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): August 4, 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 2.02. Results of Operations and Financial Condition

On August 4, 2021, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended June 30, 2021. 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 August 4, 2021 titled "Dynavax Announces Second Quarter 2021 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: August 4, 2021

By: /s/ Kelly MacDonald
Kelly MacDonald
Senior Vice President, CFO

Exhibit 99.1

DYNAVAX

Dynavax Announces Second Quarter 2021 Financial Results

- Second quarter 2021 total revenue of $52.8 million, which includes HEPLISAV-B's highest quarterly revenue to date at $13.7 million
- Executed multiple commercial supply agreements for CpG 1018® adjuvant with our COVID-19 vaccine collaborators
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, CA – August 4, 2021 – Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the second quarter of 2021.

"Our successful execution in the second quarter of 2021 continued to build on the progress made in 2020. With the combined strength of opportunities from HEPLISAV-B and CpG 1018, we believe 2021 will be a transformational year for Dynavax," commented Ryan Spencer, Chief Executive Officer of Dynavax. "HEPLISAV-B achieved its highest quarterly revenue at $13.7 million and continues to increase market share, which reinforces our belief that it will become the standard of care in the U.S. for adult hepatitis B vaccinations."

Mr. Spencer continued, "Dynavax is also making progress on numerous collaborations for its proven CpG 1018 vaccine adjuvant across multiple indications, including COVID-19, pertussis, and universal flu. Our COVID-19 collaborations have advanced significantly in recent months with the execution of commercial supply agreements with Biological E and Clover Biopharmaceuticals, in addition to the two previously executed agreements with Valneva and Medigen. Multiple partners have reported that they currently intend to apply for emergency or conditional authorization for their COVID-19 vaccines in the second half of 2021. Importantly, these collaborations are generating meaningful revenue for Dynavax, with second quarter CpG 1018 revenue of $39 million. We continue to be excited about each of our partners' clinical programs and believe that the emerging portfolio of product opportunities with CpG 1018 adjuvant has the potential to continue generating meaningful future value for Dynavax."

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

- Net product revenue for HEPLISAV-B was $13.7 million during the second quarter 2021, representing the highest quarterly HEPLISAV-B net sales to date, compared to $2.4 million for the second quarter 2020. This increase was primarily driven by continued success in the field targeted accounts and ongoing progress in national accounts.
- Market share in accounts targeted by the field sales team increased to 30%, up from 21% in the second quarter of 2020.
- Dynavax and Bavarian Nordic entered into a commercialization agreement for the marketing and distribution of HEPLISAV B in Germany.

CpG 1018® (Advanced Vaccine Adjuvant)

- Net product revenue for CpG 1018 adjuvant during the second quarter 2021 was $39.0 million.
- Dynavax and Biological E (Bio E) entered into a commercial supply agreement for the use of CpG 1018 adjuvant in the commercial production of Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™. Upon completion of their Phase 2/3 and subsequently emergency use

authorization (EUA) India's Union Ministry of Health has reserved 300 million doses of CORBEVAX™.

- Dynavax and Clover Biopharmaceuticals entered into a commercial supply agreement for the use of CpG 1018 adjuvant in the commercial production of Clover's COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum). In parallel, Clover announced an advanced purchase agreement with GAVI to supply up to 414 million doses of SCB-2019 (CpG 1018/Alum) through 2022 for the COVAX Facility.
- The Coalition for Epidemic Preparedness Innovations (CEPI) expanded its agreement with Dynavax to provide funding to manufacture CpG 1018 for CEPI's COVID-19 vaccine grantees, increasing total funding under the loan agreement from $99.0 million to $176.4 million to support Dynavax's manufacturing costs.
- Medigen Vaccine Biologics Corporation received EUA from the Taiwan Food and Drug Administration and received approval for inclusion in Taiwan's COVID-19 vaccination immunization program for MVC-COV1901, its COVID-19 vaccine adjuvanted with CpG 1018.
- Valneva SE reported positive initial results for Part A of the Phase 1/2 clinical trial of its COVID-19 vaccine candidate, VLA2001 adjuvanted with CpG 1018. Based on the positive results Valneva initiated a pivotal Phase 3 clinical trial, which is now fully enrolled. Valneva is also participating in a UK government-funded clinical trial looking at various COVID-19 'booster' vaccines.

Convertible Debt Offering

- In May 2020, we issued $225.5 million in aggregate principal amount of 2.50% convertible senior notes due 2026. As of June 30, 2021, the aggregate principal amount of our Convertible Notes was $225.5 million, excluding debt discount of $5.5 million.
- A portion of the net proceeds from the offering were used to pay off an existing $190.2 million term loan in full, including the termination payment. In connection with the offering, we also entered into capped call transactions with certain financial institutions that are expected generally to reduce the potential dilution to common stock in certain circumstances, upon conversion of the notes.
- This debt refinancing is expected to reduce interest expense by approximately $12.1 million on an annualized basis.

Upcoming Milestones

- CDC Advisory Committee on Immunization Practices expected to vote on a universal hepatitis b recommendation for all previously unvaccinated adults in October.
- Multiple data readouts from our CpG 1018 COVID-19 collaboration partners with potential for emergency or conditional use authorization by the end of 2021.
- Data from Tdap-1018 in the ongoing Phase 1 clinical trial, for an improved tetanus, diphtheria, and acellular pertussis booster vaccine candidate adjuvanted with CpG 1018 expected in first quarter 2022.

