

# 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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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): April 3, 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))
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**Item 8 .01. Other Events**

On April 3, 2017, Dynavax Technologies Corporation issued a press release titled “Dynavax Announces FDA Advisory Committee Meeting to Review 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 April 3, 2017, titled “Dynavax Announces FDA Advisory Committee Meeting to Review HEPLISAV-B”

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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: April 3, 2017

By: /s/ STEVEN N. GERSTEN

Steven N. Gersten

Vice President

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## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
EX-99.1	Press Release, dated April 3, 2017, titled “Dynavax Announces FDA Advisory Committee Meeting to Review HEPLISAV-B”



**Dynavax Announces FDA Advisory Committee Meeting to Review HEPLISAV-B**  
*Meeting Scheduled for July 28, 2017*

BERKELEY, CA – April 3, 2017 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that the U.S. Food and Drug Administration (FDA) has informed the company that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will review HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)] at its meeting scheduled for July 28, 2017. The scheduled VRBPAC meeting is close to the HEPLISAV-B Prescription Drug User Fee Act (PDUFA) date of August 10, 2017 solely as a function of meeting logistics. The PDUFA date remains unchanged. The FDA will communicate specific questions for the VRBPAC to address closer to the meeting date, and will post a draft agenda and draft questions on its website 48 hours prior to the meeting. HEPLISAV-B is the company's vaccine candidate for immunization against hepatitis B infection in adults ages 18 years of age and older.

“The notification of a VRBPAC meeting comes as no surprise and thus we are prepared for it,” said Eddie Gray, chief executive officer of Dynavax. “The company looks forward to continuing to work with the FDA through the review process and discussing HEPLISAV-B with the advisory committee.”

The VRBPAC reviews and evaluates data regarding the safety and efficacy of vaccines and related biological products that are intended for use in the prevention, treatment, or diagnosis of human diseases.

**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.<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.

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<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.

## **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 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 VRBPAC meeting will be cancelled or postponed, 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

## **Contact:**

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