# 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): 02/22/2011

# **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 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

On February 22, 2011, Dynavax Technologies Corporation (Dynavax) issued two press releases titled "Dynavax Reports New Phase 1a and Phase 1b Data for Universal Flu Vaccine Candidate" and "Dynavax Reports Additional Positive Phase 1B Immunogenicity Data for Hepatitis B Therapy Candidate." Copies of the press releases are attached as Exhibit 99.1 and Exhibit 99.2 respectively to this current report and are incorporated herein by reference.

On February 23, 2011, Dynavax issued a press release titled "Dynavax's Two Phase 3 HEPLISAV Trials Cleared by DSMB to Continue to Study Completion." A copy of the press release is attached as Exhibit 99.3 to this current report and is incorporated herein by reference.

#### Item 9.01. Financial Statements and Exhibits

(d) Exhibits
Exhibit No. Description
99.1 Press Release, dated February 22, 2011, titled "Dynavax Reports New Phase 1a and Phase 1b Data for Universal Flu Vaccine Candidate."
99.2 Press Release, dated February 22, 2011, titled "Dynavax Reports Additional Positive Phase 1B Immunogenicity Data for Hepatitis B Therapy
Candidate."
99.3 Press Release, dated February 23, 2011, titled "Dynavax's Two Phase 3 HEPLISAV Trials Cleared by DSMB to Continue to Study Completion."

## 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: February 24, 2011

By: /s/ Michael S. Ostrach

Michael S. Ostrach Vice President

# EXHIBIT INDEX

# Exhibit No. Description

EX-99.1	Press Release, dated February 22, 2011, titled "Dynavax Reports New Phase 1a and Phase 1b Data for Universal Flu Vaccine Candidate."
EX-99.2	Press Release, dated February 22, 2011, titled "Dynavax Reports Additional Positive Phase 1B Immunogenicity Data for Hepatitis B Therapy
	Candidate."
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EX-99.3 Press Release, dated February 23, 2011, titled "Dynavax's Two Phase 3 HEPLISAV Trials Cleared by DSMB to Continue to Study Completion."

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

Contact: Michael Ostrach Vice President and Chief Business Officer 510-665-7257 mostrach@dynavax.com

# DYNAVAX REPORTS NEW PHASE 1A AND PHASE 1B DATA FOR UNIVERSAL FLU VACCINE CANDIDATE

BERKELEY, CA – February 22, 2011 – Dynavax Technologies Corporation (NASDAQ: DVAX) reported last Friday, February 18 in Geneva, Switzerland at the World Health Organization 7th Meeting on Evaluation of Pandemic Influenza Prototype Vaccines in Clinical Trials new Phase 1a and Phase 1b safety and immunogenicity data for its universal flu candidate vaccine. In an oral presentation, Dynavax's Robert Janssen, M.D., Senior Director, Clinical Research, described new findings for N8295, a fusion protein comprised of NP and M2e, two highly conserved influenza antigens covalently linked to Dynavax's proprietary second-generation TLR9 agonist, in combination with an investigational H5N1 avian influenza vaccine. The study evaluated 54 subjects, including 39 from the Phase 1a dose escalation study of N8295 and 15 from the Phase 1b dose escalation study of H5N1/N8295.

Data from the Phase 1a and the Phase 1b study, initiated in September 2010, showed:

- N8295 alone or combined with H5N1 vaccine was very safe and generally well tolerated;
- · The most common adverse events were mild, self-limited injection site reactions;
- · There were no SAEs;
- · All N8295 dose groups had an antibody response to M2e, and the placebo group did not;
- · All N8295 dose groups had an antibody response to NP, and the placebo group did not;
- · All N8295 dose groups had a cellular immune response to NP, and the placebo group did not;
- The addition of N8295 to a non-immunogenic dose of H5N1 vaccine resulted in H1 responses in all N8295 dose groups.1

Dr. J. Tyler Martin, M.D., Dynavax President and Chief Medical Officer, said, "The results of these trials demonstrate that N8295 has the attributes we intended: safety, M2e and NP immunogenicity, and the ability to adjuvant the H1 response to a HA based vaccine. These data will allow us to move forward with planning for a Phase 2 proof-of-concept trial."

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1 The Journal of Infectious Diseases 2008; 198:1309--16 and Vaccine 28 (2010) 840-848

Dynavax's Universal Flu Vaccine is designed to offer protection against divergent influenza strains as well as to increase the efficacy of a conventional influenza vaccine. Preclinical data have confirmed the expected immunogenicity and mechanistic effects of the vaccine candidate's novel components. The production of cytotoxic T-cells by NP and cytotoxic antibodies by M2e have been demonstrated in preclinical studies, as has an increase in neutralizing antibodies provided by a co-administered conventional influenza vaccine. A GLP toxicity study demonstrated that this Universal Flu vaccine candidate is well-tolerated.

