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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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): February 22, 2017

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware	**33-0728374**
(State or other jurisdiction of incorporation)	**(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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(e)

On February 22, 2017, the Compensation Committee (the "Compensation Committee") of the Board of Directors of Dynavax Technologies Corporation (the "Company"), approved 2017 retention and annual equity awards for the Company's named executive officers ("executive officers"), which are detailed below. In addition, the Compensation Committee determined that the executive officers would receive no 2017 salary increase and no bonus awards for 2016.

Retention Equity Grants

On February 22, 2017, the Compensation Committee of the Company approved the following equity awards consisting of restricted stock units ("RSUs") for the Company's executive officers, as follows (the "Initial Retention Grants"):

Name	RSUs
Eddie Gray *Chief Executive Officer*	150,000
Michael Ostrach *Senior Vice President and Chief Financial Officer*	99,609
Robert Coffman, Ph.D. *Senior Vice President and Chief Scientific Officer*	109,405
Robert Janssen *Chief Medical Officer and Vice President, Clinical Development*	93,750
David Novack *Senior Vice President, Operations and Quality*	90,527

The Initial Retention Grants were made pursuant to the Company's Amended and Restated 2011 Equity Incentive Plan and related grant documentation (collectively, the "2011 Plan"), previously filed with the Securities and Exchange Commission. Subject to each individual's continuous service, 50% of the RSUs subject to each Initial Retention Grant will vest on February 22, 2018 and the remainder will vest on February 22, 2019.

Additionally, subject to stockholder approval of an amendment of the 2011 Plan to increase the authorized shares available thereunder, the Compensation Committee approved for grant as of June 1, 2017 the remainder of the retention grants consisting of the number of RSUs for each individual as set forth in the table above or, at the election of the individual, stock options in the amount of 1.35 times the number of RSUs set forth in the table. If an individual does not make an election, the grant will be delivered as a RSU (the "Contingent Retention Grants"). Subject to each individual's continuous service, 50% of the RSUs subject to each Contingent Retention Grant will vest on June 1, 2018 and the remainder will vest on June 1, 2019.

Annual Equity Grants

Also on February 22, 2017, the Compensation Committee approved the following equity awards consisting of RSUs for the Company's executive officers, as follows (the "Annual Grants"):

Name	RSUs
Eddie Gray *Chief Executive Officer*	111,000
Michael Ostrach *Senior Vice President and Chief Financial Officer*	25,500
Robert Coffman, Ph.D. *Senior Vice President and Chief Scientific Officer*	25,500
Robert Janssen *Chief Medical Officer and Vice President, Clinical Development*	25,500
David Novack *Senior Vice President, Operations and Quality*	25,500

The Annual Grants were made pursuant to the Company's 2011 Plan. Subject to each individual's continuous service, one-third of the RSUs subject to each Annual Grant will vest on February 22, 2018, one third will vest on February 22, 2019 and the remainder will vest on February 22, 2020.

Additionally, subject to the determination by the Compensation Committee of the grant date and performance criteria for the respective executive officers, the Compensation Committee approved the following performance-based awards consisting of RSUs for the Company's executive officers (the "Annual Performance Grants"):

Name	RSUs
Eddie Gray *Chief Executive Officer*	27,750
Michael Ostrach *Senior Vice President and Chief Financial Officer*	6,375
Robert Coffman, Ph.D. *Senior Vice President and Chief Scientific Officer*	6,375
Robert Janssen *Chief Medical Officer and Vice President, Clinical Development*	6,375
David Novack *Senior Vice President, Operations and Quality*	6,375

The foregoing description of the Initial Retention Grants, Contingent Retention Grants, Annual Grants and Annual Performance Grants are qualified in their entirety by reference to the terms of the 2011 Plan, as may be amended from time to time, and each executive's grant documentation.

Item 8.01. Other Events

On February 28, 2017, Dynavax issued a press release titled "Dynavax Announces FDA Acceptance for Review of its Complete Response to November 2016 CRL and PDUFA Action Date for HEPLISAV-B™." A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is filed herewith:

99.1 Press Release, dated February 28, 2017, titled "Dynavax Announces FDA Acceptance for Review of its Complete Response to November 2016 CRL and PDUFA Action Date for HEPLISAV-B™"

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: February 28, 2017

By: /s/ MICHAEL OSTRACH
Michael Ostrach
Senior Vice President

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, dated February 28, 2017, titled "Dynavax Announces FDA Acceptance for Review of its Complete Response to November 2016 CRL and PDUFA Action Date for HEPLISAV-B™"

DYNAVAX
INNOVATING IMMUNOLOGY

Dynavax Announces FDA Acceptance for Review of its Complete Response to November 2016 CRL and PDUFA Action Date for HEPLISAV-B™

BERKELEY, CA – 2/28/17 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review Dynavax's responses to the Complete Response Letter (CRL) issued by the FDA in November 2016 for the Biologics License Application for HEPLISAV-B, the company's vaccine candidate for immunization against hepatitis B infection in adults 18 years of age and older. The FDA has established August 10, 2017 as the Prescription Drug User Fee Act (PDUFA) action date.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and can lead to cirrhosis of the liver, hepatocellular carcinoma and death. In the United States, the Centers for Disease Control and Prevention estimates that 19,000 hepatitis B infections continue to occur annually, with the vast majority occurring in adults. There is no cure for hepatitis B, and disease prevention through more effective vaccines is critical to reducing the spread of the disease.

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. [1] Those who do not complete the series may not be adequately protected against hepatitis B.

Dynavax has worldwide commercial rights to HEPLISAV-B.

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[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.

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 .

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding HEPLISAV-B and FDA review. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the FDA will find the response to the CRL to be satisfactory to support approval; whether the FDA will require additional information or studies; whether the FDA will identify additional issues following review of Dynavax's response to the CRL; whether the FDA will schedule a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and if so whether it will impact the timing of FDA review, negatively impact the review or whether the VRBPAC will recommend approval; whether additional manufacturing process enhancements will be required or other issues will arise that will negatively impact the review and approval by the FDA; if approvable, whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; and other risks detailed in the "Risk Factors" section of our most recent current 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