

DYNAVAX

Dynavax Reports Second Quarter 2024 Financial Results and Provides Business Updates

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- Achieved record quarterly HEPLISAV-B® net product revenue of \$70.2 million, growing 24% year-over-year
- Reaffirming full year 2024 HEPLISAV-B net product revenue guidance of \$265 - \$280 million
- Initiated dosing in Phase 1/2 trial of novel shingles vaccine program with clinical data expected in 2H 2025
- Conference call today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., Aug. 6, 2024 /PRNewswire/ -- [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 June 30, 2024.



"We continue to strengthen our leadership position in the U.S. adult hepatitis B vaccine market with another record quarter for HEPLISAV-B, providing confidence in our current year expectations and reaffirming our long-term view of the product opportunity. We are highly optimistic about the adult hepatitis B vaccine market of over 130 million eligible patients, which is one of the largest addressable patient populations for vaccines in the U.S. We expect the market opportunity for HEPLISAV-B to grow to over \$800 million by 2027, and continue expanding through the end of the decade. The expected growth in the market opportunity, combined with our expectations to continue to increase market share, provides a substantial, long-term revenue opportunity for HEPLISAV-B," said Ryan Spencer, Chief Executive Officer of Dynavax.

"For our pipeline development, we are pleased to have recently initiated our Phase 1/2 trial for our novel shingles vaccine program, and remain excited for several upcoming milestones, including data readouts from the shingles study as well as our Tdap and plague vaccine programs expected across 2024 and 2025. In addition to this progress, and bolstered by our strong financial position, we continue to evaluate strategic opportunities to accelerate growth, further diversify our portfolio, and deliver value to our shareholders."

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 vaccine achieved record quarterly net product revenue of \$70.2 million for the second quarter of 2024, an increase of 24% compared to \$56.4 million for the second quarter of 2023.
- HEPLISAV-B total estimated market share in the U.S. increased to approximately 42%, compared to approximately 39% for the second quarter 2023.
- HEPLISAV-B estimated market share in the retail pharmacy segment increased to approximately 59%, compared to approximately 45% for the second quarter of 2023. HEPLISAV-B estimated market share in the Integrated Delivery Networks (IDNs) and Large Clinics segment increased to approximately 56%, compared to approximately 53% for the second quarter 2023.
- Dynavax expects the HEPLISAV-B market opportunity in the U.S. to expand to over \$800 million by 2027, with growth expected to continue to a peak market opportunity by 2030. Dynavax also expects HEPLISAV-B to achieve a majority share of the total U.S. market by 2027, with share gains continuing post-peak market. Additionally, Dynavax expects the HEPLISAV-B market opportunity to remain substantial beyond 2030 due to the ongoing penetration of the unvaccinated adult cohort.

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 for Adults on Hemodialysis

Dynavax is developing a four-dose HEPLISAV-B® vaccine regimen for adults on hemodialysis.

- In May 2024, Dynavax announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) in response to the Company's supplemental Biologics License Application (sBLA) to include a four-dose HEPLISAV-B® vaccine regimen for adults on hemodialysis on the U.S. label.
- The Company intends to meet with the FDA in the second half of 2024, as part of the standard post-CRL regulatory process, to discuss pathways to amend its sBLA with additional data to support the four-dose regimen for the adult hemodialysis population in the U.S.

Shingles vaccine program:

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

- In June 2024, Dynavax announced the initiation of 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 one month after the second of two vaccine doses.

Tdap vaccine program:

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

- Dynavax plans to evaluate the persistence of pertussis immunogenicity of Tdap-1018 through a long-term follow-up study of participants that completed a Phase 1 trial of a booster dose of Tdap-1018 compared to an active control. The extension study is expected to follow participants for up to three years following initial vaccination. Results from the Phase 1 extension study are expected in the fourth quarter of 2024.

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.

- Dynavax anticipates providing a program update, based on results from both a randomized, active-controlled Phase 2 clinical trial and a nonhuman primate challenge study of the plague vaccine candidate, in the fourth quarter of 2024.

SECOND QUARTER 2024 FINANCIAL HIGHLIGHTS**Total Revenues and Net Product Revenue.**

- Total revenues for the second quarter of 2024 were \$73.8 million, a 22% year-over-year increase compared to \$60.2 million for the second quarter of 2023.
- HEPLISAV-B net product revenue was \$70.2 million for the second quarter of 2024, a 24% year-over-year increase compared to \$56.4 million for the second quarter of 2023.
- Other revenue was \$3.6 million for the second quarter of 2024, a 5% decrease compared to \$3.8 million for the second 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 second quarter of 2024 decreased to \$12.0 million, compared to \$13.5 million for the second quarter of 2023. The decrease was primarily due to lower per-unit manufacturing costs as the result of previous process improvements.

