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): February 19, 2021

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.)**

2100 Powell Street, Suite 900
Emeryville, CA 94608
(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))**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading symbol(s):**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value	DVAX	The Nasdaq Stock Market LLC

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 February 19, 2021, Dynavax Technologies Corporation issued a press release entitled, "Dynavax Announces European Commission Marketing Authorization for HEPLISAV B®, a 2 Dose Adult Hepatitis B Adjuvanted Vaccine," a copy of which is attached hereto as exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Number	**Description**
99.1	Press Release dated February 19, 2021 entitled "Dynavax Announces European Commission Marketing Authorization for HEPLISAV B®, a 2 Dose Adult Hepatitis B Adjuvanted Vaccine"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 19, 2021

By: /s/ STEVEN N. GERSTEN
Steven N. Gersten
Senior Vice President

Exhibit 99.1

Dynavax Announces European Commission Marketing Authorization for HEPLISAV B®, a 2 Dose Adult Hepatitis B Adjuvanted Vaccine

- Approval follows positive opinion by European Committee for Medicinal Products for Human Use
- Approval based on safety and immunogenicity results from three Phase 3 clinical trials
- Statistically significantly higher and faster rates of protection and similar safety compared to Engerix-B in all 3 trials
- HEPLISAV B is the only 2-dose adult hepatitis B vaccine offering protection in just 1 month

EMERYVILLE, CA – February 19, 2021 – Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced that the European Commission (EC) has granted Marketing Authorization for HEPLISAV B (Hepatitis B Vaccine (Recombinant), Adjuvanted) for the active immunization against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. The approval was issued following the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinion on the company's Marketing Authorization Application. The approval and CHMP recommendation were based on the positive benefit-risk for HEPLISAV B as demonstrated by the safety and immunogenicity results of three Phase 3 clinical trials.

"Hepatitis B is a highly infectious and potentially deadly virus with increasing infection rates, and over 250 million people infected worldwide. Thankfully, it can be prevented with effective vaccination," commented Ryan Spencer, Chief Executive Officer of Dynavax. "With a two-dose regimen that takes only one month to complete and a statistically significantly higher seroprotection rate in head-to-head clinical trials, HEPLISAV B provides a unique opportunity to address known challenges with compliance, while delivering higher levels of protection compared to the three-dose regimen of the comparator vaccine. We are pleased that HEPLISAV B has received this latest approval and look forward its launch in Europe expected later this year."

European Commission marketing authorization approval is valid in all EU and EEA-European Free Trade Association (EFTA) states (Norway, Iceland and Liechtenstein). HEPLISAV-B is now approved in the U.S. and EU.

Please see Important Safety Information below.

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, 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.

About HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist adjuvant CpG 1018 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

Important EU/EEA Product Information

HEPLISAV B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.
The use of HEPLISAV B should be in accordance with official recommendations.
It can be expected that hepatitis D will also be prevented by immunisation with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

Important EU/EEA Safety information

Do not receive HEPLISAV B if you have had a sudden life-threatening, allergic reaction after receiving HEPLISAV B in the past, or if you are allergic to any of components of this vaccine, including yeast. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.
Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reactions following the administration of the vaccine.
The administration of HEPLISAV B should be postponed in subjects suffering from acute severe febrile illness.
Immunocompromised persons may have a diminished immune response to HEPLISAV B.
Because of the long incubation period of hepatitis B, it is possible for unrecognised HBV infection to be present at the time of immunisation. HEPLISAV B may not prevent HBV infection in such cases.
There are very limited data on the immune response to HEPLISAV B in individuals who did not mount a protective immune response to another hepatitis B vaccine.
As a precautionary measure, it is preferable to avoid the use of HEPLISAV B during pregnancy. Vaccination during pregnancy should only be performed if the risk-benefit ratio at the individual level outweighs possible risks for the fetus.
The most common patient-reported side effects reported within 7 days of vaccination were pain, swelling or redness at the injection site, feeling tired, headache, muscle aches, feeling unwell and fever.

Important U.S. Product Information

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

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

Important U.S. 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%).

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the European launch of HEPLISAV B. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the timing of the launch of HEPLISAV B in Europe, what countries it will be launched in and when, whether commercialization of HEPLISAV B in Europe will be successful, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. 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.

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