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 5, 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 November 5, 2020, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended September 30, 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 November 5, 2020, titled "Dynavax Announces Third 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: November 5, 2020

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

Exhibit 99.1

Dynavax Announces Third Quarter 2020 Financial Results

- Third quarter 2020 HEPLISAV-B® net product revenue highest since launch at $11.6 million, despite impact of COVID-19
- Initial CpG 1018 revenue and deferred revenue totaling $23.4 million in third quarter, with potential 2021 revenue between approximately $130 to $230 million
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, CA – November 5, 2020 – Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the third quarter of 2020.

"The current global pandemic highlights the need for continued development of new and improved vaccines," commented Ryan Spencer, Chief Executive Officer of Dynavax. "Our team at Dynavax is leveraging its expertise in vaccine development and commercialization to build a leading vaccine company around our FDA-approved adult hepatitis B vaccine, HEPLISAV-B, which we believe has the potential to become the standard of care in the U.S., as well as our pipeline of opportunities enabled by our vaccine adjuvant CpG 1018."

Mr. Spencer added, "The overall vaccine market continues to rebound from the significant declines seen in the first and second quarters, with the adult hepatitis B vaccine market recovering to approximately 75% of the same period last year. HEPLISAV-B sales have come back even stronger based on success in key national accounts and continued growth in field targeted account market share, resulting in our highest quarterly revenue to date. In addition, we have entered into numerous collaborations to develop adjuvanted vaccines across multiple indications, including COVID-19, TdaP, and universal flu. This portfolio of CpG 1018 opportunities is driving the next leg of growth beyond HEPLISAV-B, as initially seen with our commercial supply agreement with Valneva, where we have the potential for 2021 CpG 1018 revenue between approximately $130 and $230 million."

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

- Net product revenue for HEPLISAV-B during the third quarter 2020 was $11.6 million, up from $10.2 million for the third quarter of 2019, despite the ongoing reduction in vaccine utilization due to COVID-19.
- Market share in accounts targeted by the field sales team increased to approximately 23%, up from approximately 21% in the previous quarter.
- Successful conversion of a top 5 national retail chain to HEPLISAV-B, resulting in stocking over 2,000 store locations in the third quarter.

CpG 1018 (proprietary toll-like receptor 9 (TLR9) agonist adjuvant)

- In September 2020, Dynavax and Valneva SE entered into a commercial supply agreement to provide Valneva with CpG 1018 to produce 60 to 100 million doses of vaccine in 2021. Valneva has the option to purchase CpG 1018 to produce up to an additional 90 million doses through 2024. Under our commercial supply agreement with Valneva, Dynavax has the potential for 2021 CpG 1018 revenue between approximately $130 and $230 million, with a total revenue potential over $400 million through 2024, contingent on the continued success of the program.
- Phase 1 data from Medicago and Clover Biopharmaceuticals are expected to be released by mid-November and year-end 2020, respectively.

- Based on the positive Phase 1 data to date, Clover Biopharmaceuticals intends to develop two adjuvanted COVID-19 vaccine programs to fully utilize their available antigen production capacity and anticipates initiating a pivotal clinical trial with CpG 1018 to address global demand.
- Multiple ongoing global, collaborations are advancing the development of adjuvanted vaccine candidates using Dynavax's CpG 1018. Dynavax expects to continue to broaden its portfolio of vaccine product opportunities through additional business arrangements. A summary of current CpG 1018 collaborations is provided below.

Indication	Collaborator	Status
COVID-19	Clover Biopharmaceuticals	Phase 1
	Medicago	Phase 1
	Medigen Vaccine Biologics	Phase 1
	Valneva	Preclinical
TdaP	Serum Institute of India	Preclinical
Universal Influenza	Mount Sinai	Preclinical

Additional Corporate Updates

- Appointed Julie Eastland, Brent MacGregor, and Peter Paradiso, Ph.D. to Board of Directors
- Communicated Michael Ostrach's plan to retire as Chief Financial Officer in 2021
- Amended term loan agreement with CRG to modify the net sales threshold requirement to include sales of CpG 1018 and remove the annual net sales threshold requirement for the twelve-month period beginning July 1, 2020 and ending on June 30, 2021

2020 Milestones

- Final immunogenicity data from the ongoing study of HEPLISAV-B in patients on hemodialysis anticipated in the fourth quarter with publication planned in the first half of 2021
- Completion of safety follow-up period for HEPLISAV-B post-marketing studies in the fourth quarter with the final report expected in Q2 2021
- Completion of Phase 1-enabling animal studies and toxicology for an improved TdaP vaccine with CpG 1018 is planned for the fourth quarter

Financial Results

Product Revenue, Net. Total product revenue, net for the third quarter 2020 was $13.3 million. HEPLISAV-B product revenue, net increased to $11.6 million in the third quarter of 2020 compared to $10.2 million in the same period in 2019. For the nine months ended September 30, 2020, the increase in HEPLISAV-B product revenue, net in the first and third quarters was offset by lower sales volume in the second quarter due to lower adult vaccine utilization caused by the COVID-19 global pandemic. Utilization of adult vaccines improved during the third quarter as health care providers gradually expanded their services and distributors replenished inventory. Sales during the third quarter also include an initial stocking order from a large retail chain and the effect of seasonal Department of Defense purchases. CpG 1018 product revenue, net was $1.7 million in the third quarter of 2020 compared to $0.0 million in the same period in 2019.

