

# DYNAVAX TECHNOLOGIES CORP

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

Filed 07/31/17 for the Period Ending 07/28/17

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): July 28, 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)

**(Registrant's telephone number, including area code) (510) 848-5100**

(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 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year**

On July 31, 2017, the stockholders of the Company approved an amendment to the Company's Sixth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of the Company's common stock, par value \$0.001 from 69,500,000 shares to 139,000,000 shares. The increase in authorized shares was effected pursuant to a Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (the "Certificate of Amendment"), filed with the Secretary of State of the State of Delaware on July 31, 2017. A copy of the Certificate of Amendment is attached as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated into this Item 5.03 by reference.

**Item 5.07. Submission of Matters to a Vote of Security Holders**

On July 31, 2017, the Company held its Special Meeting of Stockholders (the "Special Meeting"), at the Company's executive office in Berkeley, California. A total of 54,747,656 shares of the Company's common stock were entitled to vote as of June 30, 2017, the record date for the Special Meeting. There were 43,316,072 shares present in person or by proxy at the Special Meeting, at which the stockholders were asked to vote on two (2) proposals. Set forth below are the matters acted upon by the stockholders, and the final voting results of each such proposal. The proposals are described in detail in the Company's Proxy Statement for a Special Meeting of Stockholders.

Proposal 1. Amend the Company's Sixth Amended and Restated Certificate of Incorporation.

The stockholders approved to amend the Company's Sixth Amended and Restated Certificate of Incorporation, as amended, to increase the authorized number of shares of common stock from 69,500,000 to 139,000,000. The votes were as follows:

<u>For</u>	<u>Against</u>	<u>Abstain</u>
35,935,589	6,888,876	491,607

Proposal 2. Authorize an adjournment of the meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal 1.

The stockholders approved to authorize an adjournment, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal 1. The votes were as follows:

<u>For</u>	<u>Against</u>	<u>Abstain</u>
35,058,281	7,918,240	339,551

**Item 8.01. Other Events**

On July 28, 2017, Dynavax Technologies Corporation issued a press release titled "Dynavax Announces FDA Advisory Committee Vote in Favor of 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 exhibits are filed herewith:

- 3.1 Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation.
- 99.1 Press Release, dated July 28, 2017, titled "Dynavax Announces FDA Advisory Committee Vote in Favor of 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: July 31, 2017

By: /s/ STEVEN N. GERSTEN

Steven N. Gersten  
Vice President

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**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
EX-3.1	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation.
EX-99.1	Press Release, dated July 28, 2017, titled "Dynavax Announces FDA Advisory Committee Vote in Favor of HEPLISAV-B™"

**CERTIFICATE OF AMENDMENT OF THE  
SIXTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF  
DYNAVAX TECHNOLOGIES CORPORATION**

**DYNAVAX TECHNOLOGIES CORPORATION**, a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the “*Corporation*”), hereby certifies that:

**FIRST** : The name of the Corporation is **DYNAVAX TECHNOLOGIES CORPORATION**

**SECOND** : The Corporation was originally incorporated under the same name and the original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on November 6, 2000.

**THIRD** : The Board of Directors of the Corporation, acting in accordance with the provisions of Sections 141 and 242 of the General Corporation Law of the State of Delaware, adopted resolutions to amend its Sixth Amended and Restated Certificate of Incorporation as follows:

1. Article IV shall be amended and restated to read in its entirety as follows:

“The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock and Preferred Stock. The Corporation shall be authorized to issue 139,000,000 shares of Common Stock at \$0.001 par value, and 5,000,000 shares of Preferred Stock at \$0.001 par value. The Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board). The rights, preferences, privileges and restrictions granted to or imposed upon the Preferred Stock or any series of Preferred Stock will be determined or altered by the Board of Directors. The Board of Directors shall have the authority to fix or alter the number of shares of any series of Preferred Stock and the designation of any such series of Preferred Stock. The Board of Directors, within the limits and restrictions stated in any resolution or resolutions of the Board of Directors originally fixing the number of shares constituting any series, may increase or decrease (but not below the number of shares in any such series then outstanding), the number of shares of any series subsequent to the issue of shares of that series.”