# 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<sup>™</sup>, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. For more information, visit <u>www.dynavax.com</u>.

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

Contact: Michael Ostrach Vice President and Chief Business Officer 510-665-7257 mostrach@dynavax.com

## DYNAVAX REPORTS ADDITIONAL POSITIVE PHASE 1B IMMUNOGENICITY DATA FOR HEPATITIS B THERAPY CANDIDATE

BERKELEY, CA – February 22, 2011 – Dynavax Technologies Corporation (NASDAQ: DVAX) reported in a poster session Saturday, February 19 at the 21st Conference of the Asian Pacific Association for the Study of the Liver (APASL 2011) in Bangkok Thailand new Phase 1b immunogenicity data for DV-601, its proprietary hepatitis B therapeutic vaccine. The study evaluated three doses of the candidate therapeutic vaccine escalation in 14 patients with chronic hepatitis B infection, including six patients that were HBeAg negative and eight patients who were HBeAg positive, and found:

- · The therapeutic regimen was safe and generally well tolerated at all dose levels;
- Most common systemic reactions were fatigue and malaise. No SAEs were recorded;
- · DV601 was found to elicit immune responses at all dose levels, and anti-HBe antibodies were elicited in two of eight (2/8) patients;
- · Anti-HBs antibodies were elicited in four of 14 (4/14) patients;
- Amongst the eight HBeAg positive patients, two had HBeAg clearance, and one of those individuals also had HBsAg clearance;
- Three patients are still in the follow-up observation period.

According to Tyler Martin, M.D., President and Chief Medical Officer, "This trial was primarily designed to assess the safety of our vaccine. The positive immunogenicity results, in particular, the two HBeAg seroconversions, including one HBsAg serocoversion, provide a strong rationale for an expanded evaluation of our approach in collaboration with a potential partner."

Dynavax in December 2010 reported that all doses were generally safe and well tolerated and that individual immunologic and virologic responses had been observed across cohorts at all dose levels.

Dynavax's treatment approach combines both the surface and core hepatitis B virus (HBV) antigens with ISCOMATRIX® adjuvant originally entered into development by Rhein Biotech

- more -

prior to its acquisition by Dynavax in 2006. The candidate vaccine, DV-601, is designed to induce an immune response against HBV-infected cells and if proven to be safe and effective, may offer an alternative therapeutic option for patients chronically infected with HBV.

#### 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<sup>™</sup>, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. For more information, visit <u>www.dynavax.com</u>.

ISCOMATRIX<sup>®</sup> is a registered trademark of ISCOTEC AB, a CSL Limited Company

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Contact: Michael Ostrach Vice President and Chief Business Officer 510-665-7257 mostrach@dynavax.com

# DYNAVAX'S TWO PHASE 3 HEPLISAV TRIALS CLEARED BY DSMB TO CONTINUE TO STUDY COMPLETION

#### **Planned Safety Assessments Complete**

BERKELEY, CA – February 23, 2011 – Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the Data Safety Monitoring Board (DSMB) established for Dynavax's two ongoing Phase 3 trials for HEPLISAV<sup>TM</sup> has completed its planned safety assessments. The DSMB determined that the studies may continue without protocol modification, and that no other formal meetings of the DSMB are required.

Tyler Martin, M.D., President and Chief Medical Officer, commented, "This DSMB review is an important milestone for our Phase 3 program. All subjects in our large safety and lotto-lot consistency trial randomized to HEPLISAV are now eight months past their last dose. It would be unlikely to see a serious adverse event related to HEPLISAV at this time. Based on our progress, we look forward to completing the trials as planned and filing our BLA by the end of 2011."

The DSMB reviewed safety data from two ongoing multi-center Phase 3 trials evaluating HEPLISAV, the first a lot-to-lot consistency trial in adults 40 years and older, and the second a trial in chronic kidney disease patients. The DSMB is comprised of an independent group of medical experts who are responsible for reviewing and evaluating subject safety data at regular intervals during the ongoing trials.

### About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. The vaccine candidate is being evaluated in two Phase 3 studies that are directed toward fulfilling licensure requirements in the U.S., Canada and Europe. Enrollment has been completed for both studies. In a completed pivotal Phase 3 trial, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV and is

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developing the vaccine for large, high-value populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known as ISS to enhance the immune response.

#### 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 enhance protection more rapidly with fewer doses than current licensed vaccines. For more information visit <u>www.dynavax.com</u>.

#### **Forward Looking Statements**

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements regarding the timing of study completion and the BLA submission. 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 or clinical trial enrollment, whether the studies can support registration for commercialization of HEPLISAV; 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; 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. Information on Dynavax's website at <u>www.dynavax.com</u> is not incorporated by reference in the Company's current periodic reports with the SEC.

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