DYNAVAX TECHNOLOGIES CORP
Form 8-K
October 22, 2008

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): 10/17/2008

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Commission File Number: 000-50577

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

In October 2008, Dynavax Technologies Corporation (Dynavax) and Merck & Co., Inc. (Merck) received communication from the U.S. Food and Drug Administration (FDA) regarding the two companies' response to the agency's request for safety information relating to the clinical hold on the two Investigational New Drug (IND) Applications for HEPLISAV(TM), an investigational hepatitis B virus (HBV) vaccine.

The FDA has advised the companies that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The FDA has also advised the companies that there may be potential for an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from the companies before considering further pursuit of clinical studies in those patients. Dynavax and Merck are evaluating the FDA's response in considering next steps. In the meantime, the clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect.

This current report contains "forward-looking statements," including statements related to the assessment of and next steps with respect to the FDA response to the clinical hold on HEPLISAV, whether Merck will continue our collaboration agreement and the determination of whether further clinical development of HEPLISAV will be undertaken. Actual results may differ materially from those set forth in this current report due to the risks and uncertainties inherent in our business, including difficulties or delays in development, initiation and completion of clinical trials, the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process; achieving our Merck collaborative agreement objectives; the scope and validity of patent protection and the possibility of claims against us based on the patent rights of others; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Signature(s)

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 22, 2008

By: /s/ Deborah A. Smeltzer

Deborah A. Smeltzer
Vice President, Operations and Chief Financial Officer