DYNAVAX TECHNOLOGIES CORP
Form 8-K
October 03, 2016

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): October 3, 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

Dynavax Technologies Corporation ("Dynavax") received anticipated requests for information from the U.S. Food and Drug Administration's ("FDA") review team in connection with the pending Biologics License Application ("BLA") for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)]. The review team's questions are in line with the company's expectations.

The company is working with the FDA to resolve remaining questions regarding the BLA in order to enable the FDA to complete its review by the scheduled Prescription Drug User Fee Act ("PDUFA") action date of December 15, 2016, which remains unchanged.

This report on Form 8-K contains forward-looking statements, including statements regarding interactions with the FDA and the status of the 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 Vaccines and Related Biological Products Advisory Committee 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 report. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available.

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: October 3, 2016 By: /s/ MICHAEL OSTRACH
Michael Ostrach
Senior Vice President