
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): 10/16/2013

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 October 16, 2013, we issued a press release titled "Dynavax Reports on HEPLISAV(TM) Regulatory Path." 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:

EX-99.1 Press Release, dated October 16, 2013, titled "Dynavax Reports on HEPLISAV(TM) Regulatory Path".

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: October 18, 2013

By: /s/ Michael Ostrach

Michael Ostrach
Vice President

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Dynavax Reports on HEPLISAV(TM) Regulatory Path.

Dynavax

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 ON HEPLISAV™ REGULATORY PATH

- Conference Call Tomorrow, October 17th at 8:30 a.m. ET -

BERKELEY, CA - October 16, 2013 - Dynavax Technologies Corporation (NASDAQ: DVAX) today announced the design of its next large-scale clinical study of HEPLISAV, its investigational adult hepatitis B vaccine, following discussions with the U.S. Food and Drug Administration (FDA or Agency). The planned study, HBV-23, is intended to provide a sufficiently-sized safety database for the Agency to complete its review of Dynavax's Biologics License Application (BLA). It will be an 8,000 subject, Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV compared with Engerix-B® in adults 18 to 70 years of age.

The primary objectives of HBV-23 will be:

- To evaluate the overall safety of HEPLISAV with respect to clinically significant adverse events; and
- To demonstrate the noninferiority of the peak seroprotection rate (SPR) induced by HEPLISAV to Engerix-B in subjects with type 2 diabetes mellitus.

HBV-23 will include 5,500 HEPLISAV subjects and 2,500 Engerix-B subjects, randomized 2:1 and stratified by age and diabetes diagnosis. HEPLISAV subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months. All HEPLISAV subjects will be evaluated for safety for one year following the second dose and all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee. Immunogenicity assessments will be conducted in a subset of subjects, including those with type 2 diabetes.

"Following extensive discussion with FDA, we've finalized a study design that we believe will provide confidence to the Agency regarding HEPLISAV's safety profile, and importantly, will provide Dynavax with the opportunity to prospectively generate additional immunogenicity data in persons with diabetes, a population for whom there is a clear unmet medical need," commented Eddie Gray, Dynavax Chief Executive Officer.

Dynavax intends to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015 and estimates the external costs of the study to be in the range of \$50-55 million.

Dynavax's Marketing Authorization Application for HEPLISAV remains on file in Europe. The Company is currently preparing its response to the European Medicines Agency's (EMA) 120-Day List of Questions to be submitted in the fourth quarter of 2013, following which the EMA will provide Dynavax its 180-Day List of Outstanding Issues expected in the first quarter 2014.

The 120-Day response will incorporate the target population for HEPLISAV and size of the safety database, and will address Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP)-related items, including questions arising from a recent EMA GCP inspection. Dynavax will continue to work through the European regulatory review process to determine the appropriate next steps, corrective actions, and possible post-approval commitments. The Company anticipates that some of these matters will need to be resolved following issuance of the 180-Day List of Outstanding Issues, which when received, will enable Dynavax to provide further clarification on HEPLISAV's potential path forward in Europe.

Engerix-B® is a registered trademark of GlaxoSmithKline.

Conference Call Tomorrow

Dynavax management will host a conference call tomorrow at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) and individuals may participate in the conference call by dialing (866) 428-9517 (domestic) or (224) 357-2389 (international).

To access a live audio webcast of the conference call, please visit the Company's website at <http://investors.dynavax.com/newsevents.cfm>

A replay of the webcast will be available on the Dynavax website approximately two hours after the conference call concludes through October 31, 2013.

About HEPLISAV

HEPLISAV 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.

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, a Phase 3 investigational adult hepatitis B vaccine. For more information visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for HEPLISAV, our discussions with the FDA and the impact on our further plans to achieve approval, and the timing and nature of our responses to correspondence in the European regulatory review process, and whether our efforts may be sufficient to achieve approval in a timely manner or within the projected expense levels identified. 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 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 in either or both of the US and Europe; the timing for and costs of achieving the size of the safety database that the FDA has provided guidance on; 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 BLA or European licensure application will be approved; our ability to obtain additional financing to support the development and commercialization of HEPLISAV and our other operations; possible claims against us, including enjoining sales of HEPLISAV, 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.

###