Financial Results

Total Revenue. Total revenues for the second quarter of 2021 were $52.8 million, including $52.7 million of net product revenue, an increase from total revenue for the second quarter of 2020 of $2.7 million.

Product Revenue, Net. HEPLISAV-B product revenue, net was $13.7 million in the second quarter of 2021 compared to $2.4 million in the same period in 2020. CpG 1018 product revenue, net was $39.0

million in the second quarter of 2021 and there was no revenue in the same period in 2020. As CpG 1018 revenues are generally recorded upon shipment to a customer, there may be fluctuations in revenues between quarters as shipments often consist of large-sized batches.

Cost of Sales - Product. Cost of sales - product for the second quarter 2021 increased to $14.8 million, compared to $1.0 million for the second quarter of 2020. The increase was primarily due to manufacturing costs for increased volumes of CpG 1018 and HEPLISAV-B sold to customers.

Research and Development Expenses (R&D). R&D expenses for the second quarter of 2021 increased to $7.2 million, compared to $5.9 million for the second quarter of 2020. The increase is primarily associated with higher headcount and outside services to support vaccine clinical and development activities.

Selling, General and Administrative Expenses (SG&A). SG&A expenses for the second quarter of 2021 increased to $21.6 million, compared to $19.0 million for the second quarter of 2020. This increase is primarily driven by compensation and related personnel costs, including non-cash stock-based compensation, associated with higher headcount.

Income (loss) from Operations and Net Income (loss). Income from operations for the second quarter of 2021 was $9.2 million compared to a loss from operations of $23.3 million in the second quarter of 2020. Net income for the second quarter of 2021 was $4.5 million compared to a net loss of $51.6 million for the second quarter of 2020.

Earnings per share. Basic and diluted net income per share were $0.04 and $0.02, respectively, for the second quarter of 2021, compared to basic and diluted net loss per share of ($0.53) and ($0.53), respectively, in the second quarter of 2020.

Cash Position. Cash, cash equivalents and marketable securities totaled $345.8 million at June 30, 2021.

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 9970706. 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.

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.

Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

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%).

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 immunization with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

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

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.

About CpG 1018 Adjuvant
CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 adjuvant provides a well- developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine.

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. and the European Union 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 adjuvant 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 and potential approval of vaccines containing CpG 1018 and potential future sales of CpG 1018 or HEPLISAV-B, the timing of initiation and completion of clinical studies and the publication of results, the timing of our collaborators seeking emergency use authorization of COVID-19 vaccines containing CpG 1018 adjuvant, our ability to scale manufacturing capacity, the expected demand for our products, our efforts to develop an improved pertussis vaccine and a seasonal flu vaccine, our collaboration partners' efforts to develop a vaccine for COVID-19 and a universal flu vaccine, entering into strategic relationships and expected results of such relationships, the potential for CpG 1018 to accelerate development and large scale manufacturing of a COVID-19 vaccine 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 and result of the ACIP vote on a universal hepatitis b recommendation, risks related to the timing of completion and results of current clinical studies, risks that our collaborators will not get approval of their vaccine candidates, 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, 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, 2020, 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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenues, net	$ 52,677	$ 2,405	$ 135,562	$ 12,919
Other revenue	90	263	540	668
Total revenues	**52,767**	**2,668**	**136,102**	**13,587**
Operating expenses:				
Cost of sales – product	14,845	967	39,470	3,321
Cost of sales - amortization of intangible assets	-	202	-	2,500
Research and development	7,167	5,884	14,925	10,537
Selling, general and administrative	21,583	18,954	44,006	39,880
Total operating expenses	**43,595**	**26,007**	**98,401**	**56,238**
Income (loss) from operations	9,172	(23,339)	37,701	(76,825)
Other income (expense):				
Interest income	48	331	95	921
Interest expense	(3,109)	(4,732)	(7,821)	(9,463)
Sublease income	1,670	1,927	3,692	3,853
Loss on debt extinguishment	(5,232)	-	(5,232)	-
Change in fair value of warrant liability	2,097	(25,655)	(23,455)	(17,045)
Other	(173)	(111)	384	211
Net income (loss)	**$ 4,473**	**$ (51,579)**	**$ 5,364**	**$ (64,174)**
Net income (loss) per share – basic	**$ 0.04**	**$ (0.53)**	**$ 0.04**	**$ (0.70)**
Weighted average shares used to compute basic net income (loss) per share	**114,629**	**97,339**	**113,339**	**91,408**
Net income (loss) per share – diluted	**$ 0.02**	**$ (0.53)**	**$ 0.04**	**$ (0.70)**
Weighted average shares used to compute diluted net income (loss) per share	**118,830**	**97,339**	**114,978**	**91,408**

DYNAVAX

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

	June 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 345,804	$ 165,036
Inventories, net	86,451	63,689
Property and equipment, net	32,547	30,567
Operating lease right-of-use assets	25,164	26,583
Goodwill	2,225	2,297
Other assets	155,718	65,100
Total assets	**$ 647,909**	**$ 353,272**
Liabilities and stockholders' equity		
Total current liabilities	$ 204,642	$ 77,411
Total long-term liabilities	359,887	217,168
Stockholders' equity	83,380	58,693
Total liabilities and stockholders' equity	**$ 647,909**	**$ 353,272**