# 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): 09/29/2009

# **Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware (State or other jurisdiction of incorporation) 33-0728374 (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)

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)

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

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 29, 2009, Dynavax Technologies Corporation (Dynavax) issued a press release titled "Dynavax Initiates Phase 3 Registration Trial in Chronic Kidney Disease Patients for HEPLISAV(TM) Hepatitis B Vaccine." A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

# Item 9.01. Financial Statements and Exhibits

(d) Exhibit

Exhibit No. Description

99.1 Press Release, dated September 29, 2009, titled "Dynavax Initiates Phase 3 Registration Trial in Chronic Kidney Disease Patients for HEPLISAV(TM) Hepatitis B Vaccine."

#### **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 29, 2009 By: /s/ Michael S. Ostrach

Michael S. Ostrach Vice President

# EXHIBIT INDEX

# Exhibit No. Description

EX-99.1

Press Release, dated September 29, 2009, titled "Dynavax Initiates Phase 3 Registration Trial in Chronic Kidney Disease Patients for HEPLISAV(TM) Hepatitis B Vaccine."



#### DYNAVAX TECHNOLOGIES 2929 Seventh Street, Suite 100 Berkeley, CA 94710

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# DYNAVAX INITIATES PHASE 3 REGISTRATION TRIAL IN CHRONIC KIDNEY DISEASE PATIENTS FOR HEPLISAV(TM) HEPATITIS B VACCINE

BERKELEY, CA – September 29, 2009 – Dynavax Technologies Corporation (Nasdaq: DVAX) today announced the initiation of a Phase 3 registration trial for HEPLISAV(TM) hepatitis B vaccine in individuals with chronic kidney disease. A second registration trial, a Phase 3 lot-to-lot consistency trial, is expected to begin in early 2010. HEPLISAV is an investigational adult hepatitis B vaccine designed to provide increased, rapid protection with fewer doses than current licensed vaccines. Dynavax believes that these studies, taken together, could support registration filing of HEPLISAV with the Food and Drug Administration (FDA).

"After achieving pivotal trial data demonstrating HEPLISAV's clinical benefit, we currently expect to complete these two registration trials within the next 24 months," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "The unmet medical need for better hepatitis B vaccination for certain groups such as chronic kidney disease patients is significant and is a large, servable market opportunity for Dynavax."

#### **About the Trial**

Dynavax's Phase 3 trial is enrolling approximately 600 patients with chronic kidney disease. After being randomized 1 to 1, patients will receive either 3 doses of HEPLISAV (at 0, 1, and 6 months) or 8 doses of the current licensed vaccine Engerix-B(R) (2 doses at 0, 1, 2, and 6 months). The primary endpoint is seroprotection rate at month 7.

#### **Clinical Data**

Dynavax plans to present clinical data from previous trials of HEPLISAV in chronic kidney disease patients at the 47<sup>th</sup> Annual Meeting of the Infectious Disease Society of America (IDSA), October 29 through November 1, 2009 in Philadelphia, Pennsylvania. For more information on this conference, please visit the IDSA website at http://www.idsociety.org.

#### **About HEPLISAV**

HEPLISAV is a Phase 3 investigational adult hepatitis B vaccine designed to provide increased, rapid protection with fewer doses than current licensed vaccines. Over 2,500 individuals have been vaccinated with HEPLISAV, which has completed a pivotal Phase 3 study demonstrating the vaccine's immunogenicity.

— more —

Engerix-B(R) is a licensed trademark of GlaxoSmithKline.

# DYNAVAX INTIATES PHASE 3 REGISTRATION TRIAL IN CHRONIC KIDNEY DISEASE PATIENTS FOR HEPLISAV

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Dynavax is developing HEPLISAV for populations that are less responsive to current licensed vaccines, including adults over 40 years of age, individuals with chronic kidney disease, and others. The Company has worldwide commercial rights to HEPLISAV, which combines hepatitis B surface antigen (HBsAg) with a proprietary Toll-like Receptor 9 agonist to enhance the immune response.

#### **About Hepatitis B Vaccines**

The total worldwide market for adult hepatitis B vaccines is estimated at over \$500 million annually. Current vaccines leave unmet needs for more rapid and increased protection, particularly for less responsive, underserved populations.

Chronic Kidney Disease Market – A high-value segment, the chronic kidney disease market is large, growing rapidly, and is widely recommended for vaccination. There are approximately 750,000 end-stage renal disease (ESRD) patients in the United States and the 5 major European markets and approximately 150,000 new patients annually. Approximately 35% of these immunocompromised ESRD patients do not respond to vaccination and 20% require boosters. As vaccination for these patients occurs regularly at dialysis centers, this is a highly concentrated, renewable market that can be served by cost-effective, targeted sales and distribution networks.

### **About Dynavax**

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide more rapid and increased protection with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

# Forward Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements related to the nature and timing of clinical trials of HEPLISAV. Actual results may differ materially from those set forth in this press release due to the risks

and uncertainties inherent in our business, including whether successful clinical and regulatory development and approval of HEPLISAV can occur in a timely manner or without significant additional studies or difficulties or delays in development, whether the studies can support registration for commercialization of HEPLISAV, the potential size and opportunity for the chronic kidney disease market, the Company's ability to obtain additional financing to support the development and commercialization of HEPLISAV and its other operations, possible claims against the Company based on the patent rights of others; and other risks detailed in the "Risk Factors" section of our current periodic reports with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.