## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

# **FORM 8-K**

**CURRENT REPORT** PURSUANT TO SECTION 13 OR 15(D) OF THE **SECURITIES AND EXCHANGE ACT OF 1934** 

Date of report (Date of earliest event reported): November 1, 2007

# **DYNAVAX TECHNOLOGIES CORPORATION**

(Exact name of registrant as specified in charter)

Delaware (State or other jurisdiction of incorporation)

000-50577 (Commission File Number)

33-0728374 (I.R.S. Employer Identification No.)

2929 Seventh Street, Suite 100 Berkeley, California 94710

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (510) 848-5100

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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#### Item 1.01. Entry into a Material Definitive Agreement.

On October 31, 2007, Dynavax Technologies Corporation ("Dynavax") and Merck & Co., Inc. ("Merck") executed an Exclusive License and Development Collaboration Agreement and Manufacturing Agreement (the "Collaboration Arrangement") pursuant to which Dynavax and Merck entered into a global license and development collaboration to jointly develop HEPLISAV<sup>™</sup>, a novel investigational hepatitis B vaccine, which is currently being evaluated in a multi-center Phase 3 clinical trial involving adults and in patients on dialysis. Under the terms of the agreement, Merck receives worldwide exclusive rights to HEPLISAV, will fund future vaccine development and be responsible for commercialization. Dynavax will receive an initial payment of \$31.5 million, and if successful, will be eligible to receive up to \$105 million in development and sales milestone payments, and double-digit tiered royalties on global sales of HEPLISAV.

Under the Collaborative Arrangement, Dynavax will continue ongoing clinical studies under Merck's guidance pursuant to an approved budget and be responsible for manufacture of the hepatitis B surface antigen component of the vaccine on a fixed price basis. Dynavax will conduct manufacturing at Dynavax Europe in its Düsseldorf, Germany facility using Dynavax's proprietary technology developed at that site and later, at a new facility to support expected market needs.

The foregoing summary of the Collaboration Arrangement is not complete and is qualified in its entirety by reference to the agreements which will be filed with the Dynavax Quarterly Report on Form 10-K for the year ended December 31, 2007.

#### Item 8.01. Other Events.

See Item 1.01.

The press release dated November 1, 2007, titled "Dynavax and Merck & Co., Inc. Announce Partnership to Develop HEPLISAV™, an Investigational Hepatitis B Vaccine Currently in Phase 3" is attached hereto as Exhibit 99.1 and is herein incorporated by reference.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
EXHIDIU NO.	Description

99.1 Press release, dated November 1, 2007, entitled "Dynavax and Merck & Co., Inc. Announce Partnership to Develop HEPLISAV™, an Investigational Hepatitis B Vaccine Currently in Phase 3."

## 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.

Dated: November 7, 2007

Dynavax Technologies Corporation

By: <u>/s/ Michael Ostrach</u> Michael Ostrach, Vice President, Chief Business Officer and General Counsel

## INDEX TO EXHIBITS

Exhibit <u>Number</u> 99.1

Description
Press release, dated November 1, 2007, entitled "Dynavax and Merck & Co., Inc. Announce Partnership to Develop HEPLISAV™, an Investigational Hepatitis B Vaccine Currently in Phase 3."



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News Release

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## DYNAVAX and MERCK & CO., INC. ANNOUNCE PARTNERSHIP TO DEVELOP HEPLISAV™, AN INVESTIGATIONAL HEPATITIS B VACCINE CURRENTLY IN PHASE 3

Berkeley, CA. and Whitehouse Station, N.J. — November 1, 2007 — Dynavax Technologies Corporation (Nasdaq: DVAX) and Merck & Co., Inc. (NYSE: MRK) today announced a global license and development collaboration agreement to jointly develop HEPLISAV<sup>TM</sup>, a novel investigational hepatitis B vaccine, which is currently being evaluated in a multi-center Phase 3 clinical trial involving adults and in patients on dialysis.

