 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; if approvable, whether the issues will negatively impact the potential scope of the label claims and nature of the label content for HEPLISAV-B; 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 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 March 31,	
	2017	2016
Revenues:		
Collaboration revenue	\$ -	\$ 895
Grant revenue	148	39
Service and license revenue	-	8
Total revenues	148	942
Operating expenses:		
Research and development	16,345	20,067
General and administrative	6,472	8,169
Restructuring	2,783	-
Total operating expenses	25,600	28,236
Loss from operations	(25,452)	(27,294)
Other income:		
Interest income	145	225
Other income, net	20	46
Net loss	\$ (25,287)	\$ (27,023)
Basic and diluted net loss per share	\$ (0.60)	\$ (0.70)
Weighted average shares used to compute basic and diluted net loss per share	41,830	38,472

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	March 31, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	\$ 85,356	\$ 81,415
Property and equipment, net	16,633	17,174
Goodwill	2,001	1,971
Other assets	6,142	9,120
Total assets	\$ 110,132	\$ 109,680
Liabilities and stockholders' equity		
Other liabilities	12,736	20,479
Total liabilities	12,736	20,479
Stockholders' equity	97,396	89,201
Total liabilities and stockholders' equity	\$ 110,132	\$ 109,680