Cost of Sales - Product. Cost of sales - product for the third quarter 2020 increased to $4.0 million, compared to $3.8 million for the third quarter of 2019, primarily due to higher unit costs for HEPLISAV-B as we produce and then sell inventory that reflects the full cost of manufacturing. For the three months ended September 30, 2020, cost of sales-product included $0.8 million of costs to produce CpG 1018 for our collaboration partners. The Company anticipates cost of sales-product to increase substantially in 2021 due to increased manufacturing of CpG 1018 under the supply agreement with Valneva.

Research and Development Expenses. Research and development (R&D) expenses for the third quarter of 2020 decreased to $8.5 million, compared to $12.7 million for the third quarter of 2019 as personnel costs, facilities overhead cost allocations and non-cash stock-based compensation decreased due to lower R&D headcount because of our restructuring in May 2019 and the winding down of our immuno-oncology programs, offset by an increase an additional CpG 1018 development costs at our third-party manufacturing facility to support increased CpG 1018 demand from our collaboration partners for use in their development and/or commercialization of COVID-19 vaccines.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the third quarter of 2020 increased to $21.5 million, compared to $18.5 million for the third quarter of 2019 primarily due to a $2.5 million payment during the third quarter of 2020 in connection with the sale of our immuno-oncology compound, SD-101.

Loss from Operations and Net Income Loss. Loss from operations for the third quarter of 2020 decreased to $13.8 million from $30.6 million in the third quarter of 2019. Net income for the third quarter of 2020 was $4.4 million compared to a net loss of $36.7 million for the third quarter of 2019, primarily due to a gain of $21.2 million in the fair value of our warrant liability. Basic net income per share was $0.04 and diluted net loss per share was $0.15 for the third quarter of 2020, compared to $0.49 per basic and diluted net loss per share in the third quarter of 2019.

Cash Position. Cash, cash equivalents and marketable securities totaled $177.2 million at September 30, 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 or (409) 217-8237 and refer to conference ID 1475431. 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 CpG 1018
CpG 1018 is the adjuvant used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 provides a well- developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine. Upon completion of on-going scale up activities, the existing equipment capacity for CpG 1018 will be 600 million to 1.2 billion adjuvant doses annually, depending on final dose selected.

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 potential for HEPLISAV-B to become the standard of care adult hepatitis B vaccine in the U.S., establishing CpG 1018

as a leading adjuvant, the development of vaccines containing CpG 1018 and potential future sales of CpG 1018, the timing of completion of pre-clinical and clinical studies and the publication of results, our ability to scale manufacturing capacity, the expected demand for our products developing an improved pertussis vaccine, a vaccine for COVID-19, and a universal flu vaccine, entering into strategic relationships and expected results of such relationships, and sales potential under certain agreements. 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 HEPLISAV-B may not become the standard of care adult hepatitis B vaccine in the U.S., 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 timing of completion and results of current clinical studies of HEPLISAV-B, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018, and whether use of CpG 1018 will prove to be beneficial in these vaccines, risks related to whether, when and the quantity of CpG 1018 actually purchased by vaccine companies, and risks related to the use of contract manufacturers to supply CpG 1018 and financial commitments made to them, 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-r

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Product revenues, net	$ 13,276	$ 10,158	$ 26,195	$ 24,086
Other revenue	138	417	806	563
Total revenues	**13,414**	**10,575**	**27,001**	**24,649**
Operating expenses:				
Cost of sales - product	4,031	3,824	7,352	7,765
Cost of sales - amortization of intangible assets	-	2,324	2,500	6,894
Research and development	8,521	12,660	19,058	50,062
Selling, general and administrative	21,538	18,459	61,418	54,668
Gain on sale of assets	(6,851)		(6,851)	
Restructuring	-	3,937	-	12,714
Total operating expenses	**27,239**	**41,204**	**83,477**	**132,103**
Loss from operations	(13,825)	(30,629)	(54,476)	(107,454)
Other income (expense):				
Interest income	269	890	1,190	2,604
Interest expense	(4,794)	(4,779)	(14,257)	(12,111)
Sublease income	1,926	891	5,779	891
Change in fair value of warrant liability	21,245	-	4,200	-
Other	(420)	168	(209)	226
Net income (loss)	**$ 4,401**	**$ (33,459)**	**$ (59,773)**	**$ (115,884)**
Preferred stock deemed dividend		(3,267)	-	(3,267)
Net income (loss) allocable to common stockholders	$ 4,401	$ (36,726)	$ (59,773)	$ (119,111)
Basic net income (loss) per share allocable to common stockholders	**$ 0.04**	**$ (0.49)**	**$ (0.61)**	**$ (1.75)**
Weighted average shares used to compute basic and diluted net income (loss) per share allocable to common stockholders	109,816	75,106	97,589	68,032
Diluted net loss per share allocable to common stockholders	**$ (0.15)**	**$ (0.49)**	**$ (0.65)**	**$ (1.75)**
Weighted average shares used to compute diluted net loss per share allocable to common stockholders	111,973	75,106	98,577	68,032

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

	September 30, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 177,161	$ 151,055
Inventories, net	59,033	41,332
Property and equipment, net	30,379	32,022
Intangible assets, net	-	2,500
Operating lease right-of-use assets	27,353	30,252
Goodwill	2,196	2,081
Other assets	57,273	19,826
Total assets	**$ 353,395**	**$ 279,068**
Liabilities and stockholders' equity		
Total current liabilities	$ 66,625	$ 53,047
Total long-term liabilities	217,486	217,731
Stockholders' equity	69,284	8,290
Total liabilities and stockholders' equity	**$ 353,395**	**$ 279,068**