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): August 3, 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))

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 8.01. Other Events

On August 3, 2017, Dynavax Technologies Corporation issued a press release titled "Dynavax Provides U.S. Regulatory Update on HEPLISAV-B™ Following FDA Advisory Committee Meeting." 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 August 3, 2017, titled "Dynavax Provides U.S. Regulatory Update on HEPLISAV-B™ Following FDA Advisory Committee Meeting"

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: August 7, 2017

By: /s/ STEVEN N. GERSTEN
Steven N. Gersten
Vice President

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, August 3, 2017, titled “Dynavax Provides U.S. Regulatory Update on HEPLISAV-B™ Following FDA Advisory Committee Meeting”

Dynavax Provides U.S. Regulatory Update on HEPLISAV-B™ Following FDA Advisory Committee Meeting

—Conference call today at 4:30 p.m. EDT—

BERKELEY, Calif. – August 3, 2017 – Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the U.S. Food and Drug Administration (FDA) has requested more detailed information about the company's proposed post-marketing study for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)] based on feedback received from the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) during a meeting on July 28, 2017. The Advisory Committee voted 12 to 1 (with 3 abstentions) that the safety data for HEPLISAV-B support licensure for active immunization against hepatitis B infection in adults 18 years of age and older while also commenting on the design of Dynavax's proposed post-marketing study for HEPLISAV-B. Dynavax and the FDA have discussed the outcome of the VRBPAC meeting and have agreed that due to the feedback provided and the proximity to the scheduled Prescription Drug User Fee Act (PDUFA) date of August 10, 2017, more time is required to finalize key details of the post-marketing study.

"Our conversation with the Agency was open and productive and confirmed our mutual understanding of the VRBPAC's suggested requirements for the post-marketing study. We are working with our third-party providers to develop an appropriate study that addresses the advisory committee's feedback. We now have clarity on the path forward and next steps required to complete the regulatory review of HEPLISAV-B," said Eddie Gray, chief executive officer of Dynavax. "We plan to respond to the request for additional information expeditiously. We look forward to bringing this important vaccine to market to support the elimination of hepatitis B infection as a public health problem."

As indicated in the FDA's request for additional information, and consistent with the discussion regarding myocardial infarction at the VRBPAC meeting, the remaining details to address in the post-marketing study include:

- Timeline for the final protocol submission, study completion and final report submission
- Timeliness of accruing patients into the study
- Time points for data review
- Measures to control for potential biases between study arms
- Updated statistical analysis plan

In order to create sufficient time to complete this work under the existing regulatory framework, the response to the information request will trigger a major amendment to the Biologics License Application (BLA). This will provide the FDA and Dynavax up to three months to agree on the post-marketing study prior to an updated PDUFA date (expected to be no later than November 10, 2017). The FDA and Dynavax have both committed to processing this final stage of the review in the most efficient manner possible by maintaining open channels of communication. This timing does not impact the company's plans to launch HEPLISAV-B commercially in the United States in early 2018.

Teleconference/Webcast Details

Dynavax will conduct a live conference call today to provide additional context to investors and media. To participate in the call today, August 3, at 4:30 p.m. EDT, please dial (877) 479-1857 from the U.S. and Canada or +1 (503) 343-6309 internationally, and use the conference ID # 66006894. The live call is being webcast and can be accessed in the “Investors and Media” section of the company’s website at www.dynavax.com. A replay of the webcast will be available for 30 days following the live event.

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.[i] After adjusting for under-reporting, the CDC estimated that 21,900 new HBV 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 HBV in the U.S.

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.

Forward-Looking Statements

This release contains forward-looking statements and estimates, 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 approve HEPLISAV-B, notwithstanding the FDA Advisory Committee votes in favor of the safety and immunogenicity 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 study for HEPLISAV-B; the final label claims and the nature of the label content for HEPLISAV-B; 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 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.