# 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): September 4, 2016**

# 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 8.01. Other Events**

On September 4, 2016, Dynavax Technologies Corporation issued a press release titled “Dynavax Provides Regulatory Update on 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 September 4, 2016, titled “Dynavax Provides Regulatory Update on 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: September 6, 2016

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| EX-99.1 | Press Release, dated September 4, 2016, titled “Dynavax Provides Regulatory Update on HEPLISAV-B” |

DYNAVAX
INNOVATING IMMUNOLOGY

**DYNAVAX PROVIDES REGULATORY UPDATE ON HEPLISAV-B**

*– PDUFA Date of December 15, 2016, Remains Unchanged –*

BERKELEY, Calif. – September 4, 2016 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research has cancelled the scheduled November 16, 2016, Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to review the Biologics License Application (BLA) for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)].

During recent conversations between Dynavax and the FDA, the Agency communicated decisions to enable compliance with the current Prescription Drug User Fee Act (PDUFA) date of December 15, 2016. The Agency informed Dynavax that the VRBPAC meeting was cancelled and remaining questions will be addressed between Dynavax and the review team via the normal process. The FDA informed Dynavax that it plans to provide information requests related to remaining questions in the upcoming weeks. Dynavax is prepared to address these questions expeditiously in order to enable the FDA to complete its review as soon as possible.

"Our dialogue with the FDA has been very open and productive, and we look forward to providing the review team with any additional information they may need to complete their review," said Eddie Gray, chief executive officer of Dynavax. "We are committed to bringing HEPLISAV-B to market as we believe it offers a better level of protection than the currently available hepatitis B vaccines."

The FDA also confirmed to Dynavax that it will review the overall immunogenicity data from HBV-23, the company's most recent pivotal Phase 3 trial, to support the proposed indication for adults 18 years of age and over. However, the Agency has decided it will not review immunogenicity data related to sub-populations including results in individuals with diabetes because these data were not a direct response to the FDA's February 22, 2013 Complete Response Letter and therefore fell outside of the review time allocated to a Class 2 resubmission. Thus, it was suggested the data should be submitted as a supplemental BLA following approval.

The FDA subsequently issued a public notice on September 2, 2016 of the decision to cancel the previously scheduled VRBPAC meeting. That notice summarized the cancellation decision, the intent to resolve outstanding questions and scheduling of a future VRBPAC meeting, if needed.

**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 CDC estimates that approximately 20,000 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 effective vaccination is critical to reducing the spread of the disease. 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 54 percent of adults completed the currently available three-dose hepatitis B vaccine series in one year. Those who do not complete the series may not be adequately protected against hepatitis B.

**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. HEPLISAV-B is administered in two doses over one month.

In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. The investigational vaccine's safety profile is based on clinical trials that generated safety data from more than 14,000 participants. 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, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit www.dynavax.com.

**Forward-Looking Statements**
This press release contains forward-looking statements, including statements regarding recent discussions with the FDA and the status of HEPLISAV-B BLA currently under FDA review. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether there will be changes that impact the timing of and potential for approval of HEPLISAV-B and whether a determination by the FDA will occur by the scheduled PDUFA date; resolvable issues with respect to questions involving the data or interpretation of the data submitted in support of the BLA; whether the final study results will be deemed satisfactory by the FDA; whether there will be a VRBPAC meeting and if so whether it will impact the timing of FDA review or negatively impact the review and approval of the 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 approval by the FDA; if approvable, whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; initiation, enrollment and completion of pre-clinical studies and clinical trials of our other product candidates, including 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; 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.

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