

DYNAVAX TECHNOLOGIES CORP

FORM 8-K (Current report filing)

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Address	2929 SEVENTH STREET SUITE 100 BERKELEY, CA, 94710
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Sector	Healthcare
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**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): November 3, 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 November 3, 2017, Dynavax Technologies Corporation (“Dynavax”) issued a press release announcing its financial results for the quarter ended September 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 November 3, 2017, titled “Dynavax Reports Third 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: November 3, 2017

By: /s/ DAVID JOHNSON

David Johnson
Vice President



DYNAX REPORTS THIRD QUARTER 2017 FINANCIAL RESULTS

BERKELEY, CA – November 3, 2017 – Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the third quarter ended September 30, 2017. Cash, cash equivalents and marketable securities were \$191.7 million at September 30, 2017 compared to \$81.4 million at December 31, 2016. The increase was primarily due to net proceeds of approximately \$169 million during the year from an underwritten public offering and sales of common stock under an at-the-market sales agreement.

Additional Financial Results

The net loss for the three months ended September 30, 2017 was \$22.1 million, or \$0.38 per share, compared to \$34.7 million, or \$0.90 per share, for the same period in 2016. The net loss for the nine months ended September 30, 2017 was \$67.7 million, or \$1.36 per share, compared to \$90.7 million, or \$2.36 per share, for the same period in 2016.

Research and development expenses for the quarter and nine months ended September 30, 2017 were \$16.4 million and \$47.6 million, respectively, compared to \$23.2 million and \$66.1 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 the investigational product HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] clinical and manufacturing activity partially offset by increased costs relating to seeking FDA approval for HEPLISAV-B and the ongoing development of SD-101, DV281 and earlier stage oncology programs.

General and administrative expenses for the quarter and nine months ended September 30, 2017 were \$6.0 million and \$18.1 million, respectively, compared to \$11.8 million and \$29.1 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 following FDA approval of this investigational product.

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. Data from the Phase 3 trials which evaluated HEPLISAV-B administered as a two dose regimen over one month as compared to a currently licensed hepatitis B vaccine administered as 3 doses over a six month period are currently under review by FDA. Dynavax's Biologics License Application for HEPLISAV-B has a Prescription Drug User Fee Act date of November 9, 2017. Dynavax has worldwide commercial rights to HEPLISAV-B.

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.

About DV281

DV281 is Dynavax's proprietary investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. DV281 is similar in biological activity and mechanism of action to Dynavax's Phase 2 immunotherapy candidate, SD-101, but has been optimized for administration as an aerosol. Both SD-101 and DV281 activate plasmacytoid dendritic cells which then stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as DV281 and SD-101 have been shown to stimulate potent Type 1 interferon induction along with maturation of dendritic cells to effective antigen-presenting cells; both activities are important for the induction of effective anti-tumor immunity. Dynavax has initiated dosing in a phase 1B dose escalation clinical trial of DV281 in patients with non-small cell lung cancer.

For information about SD-101 and DV281 trials that are currently recruiting patients, please visit 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 and a vaccine for the prevention of hepatitis B. Dynavax's lead product candidates are SD-101 and DV281, investigational cancer immunotherapeutics currently in Phase 1 and Phase 2 studies, and HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information, visit 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 we will be able to timely develop the required commercial infrastructure to successfully launch HEPLISAV-B; whether manufacturing issues will arise that will impact our ability to have an adequate supply of HEPLISAV-B to meet demand; 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 of DV281; 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 and DV281; 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:

Ryan Spencer

VP, Corporate Strategy & Communications

510.665.4618

rspencer@dynavax.com

DYNAVAX TECHNOLOGIES CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenues:				
Collaboration revenue	\$ -	\$ -	\$ -	\$ 2,578
Grant revenue	53	162	306	289
Service and license revenue	-	-	-	884
Total revenues	53	162	306	3,751
Operating expenses:				
Research and development	16,417	23,234	47,576	66,051
General and administrative	6,027	11,766	18,111	29,086
Restructuring	-	-	2,783	-
Total operating expenses	22,444	35,000	68,470	95,137
Loss from operations	(22,391)	(34,828)	(68,164)	(91,386)
Interest income	429	170	809	615
Other income (expense), net	(166)	(26)	(378)	68
Net loss	\$(22,128)	\$(34,694)	\$(67,733)	\$(90,703)
Basic and diluted net loss per share	\$ (0.38)	\$ (0.90)	\$ (1.36)	\$ (2.36)
Weighted average shares used to compute basic and diluted net loss per share	57,650	38,512	49,785	38,493

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	September 30,	December 31,
	2017	2016
Assets		
Cash, cash equivalents and marketable securities	\$ 191,680	\$ 81,415
Property and equipment, net	16,622	17,174
Goodwill	2,213	1,971
Other assets	7,312	9,120
Total assets	\$ 217,827	\$ 109,680
Liabilities and stockholders' equity		
Other liabilities	13,393	20,479
Total liabilities	13,393	20,479
Stockholders' equity	204,434	89,201
Total liabilities and stockholders' equity	\$ 217,827	\$ 109,680