Under the terms of the agreement, Merck receives worldwide exclusive rights to HEPLISAV, will fund future vaccine development, and be responsible for commercialization. Dynavax will receive an initial payment of \$31.5 million, and will be eligible to receive up to \$105 million in development and sales milestone payments, and double-digit tiered royalties on global sales of HEPLISAV.

"Based on the clinical profile demonstrated by HEPLISAV, we believe that this vaccine could represent an important advancement in the field," said Dino Dina, chief executive officer and president of Dynavax. "In clinical trials to date, it has conferred immunogenicity after only two doses while retaining tolerability comparable to a currently marketed hepatitis B vaccine. We wanted to partner with Merck given Merck's commitment to public health and leadership in bringing innovative vaccines to the market. Importantly, we expect it to be the first marketed product containing a novel Toll-Like Receptor 9 agonist."

Under Merck's oversight, Dynavax will continue to manage the ongoing Phase 3 studies in Canada and Europe as well as other licensure-required studies. The United States Food and Drug Administration Biologics Licensing Application (BLA) and other marketing applications will be the joint responsibility of Merck and Dynavax, and will be filed by Merck. Dynavax will be responsible for manufacture of the hepatitis B surface antigen component of the vaccine for Merck, which will be produced at Dynavax Europe's Düsseldorf, Germany facility using Dynavax's proprietary technology developed there and later, at a new facility to support expected market needs.

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#### Merck to Develop, Commercialize HEPLISAV November 1, 2007 Pg. 2 of 3

"Merck has been a leader in the field of hepatitis B prevention since we introduced the first recombinant vaccine, Recombivax HB<sup>®</sup>, in 1986," said Margaret G. McGlynn, president, Merck vaccines and infectious disease. "Through this collaboration with Dynavax, we have now gained rights to HEPLISAV, and as a result, have the potential to add another important advance to Merck's broad portfolio of vaccines."

#### Dynavax Conference Call

Dynavax will webcast its conference call today at 9:00 a.m. ET (6:00 a.m. PT) to discuss the agreement with Merck. The live webcast can be accessed by visiting the investor relations section of the Company's Web site at <u>http://investors.dynavax.com/events.cfm</u>. A replay of the webcast will be available on the Dynavax web site approximately two hours after completion of the call and will be archived for two weeks on the Investor page of the Dynavax website.

#### About HEPLISAV

HEPLISAV is based on Dynavax's proprietary immunostimulatory sequence (ISS) that specifically targets Toll-Like Receptor 9 (TLR9) to stimulate an innate immune response. HEPLISAV combines ISS with HBV surface antigen (HBsAg) and is designed to enhance the speed of protection. HEPLISAV is currently being studied in a Phase 3 trial in Canada and in Europe. Dynavax reported in mid-July 2007 that this international Phase 3 trial in Europe and Canada had completed enrollment.

#### About Hepatitis B

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus. Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by: contact with a mother's blood and body fluids at the time of birth; contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores; contact with objects that could have blood or body fluids on them such as toothbrushes or razors; having unprotected sex with an infected person; sharing needles when injecting drugs; being stuck with a used needle on the job.

#### About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. Our product candidates include: HEPLISAV, a hepatitis B vaccine in Phase 3 partnered with Merck & Co. Inc.; TOLAMBA™, a ragweed allergy immunotherapy in Phase 2; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer trials and our preclinical hepatitis C therapeutic program, and Deerfield Management has committed funding for our allergy programs. While Deerfield, NIH and SDI provide program support, Dynavax has retained rights to seek strategic partners for future development and commercialization. For more information, please visit <u>http://www.dynavax.com.</u>

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#### Merck to Develop, Commercialize HEPLISAV November 1, 2007 Pg. 3 of 3

### About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit <u>www.merck.com</u>.

#### Dynavax Forward-looking Statement

This press release contains "forward-looking statements," including statements related to the potential value of payments which may be received pursuant to our collaboration with Merck & Co., Inc., the anticipated development of HEPLISAV, and the future responsibilities of the parties under the collaboration agreements. Actual results may differ materially from those set forth in this press release 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 and obtaining regulatory approval for HEPLISAV; 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.

#### Merck Forward-looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the company incorporates by reference.

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