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): May 7, 2020

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 2.02. Results of Operations and Financial Condition

On May 7, 2020, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 "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, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is furnished herewith:

99.1	Press release, dated May 7, 2020, titled "Dynavax Announces First Quarter 2020 Financial Results".
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: May 7, 2020

By: /s/ MICHAEL OSTRACH
Michael Ostrach
Senior Vice President

Exhibit 99.1

Dynavax Announces First Quarter 2020 Financial Results

- Q1 2020 HEPLISAV-B® net product revenue of $10.5 million, compared to $5.6 million in Q1 2019
- Multiple collaborations established leveraging Dynavax's vaccine adjuvant CpG 1018 in coronavirus (COVID-19) vaccine candidates across several technology platforms
- Positive interim clinical trial results for HEPLISAV-B® in dialysis patients
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, CA – May 7, 2020 – Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the first quarter of 2020.

"Now more than ever, the world is acutely aware of the crucial role vaccines play in protecting our families, communities, and those at high risk for infectious disease," commented Ryan Spencer, Chief Executive Officer of Dynavax. "Hepatitis B is a highly infectious deadly virus which, thankfully, can be prevented with effective vaccination. Our first product, HEPLISAV-B, provides adults higher levels of protection from hepatitis B in one month, compared to other hepatitis B vaccines that require six months. We believe that HEPLISAV-B has the potential to become the standard of care for adult hepatitis B vaccination in the U.S."

Mr. Spencer added, "With uncertainty spawned by the current pandemic, our focus in 2020 remains driving revenue growth of HEPLISAV-B, generating data to support a unique dosing regimen for patients on hemodialysis, and supporting policy initiatives aimed at protecting more adults through adoption of a two-dose regimen, all of which position HEPLISAV-B for substantial long-term growth. Additionally, we have established multiple research collaborations leveraging our proprietary vaccine adjuvant, CpG 1018, to support the development of coronavirus vaccines. Despite the short-term disruptions of this year, Dynavax's long-term value proposition remains intact with the added potential to accelerate the utilization of CpG 1018 globally."

HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]

- Despite sales reductions at the end of March due to coronavirus pandemic response, Dynavax achieved first quarter 2020 net product revenue of $10.5 million compared to $5.6 million for the first quarter of 2019.
- Dynavax has exceeded the HEPLISAV-B minimum product revenue covenant in its Term Loan Agreement of $30 million for the annual measurement period ending June 30, 2020.
- On-going clinical trial evaluating immunogenicity and safety of 4-dose regimen of HEPLISAV-B® in adults with end-stage renal disease (ESRD) who are initiating or undergoing hemodialysis:
    - Seroprotection rate of 86.4% demonstrated in interim analysis of 44 patients
    - Safety and efficacy have not been established in this population; full study data anticipated in the second half of 2020

COVID-19 Response

Dynavax has focused on four key areas in addressing uncertainty related to the COVID-19 pandemic:

- Protecting the health and safety of Dynavax's employees and customers
- Ensuring access to HEPLISAV-B with a secure supply chain able to meet U.S. market demand
- Continuing to advance the Company's on-going clinical trials of HEPLISAV-B

- Leveraging the Company's proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018, in collaborations to develop additional adjuvanted vaccines. Dynavax has established multiple such research collaborations to develop a coronavirus (COVID-19) vaccine:

Vaccine Approach	Collaborator	Country
Protein Subunit	University of Queensland	Australia
	Clover Biopharmaceuticals	China
Inactivated Virus	Sinovac Biotech	China
	Valneva	France

2020 Milestones

- Interim data from ongoing study of HEPLISAV-B in patients on hemodialysis reported in April 2020; final immunogenicity data anticipated in the second half of 2020
- Completion of Phase 1-enabling animal studies and toxicology for an improved pertussis vaccine with CpG 1018
- Inclusion of CpG 1018 in at least one coronavirus vaccine advanced to Phase 1 clinical evaluation
- Entrance into multiple strategic relationships focused on initial research in a variety of vaccine candidates to establish CpG 1018 as a leading adjuvant
- Completion of safety follow-up for HEPLISAV-B post-marketing studies in Q4 2020

Financial Results

Product Revenue, Net. Product revenue, net increased to $10.5 million in the first quarter of 2020 compared to $5.6 million in the same period in 2019 due to higher sales volume as additional healthcare providers completed operational activities required to switch to HEPLISAV-B and existing customers placed repeat orders. Although there was a modest impact from COVID-19 on HEPLISAV-B net product sales in the first quarter, most medical centers restricted access to their facilities and focused on providing care to only the most severely affected patients by mid-March. This has resulted in significantly reduced utilization of vaccines, including HEPLISAV-B, which is likely to continue until the U.S. returns to more normal conditions.

