

**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 7, 2024

Dynavax Technologies Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-34207
(Commission File Number)

33-0728374
(IRS Employer
Identification No.)

2100 Powell Street, Suite 720

Emeryville, CA
(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	Nasdaq Global Select Market
Preferred Share Purchase Rights	N/A	Nasdaq Global Select 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 November 7, 2024, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the quarter ended September 30, 2024. 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 7, 2024 titled "Dynavax Reports Third Quarter 2024 Financial Results and Provides Business Updates." |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |
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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 7, 2024

By: /s/ Kelly MacDonald

Kelly MacDonald
Senior Vice President, CFO

Dynavax Reports Third Quarter 2024 Financial Results and Provides Business Updates

- *HEPLISAV-B® quarterly net product revenue of \$79.3 million, representing 27% year-over-year growth*
- *Hepatitis B adult vaccine market expected to expand to a peak of over \$900 million by 2030, with HEPLISAV-B expected to achieve at least 60% estimated total market share*
- *Expect positive net income in 2024, achieving full year profitability*
- *Strengthened cash position to \$764 million in Q3'24*
- *\$200 million share repurchase program announced as part of balanced capital allocation strategy*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, CA – November 7, 2024 – 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, 2024.

“We are confident that the continued top-line growth of HEPLISAV-B sets the foundation for durable, long-term value creation. We believe our commercial execution to date, overall financial position, and our commitment to achieving profitability, afford us the capacity to return cash to shareholders through the share repurchase program announced today. We will continue to execute on our strategic growth pillars focused on maximizing the HEPLISAV-B opportunity, delivering on our clinical pipeline, and pursuing external opportunities to drive sustainable value for our shareholders,” said Ryan Spencer, Chief Executive Officer of Dynavax.

“Additionally, we have decided to discontinue development of our Tdap-1018 program based on results from the Phase 1 extension study. The program showed improved immunogenicity driven by CpG 1018, however, we do not believe the data support sufficient differentiation to be successful commercially. This decision aligns with our commitment to prudent management of resources aimed at generating long-term value.”

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

HEPLISAV-B vaccine is the first and only adult hepatitis B vaccine approved in the U.S., the European Union and Great Britain 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 achieved record quarterly net product revenue of \$79.3 million for the third quarter of 2024, an increase of 27% compared to \$62.3 million for the third quarter of 2023.*
- *HEPLISAV-B total estimated market share in the U.S. increased to approximately 44%, compared to approximately 41% for the third quarter 2023.*
- *HEPLISAV-B estimated market share in the retail pharmacy segment increased to approximately 55%, compared to approximately 53% for the third quarter of 2023. HEPLISAV-B estimated market share in the Integrated Delivery Networks (IDNs) and Large Clinics segment was approximately 56%, compared to approximately 54% for the third quarter of 2023.*
- *Dynavax now expects the hepatitis B adult vaccine market in the U.S. to expand to a peak of over \$900 million in annual sales by 2030, with HEPLISAV-B expected to achieve at least 60% total market share. Additionally, Dynavax believes the HEPLISAV-B U.S. market opportunity will remain substantial beyond 2030 due to the ongoing penetration of the unvaccinated eligible adult population, observed revaccination practices by healthcare providers, and continued gains in market share.*

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.

HEPLISAV-B Regulatory Updates

- In the third quarter, the U.S. Food and Drug Administration (FDA) approved the Company's supplemental Biologics License Application (sBLA) to include pregnancy information from HBV-28, a post-licensure observational retrospective cohort study, in the U.S. label for HEPLISAV-B. The HBV-28 study showed no increased risk of major birth defects or miscarriage in women who received HEPLISAV-B compared to an active comparator.
- Regarding the Complete Response Letter issued for the sBLA to include a four-dose HEPLISAV-B vaccine regimen for adults on hemodialysis on the U.S. label, Dynavax recently received feedback from the FDA regarding the potential to conduct an observational retrospective cohort study to support the sBLA filing.

Shingles vaccine program:

Z-1018 is an investigational vaccine candidate being developed for the prevention of shingles in adults aged 50 years and older.

