DYNAVAX TECHNOLOGIES CORP
Form 8-K
September 18, 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): 09/18/2008

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 September 2008, we submitted a response to the U.S. Food and Drug Administration's (FDA) request for information relating to the clinical hold on the two Investigational New Drug (IND) Applications for HEPLISA(TM), an investigational hepatitis B virus (HBV) vaccine we are jointly developing with Merck & Co., Inc. The FDA will evaluate the response and determine whether the data provided are satisfactory to allow the clinical program to resume.

As previously disclosed in March 2008, the FDA placed the two IND Applications for HEPLISAV on clinical hold. In issuing the clinical hold, the FDA requested a review of clinical and preclinical safety data for HEPLISAV, including all available information about a single case of Wegener's granulomatosis previously reported.

The response submitted to the FDA contained a thorough review of both clinical and preclinical safety data for HEPLISAV. Clinical data from 2,500 subjects who received HEPLISAV in a total of 9 clinical trials conducted over a period of nearly 10 years were provided. This includes data from the largest clinical trial of HEPLISAV to date, the PHAST (Phase 3 HeplisAv Short-regimen Trial) trial of 2,427 total subjects, which Dynavax and Merck recently reported met its primary endpoint.

In the response, we confirmed that two Serious Adverse Events (SAE) of systemic vasculitis were observed in the PHAST trial, one in the HEPLISAV group and one in the Engerix-B(R) control group. Specifically, one of the 1,819 subjects who received HEPLISAV was diagnosed as having Wegener's granulomatosis, a form of vasculitis associated with positive cytoplasmic-staining anti-neutrophil cytoplasmic antibody (c-ANCA). This individual did not have detectable c-ANCA prior to vaccination and remained negative throughout the course of HEPLISAV vaccination. The individual became positive for c-ANCA two months after the second dose of HEPLISAV. In the Engerix-B group, one of the 608 subjects developed systemic vasculitis associated with perinuclear-staining antineutrophil cytoplasmic antibody or p-ANCA four months after the second dose of Engerix-B.

Safety results showed the profile of 2 doses of HEPLISAV appeared similar to 3 doses of Engerix-B, with the exception that subjects who received HEPLISAV had a higher risk of developing injection site swelling, redness, and pain compared to those who received Engerix-B. The incidence of Adverse Events (AE) was 81.9 percent for the HEPLISAV group, compared to 81.4 percent for the Engerix-B group. The incidence of SAEs was 1.5 percent for the HEPLISAV group, compared to 2.1 percent for the Engerix-B group.

The multi-center PHAST trial evaluated 2,427 subjects from 11 to 55 years of age in Canada and Germany. This phase 3 trial met its primary endpoint and evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month, compared to a three-dose regimen of Engerix-B administered at 0, 1, and 6 months. The primary endpoint was the proportion of subjects who developed protective antibody to hepatitis B after vaccination. Results of additional analyses from this trial will be presented in the future.

Immunogenicity results from this trial demonstrated that subjects receiving HEPLISAV were seroprotected with fewer doses and at an earlier time point than subjects receiving Engerix-B. Results showed 95.1 percent of subjects who received two doses of HEPLISAV (n=1,819) at 0 and 1 month developed protective antibody to hepatitis B when measured at 12 weeks. This compared to 81.1 percent of subjects who received three doses of Engerix-B (n=608) at 0, 1, and 6 months when measured at 28 weeks.

There can be no assurance as to when the FDA will respond to our submission, whether the FDA will request additional information, or whether HEPLISAV can be developed further or that successful clinical development can occur in a timely manner or without additional studies.

Engerix-B(R) is a registered trademark of GlaxoSmith Kline.

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: September 18, 2008

By: /s/ Michael Ostrach

Michael Ostrach
Vice President, Chief Business Officer and General Counsel