# 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): 04/15/2014

# **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)

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 th 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))
гі	Pre-commencement communications pursuant to Rule 13e-A(c) under the Eychange Act (17 CER 240 13e-A(c))

#### Item 8.01. Other Events

On April 15, 2014, we issued a press release titled "Dynavax Initiates Phase 3 Study of HEPLISAV-B(TM)." 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) Exhibits. The following exhibit is furnished herewith:

99.1 Press Release, dated April 15, 2014, titled "Dynavax Initiates Phase 3 Study of HEPLISAV-B(TM)."

### **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: April 16, 2014 By: /s/ Michael Ostrach

Michael Ostrach Vice President

# EXHIBIT INDEX

Exhibit No. Description

EX-99.1 Dynavax Initiates Phase 3 Study of HEPLISAV-B(TM).

# **Dynavax Technologies**

2929 Seventh Street, Suite 100

Berkeley, CA 94710

#### **Contact:**

Michael S. Ostrach

Vice President, Chief Business and

Principal Financial Officer

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## DYNAVAX INITIATES PHASE 3 STUDY of HEPLISAV-B<sup>TM</sup>

BERKELEY, CA - April 15, 2014 - Dynavax Technologies Corporation (NASDAQ: DVAX) today announced initiation of a new phase 3 clinical trial of HEPLISAV-B, its investigational adult hepatitis B vaccine. This large safety and immunogenicity study (known as HBV-23) was designed to address the Complete Response Letter regarding the HEPLISAV-B Biologics License Application that was issued to Dynavax by the U.S. Food and Drug Administration in February, 2013.

HBV-23 will provide greater clarity regarding the safety profile of HEPLISAV-B by significantly expanding the overall database of vaccinated subjects. The study will also assess the immunogenicity of HEPLISAV-B in subjects for whom approved hepatitis B vaccines are less effective. Dynavax expects that all study subjects will be enrolled by the end of 2014 and all follow-up will be completed by the fourth quarter of 2015.

# **HBV-23 Study Design**

HBV-23 is an observer-blinded, randomized, active-controlled, trial being conducted at approximately 40 sites in the U.S. Approximately 8,250 adult subjects between the ages of 18 and 70 will be randomized in a 2:1 ratio to receive a 2-dose series of HEPLISAV-B or a 3-dose series of a control vaccine, Engerix-B<sup>®</sup>. Enrollment will be stratified by site, age group and type 2 diabetes mellitus status. Safety follow-up will continue for all subjects through study week 56.

The co-primary objectives of HBV-23 are to:

- Evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events (AEs), and
- Demonstrate the noninferiority of the seroprotection rate induced by HEPLISAV-B compared with Engerix-B at Week 28 in subjects with type 2 diabetes mellitus.

The study also includes multiple secondary objectives intended to further elucidate the safety profile of HEPLISAV-B with respect to specific outcomes and to assess its immunogenicity in subpopulations including smokers, men, individuals with higher body mass, and those aged 40 years and older.

All AEs from HBV-23 that are considered to represent potential autoimmune disorders will be reviewed by an independent Safety Evaluation and Adjudication Committee (SEAC). The SEAC will provide an opinion whether each event is autoimmune in origin, pre-existing or new-onset, and related or not related to study treatment. The full safety dataset will be reviewed periodically by an independent Data and Safety Monitoring Board (DSMB) to ensure the safety of subjects and scientific integrity of the study. The DSMB will perform at least three prespecified reviews.

Additional details regarding HBV-23 are available at www.clinicaltrials.gov.

### **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. Dynavax has worldwide commercial rights to HEPLISAV-B

# **About Dynavax**

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidate is HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information visit <a href="https://www.dynavax.com">www.dynavax.com</a>.

### Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for the conduct, timing and sufficiency of an additional clinical trial for HEPLISAV-B. 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 review and approval of HEPLISAV-B and our process for its manufacture can occur without significant delay or additional studies; whether our studies and manufacturing efforts are sufficient to support registration for commercialization of HEPLISAV-B in either or both of the US and Europe; the timing for and costs of achieving the size of the safety database; 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, including whether a US or European licensure application will be approved; our ability to obtain additional financing to support the development and commercialization of HEPLISAV-B and our other operations; possible claims against us, including enjoining sales of HEPLISAV-B, 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. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.