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 04, 2022

Dynavax Technologies Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34207**	**33-0728374**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2100 Powell Street, Suite 720 **Emeryville, California** **(Address of Principal Executive Offices)**	**94608** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 510 848-5100

(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 Global Market

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, 2022, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended June 30, 2022. 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, 2022 titled "Dynavax Reports Second Quarter 2022 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 thereunto duly authorized.

Dynavax Technologies Corporation

Date: August 4, 2022

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

Dynavax Reports Second Quarter 2022 Financial Results

- *Q2 2022 total revenue of $256.5 million, up 386% from $52.8 million for Q2 2021*
  - ***HEPLISAV-B®** vaccine net product revenue of $32.7 million, up 139% from $13.7 million for Q2 2021*
  - ***CpG 1018®** adjuvant net product revenue of $222.6 million, up 471% from $39.0 million for Q2 2021*
- *On track for second consecutive year of profitability*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, CA – August 4, 2022 – Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today reported financial results and provided a business update for the quarter ending June 30, 2022.

"During the second quarter, we continued to successfully execute on our key priorities and are on track for another profitable year with record revenues for both HEPLISAV-B and CpG 1018 adjuvant," commented Ryan Spencer, Chief Executive Officer of Dynavax. "We are well capitalized to continue to invest in programs that drive revenue growth and deliver progress across our clinical pipeline with a focus on high value vaccine programs where our proven adjuvant may provide meaningful advantages."

SECOND-QUARTER CORPORATE HIGHLIGHTS

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

HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S. and EU that enables series completion with only two doses in one month.

- HEPLISAV-B vaccine achieved net product revenue of $32.7 million for the second quarter of 2022, up 139% compared to $13.7 million for the second quarter of 2021.
- Market share in the accounts targeted by the Dynavax field sales team increased to approximately 39%, with total market share increasing to approximately 32% in the second quarter of 2022, up from approximately 30% and 19% respectively, in the second quarter of 2021.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

Dynavax has established a global portfolio of CpG 1018 adjuvant commercial supply agreements (CSA) currently focused on the development of COVID-19 vaccines across a variety of vaccine platforms.

- CpG 1018 adjuvant revenue for the second quarter of 2022 was $222.6 million, up 471% compared to $39.0 million for the second quarter of 2021.
- The Company now expects 2022 full-year CpG 1018 adjuvant COVID-19 supply revenue to be between $550 million and $600 million, based on committed orders, with an anticipated full-year gross margin of approximately 60%.

Clinical Pipeline

Dynavax is advancing a pipeline of differentiated product candidates that leverage its CpG 1018 adjuvant, which has demonstrated its ability to enhance the immune response with a favorable tolerability profile in a wide range of clinical trials and real-world commercial use.

- **Tetanus, diphtheria and pertussis (Tdap) vaccine program:** Previously reported interim adult data from an on-going Phase 1 clinical trial evaluating the Company's adjuvanted Tdap vaccine candidate demonstrated it was well tolerated without safety concerns with immunogenicity data supporting continued advancement. The Company anticipates adolescent data from the same trial in the fourth quarter of 2022.

- **Shingles vaccine program:** The Company recently completed enrollment in the ongoing Phase 1 study evaluating the safety, tolerability, and immunogenicity in adults compared to Shingrix, the leading marketed shingles vaccine in the U.S. Topline data is anticipated in the fourth quarter of 2022.
- **Plague vaccine candidate:** The Company anticipates that in August the first participant will be dosed in a Phase 2 clinical trial evaluating the immunogenicity, safety and tolerability of a plague vaccine candidate utilizing CpG 1018 adjuvant. The clinical trial is being conducted in collaboration with, and funded by, the U.S. Department of Defense.

SECOND-QUARTER FINANCIAL HIGHLIGHTS

Total Revenues and Product Revenue, Net.
Total revenues for the second quarter of 2022 were $256.5 million, compared to $52.8 million for the second quarter of 2021.

- U.S. HEPLISAV-B vaccine product revenue, net was $32.7 million for the second quarter of 2022, compared to $13.7 million for the second quarter of 2021. Additionally, approximately $0.9 million was reported in HEPLISAV-B net product sales associated with sales to the Company's commercialization partner in Germany, Bavarian Nordic.
- CpG 1018 adjuvant product revenue, net was $222.6 million in the second quarter of 2022 compared to $39.0 million in the second quarter of 2021.
- Selected financial highlights from CpG 1018 adjuvant product supply partnerships for COVID-19 vaccines and vaccine candidates:
    - The Company recorded approximately $68.0 million in CpG 1018 adjuvant product revenue under its CSA with Valneva. Dynavax does not have any further supply obligations under the CSA.
    - The Company recorded approximately $51.0 million in CpG 1018 adjuvant product revenue under its CSA with Biological E.
    - The Company recorded approximately $91.3 million in CpG 1018 adjuvant product revenue under its CSA with Clover.
    - The Company recorded approximately $12.3 million in CpG 1018 adjuvant product revenue under its CSA with Bio Farma. In May 2022, Dynavax and Bio Farma entered into a CSA for the supply of CpG 1018 adjuvant to be used in Bio Farma's subunit COVID-19 vaccine candidate, currently in a Phase 3 immunogenicity and safety study.

Cost of Sales - Product. Cost of sales - product for the second quarter of 2022 increased to $83.4 million, compared to $14.8 million for the second quarter of 2021. The increase was primarily due to manufacturing costs for increased volumes of CpG 1018 adjuvant sold to COVID-19 supply partners and increased HEPLISAV-B vaccine sales volume.

