

DYNAVAX TECHNOLOGIES CORP
Form 8-K
March 02, 2009

**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): 03/02/2009

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)

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))
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Item 2.02. Results of Operations and Financial Condition

On March 2, 2009, Dynavax Technologies Corporation (Dynavax) issued a press release announcing its financial results for fourth quarter and year ended December 31, 2008, and provided its 2009 financial outlook. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information with respect to item 2.02 in this current report and its accompanying exhibit shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this current report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Dynavax Technologies Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events

On March 2, 2009, Dynavax provided a corporate update on certain clinical development programs as follows:

Corporate Update

Phase 3 HEPLISAVTM hepatitis B vaccine - Dynavax is seeking clarification of the remaining regulatory requirements for development and licensure of HEPLISAV in the United States and Europe and expects to have sufficient information in the first half of 2009 to determine a path forward, if any. Concurrently, Dynavax is pursuing potential pharmaceutical partnerships and financing arrangements to complete clinical development if the regulatory feedback is positive. Dynavax also expects to report complete Phase 3 PHAST clinical study data from healthy adults in the second quarter of 2009.

Phase 1b SD-101 hepatitis C therapy - In mid-year 2009, Dynavax expects to report top-line data from an ongoing Phase 1b trial for SD-101 therapy for hepatitis C virus (HCV). This trial is being funded entirely under the Symphony Dynamo Inc. (SDI) arrangement.

Phase 1b DV-601 hepatitis B therapy - In mid-year 2009, Dynavax expects to begin enrolling patients in a Phase 1b trial for DV-601 therapy for hepatitis B virus (HBV).

Phase 1a studies - In the second half of 2009, Dynavax expects phase 1a studies will be initiated for AZD1419 for asthma, under a partnership with AstraZeneca, and DV1079 for autoimmune and inflammatory diseases, under a partnership with GlaxoSmithKline. In the first half of 2010, the Company plans to initiate a Phase 1a study for its Universal Flu vaccine, which is under a supply and option agreement with Novartis.

The foregoing "forward looking statements", are subject to a number of risks and uncertainties, including statements related to the nature and timing of communications with the FDA regarding the current HEPLISAV clinical hold and the potential for further development of this product, and planned initiation and completion of other clinical trials. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in our business and we undertake no obligation to update this information.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
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99.1	Press Release, dated March 2, 2009 titled "Dynavax Announces Fourth Quarter and Year-End 2008 Financial Results."
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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: March 02, 2009

By: /s/ Deborah A. Smeltzer

Deborah A. Smeltzer
Vice President, Operations and Chief Financial Officer

Exhibit Index

Exhibit No.	Description
EX-99.1	Press Release, dated March 2, 2009 titled "Dynavax Announces Fourth Quarter and Year-End 2008 Financial Results."