Cost of Sales - Product. Cost of sales - product for the first quarter 2020 was $2.4 million, compared to $1.8 million for the first quarter of 2019. The increase is due to higher sales volume and higher unit costs as we produce and then sell finished product inventory that includes components for which a portion of the cost has previously been expensed to research and development prior to approval of the pre-filled syringe presentation in March 2018.

Research and Development Expenses. Research and development expenses for the first quarter of 2020 were $4.7 million, compared to $21.2 million for the first quarter of 2019. Excluding non-cash stock-based compensation, R&D expenses decreased to $6.2 million in the first quarter of 2020, compared to $19.0

million in the first quarter of 2019. Stock-based compensation for the three months ended March 31, 2020 included reversal of expenses related to cancellation of certain equity grants.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the first quarter of 2020 were $20.9 million, compared to $18.3 million for the first quarter of 2019. The increase for the three months ended March 31, 2020 compared to 2019, was primarily related to costs related to the HEPLISAV-B post-marketing study, an increase in facility costs due to higher overhead allocation to SG&A functions and changes in non-cash stock-based compensation resulting from the restructuring.

Net Loss. Net loss allocable for the first quarter of 2020 was $12.6 million, or $0.15 per basic share and $0.25 per diluted share, compared to a net loss of $39.7 million, or $0.62 per basic and diluted share, for the first quarter of 2019.

Cash Position. Cash, cash equivalents and marketable securities totaled $129.5 million at March 31, 2020.

Conference Call and Webcast Information

Dynavax will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT. The live audio webcast may be accessed through the "Events & Presentations" page on the "Investors" section of the Company's website at www.dynavax.com. Alternatively, participants may dial (866) 420-4066 (domestic) or (409) 217-8237 (international) and refer to conference ID 1178679. A replay of the webcast will be available for 30 days following the live event.

Please see Important Safety Information below.

For more information about HEPLISAV-B, visit http://heplisavb.com.

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,[i] 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 U.S. Centers for Disease Control (CDC) recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii] 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.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[iv]

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 CpG 1018 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 developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval 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. 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 potential for HEPLISAV-B to become the standard of care adult hepatitis B vaccine in the U.S., long-term growth of HEPLISAV-B, the impact of COVID-19 on the utilization of vaccines, including HEPLISAV-B, the timing of enrollment in and completion of clinical studies, the results of clinical studies and what the results will demonstrate or support, developing an improved pertussis vaccine, a vaccine for COVID-19, and other vaccines, entering into strategic relationships, and establishing CpG 1018 as a leading adjuvant. 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 risk that the vaccine market and/or the adult hepatitis B market may not grow as expected, the risk that COVID-19 will continue to have a significant negative impact on the use of vaccines, including HEPLISAV-B, until the U.S. returns to more normal conditions, the adverse effects of the recent coronavirus pandemic on our ability to access customers and on customer decision making, adoption and implementation, the risk that HEPLISAV-B may not provide the anticipated benefits and may not become the standard of care adult hepatitis B vaccine in the U.S., the risk that our growth initiatives may not be successful, risks related to whether and when prescribers and other key decision-makers at potential purchasing entities will make the decision to switch to HEPLISAV-B, and the timing and quantity of actual purchases, risks related to the development and clinical testing of vaccines and whether use of CpG 1018 will prove to be beneficial in other vaccines, and risks related to whether existing or future collaborations 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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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

DYNAVAX TECHNOLOGIES CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Product revenue, net	$ 10,514	$ 5,627
Other revenue	405	146
Total revenues	10,919	**5,773**
Operating expenses:		
Cost of sales – product	2,354	1,800
Cost of sales - amortization of intangible assets	2,298	2,273
Research and development	4,653	21,206
Selling, general and administrative	20,926	18,348
Total operating expenses	30,231	**43,627**
Loss from operations	(19,312)	(37,854)
Other income (expense):		
Interest income	590	735
Interest expense	(4,731)	(2,734)
Sublease income	1,926	-
Change in fair value of warrant liability	8,610	-
Other income (expense), net	322	181
Net loss	**$ (12,595)**	**$ (39,672)**
Basic net loss per share	**$ (0.15)**	**$ (0.62)**
Weighted average shares used to compute basic net loss per share	**85,477**	**63,778**
Diluted net loss per share	**$ (0.25)**	**$ (0.62)**
Weighted average shares used to compute diluted net loss per share	**85,648**	**63,778**

DYNAVAX TECHNOLOGIES CORPORATION
SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 129,533	$ 151,055
Inventories, net	48,099	41,332
Property and equipment, net	30,897	32,022
Intangible assets, net	202	2,500
Operating lease right-of-use assets	28,436	30,252
Goodwill	2,061	2,081
Other assets	20,028	19,826
Total assets	**$ 259,256**	**$ 279,068**
Liabilities and stockholders' equity		
Total current liabilities	$ 29,279	$ 53,047
Total long-term liabilities	218,153	217,731
Stockholders' equity	11,824	8,290
Total liabilities and stockholders' equity	**$ 259,256**	**$ 279,068**