

DYNAVAX TECHNOLOGIES CORP

FORM 8-K (Current report filing)

Filed 01/09/18 for the Period Ending 01/08/18

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Telephone	5108485100
CIK	0001029142
Symbol	DVAX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): January 8, 2018

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))

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 8.01. Other Events

On January 8, 2018, the Company issued a press release titled "Dynavax Announces HEPLISAV-B™ is Now Available in the United States for the 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 January 8, 2018, titled "Dynavax Announces HEPLISAV-B™ is Now Available in the United States for the 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: January 9, 2018

By: /s/ STEVEN N. GERSTEN
Steven N. Gersten
Vice President, General Counsel and Chief Ethics and
Compliance Officer



Dynavax Announces HEPLISAV-B™ is Now Available in the United States for the Prevention of Hepatitis B in Adults

- HEPLISAV-B is the First and Only Two-Dose Vaccine in U.S. for Hepatitis B Prevention in Adults –

BERKELEY, Calif. – January 8, 2018 – Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] is now available in the United States for the prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. HEPLISAV-B was approved by the U.S. Food and Drug Administration (FDA) on November 9, 2017. It 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.

“Dynavax is prepared and proud to launch our first product, HEPLISAV-B, in the United States,” said Eddie Gray, chief executive officer of Dynavax. “We believe the increase in the rate of infections and poor compliance with current three-shot regimens has the medical community eager for access to HEPLISAV-B for adults. Given its two-dose schedule and delivery of high rates of protection, HEPLISAV-B is an important tool for preventing hepatitis B in the United States.”

HEPLISAV-B can now be ordered through a network of distributors, which will broaden over the next few weeks. The Wholesale Acquisition Cost (WAC) for HEPLISAV-B of \$115 per dose, or \$230 per regimen, reflects the value HEPLISAV-B brings to the healthcare system. Dynavax is currently working with an extensive network of group purchasing organizations and government entities to ensure all patients have access to HEPLISAV-B. A list of the current distributors in the Dynavax network can be accessed by calling 1-84-HEPLISAV (1-844-375-4728).

Dynavax has begun activities to support broad reimbursement of HEPLISAV-B by insurance plans. Importantly, the American Medical Association has published a new and active Current Procedural Terminology (CPT) code for a two-dose adult hepatitis B vaccine, which was created to accommodate HEPLISAV-B’s two-dose, one-month schedule. A majority of plans currently have this unique code loaded into their claims processing systems. Some plans will require recommendation from the CDC’s Advisory Committee on Immunization Practices (ACIP) prior to covering HEPLISAV-B. The next ACIP meeting is scheduled for February 21-22, 2018. Proactive payer outreach is currently ongoing, and will include updated ACIP information specific to HEPLISAV-B as it becomes available. Dynavax has staged the deployment of its field sales team to coincide with the upcoming ACIP meeting.

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, ¹ and transmission is on the rise. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally. ² 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. ³ 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. ⁴ Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year. ⁵

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 prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years 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 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 continue building the commercial infrastructure required to launch HEPLISAV-B; whether payers will provide timely reimbursement 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; and 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. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these

forward-looking statements, as well as risks relating to the business of Dynavax in general, see 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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¹ CDC. <https://www.cdc.gov/hepatitis/hbv/bfaq.htm>.

² CDC. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8>. Fig 3.2

³ CDC. <https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>.

⁴ CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.

⁵ CDC. <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.