**FOURTH**: Thereafter pursuant to a resolution of the Board of Directors, this Certificate of Amendment was submitted to the stockholders of the Corporation for their approval, and was duly adopted at the Special Meeting of Stockholders held on July 31, 2017 in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

**IN WITNESS WHEREOF**, the Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 31st day of July, 2017.

**DYNAVAX TECHNOLOGIES CORPORATION**

By: /s/ Eddie Gray

Eddie Gray, Chief Executive Officer



**Dynavax Announces FDA Advisory Committee  
Vote in Favor of HEPLISAV-B™**

**BERKELEY, Calif. – July 28, 2017** – Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the U.S. Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 12 to 1 that the safety data for HEPLISAV-B [Hepatitis B Vaccine, Recombinant (Adjuvanted)] support licensure for immunization against hepatitis B infection in adults 18 years of age and older. Three members of the panel abstained. Additionally, the Committee provided commentary on the design of Dynavax’s proposed post-marketing pharmacovigilance plan for HEPLISAV-B. The FDA did not ask this VRBPAC panel to vote on the immunogenicity of HEPLISAV-B. A prior VRBPAC panel voted 13 to 1 that the data from Phase 3 clinical trials supports the immunogenicity of HEPLISAV-B.

“We are encouraged by the committee’s positive vote in favor of HEPLISAV-B, which we believe will become an important new tool in the fight against hepatitis B infection if approved by the FDA,” said Eddie Gray, chief executive officer of Dynavax. “Clinical studies of HEPLISAV-B have shown that the vaccine provides increased rates of seroprotection. In addition, the two-dose regimen offers the potential to increase patient compliance, which physicians and advocates agree is essential to preventing more cases of hepatitis B and achieving the public health goal of eradication. We look forward to completing our ongoing discussions with the FDA regarding an appropriate post-marketing commitment as it finalizes its review.”

The incidence of hepatitis B in the U.S. is increasing <sup>i</sup> and there is no cure for the disease. Therefore, disease prevention through effective vaccination is critical to reducing its spread. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. The HEPLISAV-B regimen is two doses over one month. Results of a published Vaccine Safety Datalink study showed that only 54 percent of adults completed the currently available three-dose hepatitis B vaccine series in one year. <sup>ii</sup> Those who do not complete the series may not be adequately protected against hepatitis B.

The FDA is not bound by the committee’s recommendation but takes its advice into consideration when reviewing marketing applications. HEPLISAV-B has a Prescription Drug User Fee Act (PDUFA) date of August 10, 2017. If the FDA approves HEPLISAV-B, Dynavax will seek a recommendation from the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) during its October 2017 meeting. Dynavax plans to launch the vaccine commercially in the U.S. in early 2018 on its own or through a commercial partner.

**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 U.S., the number of reported cases of acute hepatitis B increased more than 20 percent in 2015. <sup>iii</sup> After adjusting for under-reporting, the CDC estimated that 21,900 new hepatitis B virus infections occurred in 2015. In addition to new cases of hepatitis B, chronic HBV infection remains a major public health challenge. The CDC estimates that approximately 850,000 persons are living with hepatitis B virus in the U.S.

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## 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. 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](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 Complete Response Letter (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 decide not to approve HEPLISAV-B despite a positive recommendation of the Vaccines and Related Biological Products Advisory Committee; whether the FDA will delay approval of HEPLISAV-B; whether additional manufacturing process enhancements will be required or other issues will arise that will negatively impact the review and approval by the FDA; whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; the nature and scope of any post-marketing study that the FDA will require; whether the Centers for Disease Control and Prevention's Advisory Committee on Immunization will provide a recommendation for HEPLISAV-B if approved by the FDA; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. 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.

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- i <https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm#Ref10>. Accessed July 5, 2017.
- ii Nelson JC, et al. Compliance with multiple-dose vaccine schedules among older children, adolescents and adults: Results from a Vaccine Safety Datalink study. *Am J Public Health*. 2009;99(S2); S389-S397.
- iii <https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm#Ref10>. Accessed July 5, 2017.