- Dynavax is currently conducting a randomized, active-controlled, dose escalation, multicenter Phase 1/2 trial to evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix[®] in approximately 440 healthy adults aged 50 to 69. Dynavax anticipates reporting top line immunogenicity and safety data in the second half of 2025, including a comparison of CD4+ T-cells.

Plague vaccine program:

Dynavax is developing a plague (rF1V) vaccine candidate adjuvanted with CpG 1018[®] currently in a Phase 2 clinical trial in collaboration with, and fully funded by, the U.S. Department of Defense (DoD).

- Based on the results from a randomized, active-controlled Phase 2 clinical trial of the two-dose plague vaccine adjuvanted with CpG 1018, Dynavax has submitted a proposal to the DoD regarding additional clinical and manufacturing activities.

Tdap vaccine program:

Tdap-1018 was an investigational vaccine candidate intended for active booster immunization against tetanus, diphtheria, and pertussis (Tdap).

- Dynavax announced today that it has decided to discontinue development of its Tdap-1018 program based on results from a long-term Phase 1 extension study that did not demonstrate a differentiated profile that the Company believes would be successful commercially.

THIRD QUARTER 2024 FINANCIAL HIGHLIGHTS

Total Revenues and Net Product Revenue.

- Total revenues for the third quarter of 2024 were \$80.6 million, a 16% year-over-year increase compared to \$69.5 million for the third quarter of 2023.
- HEPLISAV-B net product revenue was \$79.3 million for the third quarter of 2024, a 27% year-over-year increase compared to \$62.3 million for the third quarter of 2023.

- Other revenue was \$1.3 million for the third quarter of 2024, an 82% decrease compared to \$7.2 million for the third quarter of 2023. Other revenue primarily includes revenue from the plague vaccine agreement with the U.S. Department of Defense.

Cost of Sales - Product. Cost of sales - product for HEPLISAV-B in the third quarter of 2024 decreased to \$13.1 million, compared to \$13.2 million for the third quarter of 2023. The decrease was primarily due to lower per-unit manufacturing costs as a result of previous process improvements, partially offset by higher sales volumes.

Research and Development Expenses (R&D). R&D expenses for the third quarter of 2024 increased to \$14.4 million, compared to \$14.1 million for the third quarter of 2023. The increase was primarily driven by costs related to the ongoing Phase 1/2 clinical trial for the shingles program, partially offset by the completion of clinical trial activities for the Tdap and plague programs.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the third quarter of 2024 increased to \$43.1 million, compared to \$38.1 million for the third quarter of 2023. The increase was primarily driven by increased headcount and other investments to support HEPLISAV-B and pipeline growth.

Net Income. Net income was \$17.6 million, or \$0.13 per share basic and \$0.12 diluted in the third quarter of 2024, compared to net income of \$14.3 million, or \$0.11 per share basic and \$0.10 diluted in the third quarter of 2023.

Cash and Marketable Securities. Cash, cash equivalents and marketable securities were \$764.0 million as of September 30, 2024, an increase compared to \$742.3 million as of December 31, 2023.

Full Year 2024 FINANCIAL GUIDANCE

Dynavax is updating its full year 2024 financial guidance, based on the Company's current operating plan:

- Narrowing HEPLISAV-B net product revenue range from approximately \$265 to \$280 million, to approximately \$265 to \$270 million
- Reiterating HEPLISAV-B gross margin of approximately 80%
- Reducing and narrowing research and development expense range from approximately \$60 to \$75 million, to approximately \$55 to \$65 million
- Narrowing selling, general and administrative expense range from approximately \$160 to \$180 million, to approximately \$170 to \$180 million
- Expect positive net income for full-year 2024

Conference Call and Webcast Information

Dynavax will host a conference call and live audio webcast on Thursday, November 7, 2024, 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 at <https://investors.dynavax.com/events-presentations> and under the "Upcoming Events" section, click on "Listen to webcast". It is recommended that participants dial into the conference call or log into the webcast approximately 10 minutes prior to the call.

WHAT IS HEPLISAV-B?