Research and Development Expenses (R&D). R&D expenses for the second quarter of 2024 increased to \$15.0 million, compared to \$13.0 million for the second quarter of 2023. The increase was primarily driven by investments in our discovery, preclinical and clinical pipeline efforts.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the second quarter of 2024 increased to \$41.7 million, compared to \$37.1 million for the second quarter of 2023. The increase was primarily driven by increased headcount and other investments supporting our strategic growth.

Net Income. Net income was \$11.4 million, or \$0.09 per share basic and \$0.08 diluted in the second quarter of 2024, compared to net income of \$3.4 million, or \$0.03 per share (basic and diluted) in the second quarter of 2023.

Cash and Marketable Securities. Cash, cash equivalents and marketable securities were \$735.6 million as of June 30, 2024, compared to \$742.3 million as of December 31, 2023.

2024 FINANCIAL GUIDANCE

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

- HEPLISAV-B net product revenue between approximately \$265 - \$280 million, including approximately \$3 million in ex-U.S. sales through commercialization partnership in Germany
- HEPLISAV-B gross margin of approximately 80%
- Research and development expenses between approximately \$60 - \$75 million
- Selling, general and administrative expenses between approximately \$160 - \$180 million
- Cash, cash equivalents and marketable securities to be higher as of December 31, 2024, compared to December 31, 2023

Conference Call and Webcast Information

Dynavax will host a conference call and live audio webcast on Tuesday, August 6, 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](#). 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., 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. Dynavax is advancing CpG 1018 as a premier vaccine adjuvant used in clinical programs for shingles and Tdap, and in global collaborations currently focused on adjuvanted vaccines for COVID-19, plague, seasonal influenza and universal influenza. 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 and market share as of and for the year ended December 31, 2024, expectations regarding our future growth, extent and timing of market growth and market share beyond 2024, 2027 and 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 June 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.

For Investors/Media:

Paul Cox
pcox@dynavax.com
510-665-0499

Nicole Arndt
narndt@dynavax.com
510-665-7264

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	\$ 70,188	\$ 56,440	\$ 118,032	\$ 99,891
Other revenue	3,607	3,809	6,552	7,283
Total revenues	73,795	60,249	124,584	107,174

Operating expenses:				
Cost of sales – product	11,985	13,537	22,952	28,249
Research and development	14,950	13,046	28,478	26,651
Selling, general and administrative	41,662	37,071	85,727	73,614
Bad debt expense	-	-	-	12,313
Total operating expenses	68,597	63,654	137,157	140,827
Income (loss) from operations	5,198	(3,405)	(12,573)	(33,653)
Other income (expense):				
Interest income	9,201	7,378	18,668	13,975
Interest expense	(1,698)	(1,688)	(3,393)	(3,374)
Sublease income	2,205	1,993	603	3,591
Other	-	(71)	103	(48)
Net income (loss) before income taxes	14,906	4,207	3,408	(19,509)
Provision for income taxes	(3,520)	(776)	(743)	(1,392)
Net income (loss)	\$ 11,386	\$ 3,431	\$ 2,665	\$ (20,901)
Net income (loss) per share attributable to common stockholders:				
Basic	<u>\$ 0.09</u>	<u>\$ 0.03</u>	<u>\$ 0.02</u>	<u>\$ (0.16)</u>
Diluted	<u>\$ 0.08</u>	<u>\$ 0.03</u>	<u>\$ 0.02</u>	<u>\$ (0.16)</u>
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	<u>130,916</u>	<u>128,625</u>	<u>130,551</u>	<u>128,275</u>
Diluted	<u>154,468</u>	<u>152,142</u>	<u>133,582</u>	<u>128,275</u>

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

	<u>June 30,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 735,612	\$ 742,302
Inventories	62,462	53,290
Other current assets	83,938	63,528
Total current assets	882,012	859,120
Total non-current assets	134,309	137,976
Total assets	\$ 1,016,321	\$ 997,096
Liabilities and stockholders' equity		
Total current liabilities	\$ 62,192	\$ 62,195
Total long-term liabilities	311,280	312,829
Stockholders' equity	642,849	622,072
Total liabilities and stockholders' equity	\$ 1,016,321	\$ 997,096

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