Research and Development Expenses (R&D). R&D expenses for the second quarter of 2022 increased to $9.7 million, compared to $7.2 million for the second quarter of 2021. The increase was primarily driven by increased headcount-related compensation and personnel costs, including non-cash stock-based compensation, as well as investments in product candidates utilizing CpG 1018 adjuvant and additional discovery efforts.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the second quarter of 2022 increased to $36.2 million, compared to $21.6 million for the second quarter of 2021. The increase was primarily driven by compensation and related personnel costs, including non-cash stock-based compensation, primarily associated with increased headcount as the Company expanded its field sales team to support HEPLISAV-B vaccine commercialization in mid-2021.

Interest Expense. Interest expense was $1.7 million in the second quarter of 2022, a decrease of $1.4 million from $3.1 million in the second quarter of 2021, reflecting a decreased interest rate associated with the Company's convertible senior notes due 2026.

Net Income. GAAP net income was $128.8 million, or $1.02 per share (basic) and $0.87 per share (diluted) in the second quarter of 2022, compared to GAAP net income of $4.5 million, or $0.04 per share (basic) and $0.02 per share (diluted) in the second quarter of 2021.

Cash and Marketable Securities. Cash and marketable securities were $518.2 million as of June 30, 2022.

2022 Financial Guidance
Dynavax anticipates 2022 revenues, operating expenses, and other costs to be in the ranges shown below, updated from the Company's previous financial guidance provided on May 5, 2022:

- Full-year CpG 1018 adjuvant net product revenues of between $550 million and $600 million, with an associated gross margin anticipated to be approximately 60%
- Research and development expenses to be between approximately $50-$60 million
- Selling, general and administrative expenses to be between approximately $130-$140 million
- Interest expense of approximately $7 million

Conference Call and Webcast Information
Dynavax will host a conference call and live audio webcast on Thursday, August 4, 2022, 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 https://investors.dynavax.com/events-presentations. A replay of the webcast will be available for 30 days following the live event.

To dial into the call, participants will need to register for the call using the caller registration link. It is recommended that participants dial into the conference call or log into the webcast approximately 10 minutes prior to the call.

Important U.S. Product Information
HEPLISAV-B is indicated for the prevention of infection caused by all known subtypes of hepatitis B virus in adults aged 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 a 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 innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S. and the European Union for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018 adjuvant, currently used in multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, seasonal influenza, universal influenza, plague, shingles and Tdap. For more information about our marketed products and development pipeline, visit www.dynavax.com and follow Dynavax on LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding financial guidance, the development and potential approval of vaccines containing CpG 1018 adjuvant by us or by our collaborators, potential future sales of CpG 1018 adjuvant or HEPLISAV-B vaccine, the timing of initiation and completion of clinical studies and the publication of results. 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 actual demand for our products may differ from our expectations, risks related to the timing of completion and results of current clinical studies, risks related to the development and pre-clinical and clinical testing of vaccines containing CpG 1018 adjuvant, whether use of CpG 1018 adjuvant will prove to be beneficial in these vaccines, risks related to whether and when the quantity of CpG 1018 adjuvant actually purchased by vaccine companies will meet our expectations, as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, and 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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DYNAVAX

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

	Three Months Ended June 30,		Six Month Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product revenues, net	$ 255,320	$ 52,677	$ 367,647	$ 135,562
Other revenue	1,144	90	2,809	540
Total revenues	**256,464**	**52,767**	**370,456**	**136,202**
Operating expenses:				
Cost of sales – product	83,369	14,845	123,331	39,470
Research and development	9,689	7,167	20,784	14,925
Selling, general and administrative	36,179	21,583	68,351	44,006
Gain on sale of assets	(1,000)	-	(1,000)	-
Total operating expenses	**128,237**	**43,595**	**211,466**	**98,401**
Income from operations	128,227	9,172	158,990	37,701
Other income (expense):				
Interest income	765	48	1,026	95
Interest expense	(1,683)	(3,109)	(3,363)	(7,821)
Sublease income	2,025	1,670	3,634	3,692
Loss on debt extinguishment	-	(5,232)	-	(5,232)
Change in fair value of warrant liability	-	2,097	1,801	(23,455)
Other	40	(173)	145	384
Net income before provision for income taxes	129,374	4,473	162,233	5,364
Provision for income taxes	(619)	-	(619)	-
Net income	**$ 128,755**	**$ 4,473**	**$ 161,614**	**$ 5,364**
Net income per share attributable to common stockholders				
Basic	**$ 1.02**	**$ 0.04**	**$ 1.29**	**$ 0.04**
Diluted	**$ 0.87**	**$ 0.02**	**$ 1.08**	**$ 0.04**
Weighted-average shares used in computing net income per share attributable to common stockholders:				
Basic	**126,347**	**114,629**	**125,456**	**113,339**
Diluted	**149,905**	**118,830**	**149,821**	**114,978**

DYNAVAX

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

	June 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents, and marketable securities	$ 518,169	$ 545,950
Inventories, net	73,979	61,335
Property and equipment, net	36,286	35,020
Operating lease right-of-use assets	25,785	25,964
Goodwill	1,958	2,125
Other assets	366,822	368,852
Total assets	$ 1,022,999	$ 1,039,246
Liabilities and stockholders' equity		
Total current liabilities	$ 345,198	$ 556,402
Total long-term liabilities	255,002	260,470
Stockholders' equity	422,799	222,374
Total liabilities and stockholders' equity	$ 1,022,999	$ 1,039,246