DYNAVAX TECHNOLOGIES CORP

FORM 8-K
(Current report filing)

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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): November 8, 2017

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware	**33-0728374**
(State or other jurisdiction of incorporation)	**(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))**

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement

On November 8, 2017, Dynavax Technologies Corporation (the "Company") and inVentiv Commercial Services, LLC ("inVentiv," and together with the Company, the "Parties") entered into a project agreement (the "Project Agreement") pursuant to that certain Master Services Agreement, by and between the Parties, dated as of January 11, 2016 (the "MSA"). Pursuant to the Project Agreement, inVentiv will provide a field force of account managers to provide certain detailing services, sales operation services, compliance services and training services with respect to HEPLISAV-B to the Company in exchange for an up-front implementation fee and a fixed annual fee.

The Project Agreement terminates automatically on the second anniversary of the date of the first activity undertaken by inVentiv to detail HEPLISAV-B (the "Deployment Date") unless earlier extended upon the mutual written agreement of the Parties. The Company may terminate the Project Agreement for any reason upon timely notice; provided, however, that if the Company terminates the Project Agreement prior to the first anniversary of the Deployment Date, the Company will be obligated to pay inVentiv a termination fee, the amount of which varies depending on the date of termination.

The foregoing summary of the Project Agreement is not complete and is qualified in its entirety by reference to the Project Agreement and the MSA, which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ending December 31, 2017. Certain terms of the Project Agreement have been omitted from this Form 8-K and will be omitted from the version to be filed as an exhibit to the Form 10-K pursuant to a Confidential Treatment Request that the Company plans to submit to the Securities and Exchange Commission at the time of the filing of the Form 10-K.

Item 8.01. Other Events

On November 9, 2017, the Company issued a press release titled "Dynavax Announces FDA Approval of HEPLISAV-B ™ for Prevention of Hepatitis B in Adults". 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 filed herewith:

99.1	Press Release, dated November 9, 2017, titled "Dynavax Announces FDA Approval of HEPLISAV-B ™ for Prevention of Hepatitis B in Adults"

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: November 14, 2017

By: /s/ STEVEN N. GERSTEN

Steven N. Gersten
Vice President, General Counsel and Chief Ethics and Compliance Officer

Exhibit 99.1

Dynavax Announces FDA Approval of HEPLISAV-B™
for Prevention of Hepatitis B in Adults

— First and Only Two-Dose Vaccine in United States for Prevention of Hepatitis B in Adults —

— First New Hepatitis B Vaccine in United States in More than 25 Years —

— Company to Host Conference Call/Webcast Today at 5:00 p.m. ET —

BERKELEY, Calif. – 11/09/17 – Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the U.S. Food and Drug Administration (FDA) has approved HEPLISAV-B [Hepatitis B Vaccine, Recombinant (Adjuvanted)] for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. HEPLISAV-B is the first new hepatitis B vaccine in the United States in more than 25 years and the only two-dose hepatitis B vaccine for adults.

Hepatitis B is an extremely infectious and potentially deadly virus affecting a wide range of adults in the United States. There is no cure for hepatitis B, and infections are on the rise. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally. [i] Hepatitis B can be prevented through effective vaccination. Current hepatitis B vaccines require three shots over a six-month period, however, almost half of adults fail to complete the series within one year. [ii]

“Prevention of hepatitis B in adults through vaccination is more important than ever given the increase in the rate of infections,” said William Schaffner, M.D., professor of Preventive Medicine, Vanderbilt University Medical Center. “Too many at-risk adults remain unprotected against this virus. A two-dose schedule with higher rates of protection, along with other strategies, may help us move closer to the goal of eliminating hepatitis B as a public health problem in the United States.”

The approval of HEPLISAV-B was based on data from three Phase 3 non-inferiority trials of nearly 10,000 adult participants who received HEPLISAV-B. The pivotal studies compared HEPLISAV-B administered in two doses over one month to Engerix-B administered in three doses over a six-month schedule. Results from the largest Phase 3 trial, which included 6,665 participants, showed that HEPLISAV-B demonstrated a statistically significantly higher rate of protection of 95% compared with 81% for Engerix-B. In a subgroup analysis of 961 participants with Type 2 diabetes, HEPLISAV-B demonstrated a statistically significantly higher rate of protection of 90% compared to 65% for Engerix-B. Across the three clinical trials, the most common local reaction was injection site pain (23% to 39%). The most common systemic reactions were fatigue (11% to 17%) and headache (8% to 17%).

“HEPLISAV-B is the first FDA-approved product for Dynavax and demonstrates our ability to develop innovative products and progress them from discovery to commercialization,” said Eddie Gray, chief executive officer of Dynavax. “We would like to thank the many study participants and clinical trial investigators who contributed to the development of HEPLISAV-B. We expect that it will become an essential tool in the public health community’s fight to prevent hepatitis B, and we look forward to making HEPLISAV-B available to clinicians and their adult patients.”

Dynavax expects to commercially launch HEPLISAV-B in the United States in the first quarter of 2018. In preparation for launch, Dynavax has been building commercial infrastructure and optimizing manufacturing processes to meet anticipated demand.

Conference Call Details

The Dynavax management team will host a conference call and webcast today, Thursday, November 9, 2017 at 5:00 p.m. Eastern Time, to provide more information about the FDA approval of HEPLISAV-B. The live call can be accessed by phone by dialing (877) 479-1857 from the U.S. and Canada or +1 (503) 343-6309 internationally and using the passcode 5357789. The live call is being webcast and can be accessed in the "Investors and Media" section of the Company's website at www.dynavax.com . A replay of the webcast will be available for 30 days following the live event.

About Hepatitis B

Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV, [iii] and transmission is on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease. In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas. [iv] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion. [v] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year. [vi]

About HEPLISAV-B

HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

Indication and Use

HEPLISAV-B is indicated for active immunization against infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

Important Safety Information (ISI)

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%) and headache (8% to 17%).

For full Prescribing Information for HEPLISAV-B, click here .

About Dynavax

Dynavax is a commercial-stage biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company's first commercial product, HEPLISAV-B, a hepatitis B vaccine for adults, is approved in the United States. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com .

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercial launch and manufacturing of HEPLISAV-B. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the company will be able to build the commercial infrastructure required to launch HEPLISAV-B; whether we will launch HEPLISAV-B in the first quarter of 2018; whether we will be able to ramp up manufacturing activities to meet demand for HEPLISAV-B; whether the CDC's Advisory Committee on Immunization Practices (ACIP) will add HEPLISAV-B to its adult vaccination schedule during its February 2018 meeting, or at all; whether potential claims against us, including those based on patent rights of others, will result in an injunction against sales or otherwise impact commercialization and sales; and the results of clinical studies of Dynavax's product candidates, such as SD-101, and the impact of those results on the initiation or continuation of subsequent studies for those product candidates, and issues arising in the regulatory process; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, 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.

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i CDC. https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8 . Fig 3.2

ii Nelson J, et al. Compliance with multiple-dose vaccine schedules among older children, adolescents and adults: results from a Vaccine Safety Datalink Study. *American Journal of Public Health.* 2009;99:S2.

iii CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm .

iv CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm .

v CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf .

vi CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf .