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 03, 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 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 3, 2022, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended September 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 November 3, 2022 titled "Dynavax Reports Third 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: November 3, 2022

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

Dynavax Reports Third Quarter 2022 Financial Results

- *Q3 2022 total revenue of $167.7 million, up 55% from $108.3 million for Q3 2021*
  - ***HEPLISAV-B®** vaccine net product revenue of $37.5 million, up 65% from $22.7 million for Q3 2021*
  - ***CpG 1018®** adjuvant net product revenue of $126.3 million, up 50% from $84.3 million for Q3 2021*
- *Reiterates guidance for full-year CpG 1018 adjuvant net product revenues of between $550 million and $600 million*
- *On track for a second consecutive year of profitability*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, CA – November 3, 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 ended September 30, 2022.

"For the third quarter, we demonstrated another quarter of successful execution on our key priorities and remain on track for profitability with record revenues anticipated for both HEPLISAV-B and our CpG 1018 adjuvant in 2022," commented Ryan Spencer, Chief Executive Officer of Dynavax. "We believe we are well capitalized to invest in driving revenue growth for HEPLISAV-B and to deliver progress across our clinical pipeline, focusing on high value vaccine programs where our proven adjuvant may provide meaningful differentiation."

THIRD-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. Hepatitis B vaccination is universally recommended for adults aged 19-59 in the U.S.

- HEPLISAV-B vaccine achieved net product revenue of $37.5 million for the third quarter of 2022, up 65% compared to $22.7 million for the third quarter of 2021.
- Market share in the accounts targeted by the Dynavax field sales team increased to approximately 43%, with total market share increasing to approximately 32% in the third quarter of 2022, up from approximately 32% and 25%, respectively, in the third quarter of 2021.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

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

- CpG 1018 adjuvant revenue for the third quarter of 2022 was $126.3 million, up 50% compared to $84.3 million for the third quarter of 2021.
- The Company reiterates its expectation of 2022 full-year CpG 1018 adjuvant COVID-19 supply revenue to be between $550 million and $600 million, based on committed orders under our CSAs, 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:

- In October, the Company presented adult and adolescent safety data from the Phase 1 clinical trial demonstrating the Tdap vaccine candidate was well tolerated without safety concerns. Immunogenicity in adults was consistent with the Company's expectations and support its plan to continue advancement of this clinical program. These clinical results were presented at ID Week.

Shingles vaccine program:

- In August, enrollment was completed in the ongoing randomized Phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity in adults of the Company's shingles vaccine candidate adjuvanted with CpG 1018 compared to the leading marketed shingles vaccine in the U.S.
- Data from this clinical trial is anticipated before the end of 2022.

Plague vaccine candidate:

- In August, the first participant was dosed in the Phase 2 clinical trial evaluating the immunogenicity, safety and tolerability in adults of a plague (rF1V) vaccine candidate adjuvanted with CpG 1018. The clinical trial is being conducted in collaboration with, and funded by, the U.S. Department of Defense.

THIRD-QUARTER FINANCIAL HIGHLIGHTS

Total Revenues and Product Revenue, Net.
Total revenues for the third quarter of 2022 were $167.7 million, compared to $108.3 million for the third quarter of 2021.

- HEPLISAV-B vaccine product revenue, net was $37.5 million for the third quarter of 2022, compared to $22.7 million for the third quarter of 2021.
- CpG 1018 adjuvant product revenue, net was $126.3 million in the third quarter of 2022 compared to $84.3 million in the third quarter of 2021.
- Selected financial highlights from CpG 1018 adjuvant product supply partnerships for COVID-19 vaccines and vaccine candidates:
    - The Company recorded approximately $87.5 million in CpG 1018 adjuvant product revenue under its CSA with Clover.
    - The Company recorded approximately $27.6 million in CpG 1018 adjuvant product revenue under its CSA with Biological E.
    - The Company recorded approximately $11.2 million in CpG 1018 adjuvant product revenue under its CSA with Bio Farma.

Cost of Sales - Product. Cost of sales - product for the third quarter of 2022 increased to $61.3 million, compared to $60.1 million for the third quarter of 2021. The increase was due to manufacturing costs for increased volumes of CpG 1018 adjuvant sold to COVID-19 supply partners, an inventory write-down of $14.5 million related to the reduction in demand for CpG 1018 and increased HEPLISAV-B vaccine sales volume.

Research and Development Expenses (R&D). R&D expenses for the third quarter of 2022 increased to $13.0 million, compared to $6.2 million for the third 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 for TDAP, shingles and plague.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the third quarter of 2022 increased to $32.0 million, compared to $26.9 million for the third quarter of 2021. The increase was primarily driven by

compensation and related personnel costs, including non-cash stock-based compensation coupled with increased external commercial and marketing activities related to the universal recommendation for hepatitis B vaccination.

Net Income. GAAP net income was $63.8 million, or $0.50 per share (basic) and $0.43 per share (diluted) in the third quarter of 2022, compared to GAAP net loss of $28.4 million, or $0.24 per share (basic) and $0.24 per share (diluted) in the third quarter of 2021.

Cash and Marketable Securities. Cash and marketable securities were $586.5 million as of September 30, 2022.

2022 Financial Guidance
Dynavax anticipates 2022 revenues, operating expenses, and other costs to be in the ranges shown below, consistent with the Company's previous financial guidance provided on August 4, 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, November 3, 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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements. Forward-looking statements can generally be identified by the use of words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intend,” “will,” “may,” “plan,” “project,” “potential,” “seek,” “should,” “think,” “will,” “would” and similar expressions, or the negatives thereof, or they may use future dates . Forward-looking statements made in this document include 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 September 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, are qualified in their entirety by this cautionary statement 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product revenues, net	$ 163,815	$ 106,996	$ 531,462	$ 242,558
Other revenue	3,920	1,274	6,729	1,814
Total revenues	**167,735**	**108,270**	**538,191**	**244,372**
Operating expenses:				
Cost of sales – product	61,334	60,090	184,665	99,560
Research and development	12,962	6,186	33,746	21,111
Selling, general and administrative	32,042	26,926	100,393	70,932
Gain on sale of assets	-	(1,000)	(1,000)	(1,000)
Total operating expenses	**106,338**	**92,202**	**317,804**	**190,603**
Income from operations	61,397	16,068	220,387	53,769
Other income (expense):				
Interest income	2,562	39	3,588	134
Interest expense	(1,685)	(1,676)	(5,048)	(9,497)
Sublease income	2,026	2,022	5,660	5,714
Loss on debt extinguishment	-	-	-	(5,232)
Change in fair value of warrant liability	-	(45,121)	1,801	(68,576)
Other	(208)	238	(63)	622
Net income (loss) before income taxes	64,092	(28,430)	226,325	(23,066)
Provision for income taxes	(283)	-	(902)	-
Net income (loss)	**$ 63,809**	**$ (28,430)**	**$ 225,423**	**$ (23,066)**
Net income (loss) per share attributable to common stockholders:				
Basic	**$ 0.50**	**$ (0.24)**	**$ 1.79**	**$ (0.20)**
Diluted	**$ 0.43**	**$ (0.24)**	**$ 1.51**	**$ (0.20)**
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	**127,062**	**116,903**	**125,997**	**114,540**
Diluted	**151,538**	**116,903**	**150,433**	**114,540**

DYNAVAX

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

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 586,486	$ 545,950
Inventories, net	102,609	61,335
Property and equipment, net	35,352	35,020
Operating lease right-of-use assets	25,680	25,964
Goodwill	1,835	2,125
Other assets	247,375	368,852
Total assets	**$ 999,337**	**$ 1,039,246**
Liabilities and stockholders' equity		
Total current liabilities	$ 244,080	$ 556,402
Total long-term liabilities	254,681	260,470
Stockholders' equity	500,576	222,374
Total liabilities and stockholders' equity	**$ 999,337**	**$ 1,039,246**