HEPLISAV-B is a shot given to adults 18 years of age and older to help prevent infection caused by the hepatitis B virus.

HEPLISAV-B is usually given in the arm muscle. HEPLISAV-B is given in 2 doses, 1 month apart, by a healthcare provider.

IMPORTANT SAFETY INFORMATION

If you have a history of severe allergic reaction after a previous dose of any hepatitis B vaccine, or to any ingredient of HEPLISAV-B, including yeast, do not take HEPLISAV-B.

HEPLISAV-B must be given by a medical professional, who will monitor you afterwards, to check for allergic reaction.

If you are immunocompromised, or receiving immunosuppressant therapy, you may have less of an immune response to HEPLISAV-B.

Some people have hepatitis B infection without being aware of it or showing any symptoms. If you already have hepatitis B present in your body, HEPLISAV-B may not prevent hepatitis B infection.

The most common side effects include pain at the injection site, tiredness, and headache.

HEPLISAV-B was not studied in pregnant or nursing women. Tell your provider if you are pregnant or plan to become pregnant or are breast feeding.

Vaccination with HEPLISAV-B may not protect all individuals.

Talk to your healthcare provider to determine if HEPLISAV-B is right for you.

For full U.S. Prescribing Information for HEPLISAV-B, please visit the following website at <https://www.heplisavbhcp.com>, and click the "Prescribing Information" link in the "Important Safety Information" section.

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., the European Union and Great Britain 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 HEPLISAV-B and multiple adjuvanted COVID-19 vaccines. For more information about our marketed products and development pipeline, visit www.dynavax.com.

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," "toward," "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 our expected financial results for the year ended December 31, 2024, expectations regarding our future growth, extent and timing of market growth and market share beyond 2030, the timing of IND filings, initiation and completion of clinical studies, expected timing for data readouts, and interaction with regulators. 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 relating to our ability to commercialize and supply HEPLISAV-B, 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, as well as other risks detailed in the "Risk



Factors" section of our Quarterly Report on Form 10-Q for the three months ended September 30, 2024 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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DYNNAVAX TECHNOLOGIES CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	\$ 79,345	\$ 62,318	\$ 197,377	\$ 162,209
Other revenue	1,285	7,196	7,837	14,479
Total revenues	80,630	69,514	205,214	176,688
Operating expenses:				
Cost of sales - product	13,084	13,229	36,035	41,478
Research and development	14,403	14,116	42,881	40,767
Selling, general and administrative	43,061	38,053	128,788	111,667
Gain on sale of assets	—	(1,000)	—	(1,000)
Bad debt expense	—	—	—	12,313
Total operating expenses	70,548	64,398	207,704	205,225
Income (loss) from operations	10,082	5,116	(2,490)	(28,537)
Other income (expense):				
Interest income	9,382	8,462	28,050	22,437
Interest expense	(1,699)	(1,691)	(5,090)	(5,065)
Sublease income	2,205	1,993	2,808	5,584
Other	(152)	266	(52)	218
Net income (loss) before income taxes	19,818	14,146	23,226	(5,363)
(Provision for) benefit from income taxes	(2,224)	147	(2,967)	(1,245)
Net income (loss)	\$ 17,594	\$ 14,293	\$ 20,259	\$ (6,608)
Net income (loss) per share attributable to common stockholders				
Basic	\$ 0.13	\$ 0.11	\$ 0.15	\$ (0.05)
Diluted	\$ 0.12	\$ 0.10	\$ 0.15	\$ (0.05)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	131,133	128,988	130,746	128,515
Diluted	154,807	154,196	133,644	128,515

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

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	\$ 763,992	\$ 742,302
Inventories	62,402	53,290
Other current assets	99,847	63,528
Total current assets	926,241	859,120
Total non-current assets	135,749	137,976
Total assets	\$ 1,061,990	\$ 997,096
Liabilities and stockholders' equity		
Total current liabilities	70,030	62,195
Total long-term liabilities	310,533	312,829
Stockholders' equity	681,427	622,072
Total liabilities and stockholders' equity	\$ 1,061,990	\$ 997,096