Dynavax Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Full Year 2024 Financial Guidance

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- *HEPLISAV-B® 2023 net product revenue grew 69% year-over-year to $213 million*
- *Achieved market leader status in key segments retail pharmacy and IDNs in 2023*
- *2024 HEPLISAV-B net product revenue expected to be $265 - $280 million*
- *Cash position increased to $742 million at year end and expect to be cash flow positive for full year 2024*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, Calif., Feb. 22, 2024 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today reported financial results for the fourth quarter and full year ended December 31, 2023.

"2023 was characterized by record revenue growth for HEPLISAV-B, and the achievement of becoming the market share leader in the two largest growth segments, demonstrating important progress toward our goal of establishing HEPLISAV-B as the leading vaccine in the U.S. adult hepatitis B vaccine market," said Ryan Spencer, Chief Executive Officer of Dynavax. "We expect 2024 to be an important year in building a vaccine portfolio of best-in-class products, including further growing the HEPLISAV-B brand as well as advancing our pipeline programs into clinical trial initiations and data readouts. Importantly, our strong financial position provides us with the optionality to continue to build value across our business, including through investing to drive the HEPLISAV-B market opportunity, advancing and expanding our R&D efforts, and pursuing strategic opportunities to accelerate our growth."

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 net product revenue for the fourth quarter and full year 2023 were approximately $51.1 million and $213.3 million, respectively, representing year-over-year growth of approximately 46% and 69% compared to the fourth quarter and full year 2022.
- HEPLISAV-B total market share in the U.S. increased to approximately 42% at the end of 2023, compared to approximately 35% at the end of 2022.
- HEPLISAV-B market share in the retail pharmacy segment increased to approximately 58% at the end of 2023, compared to approximately 42% at the end of 2022. HEPLISAV-B market share in the Integrated Delivery Networks (IDNs) and Large Clinics segment increased to approximately 56% at the end of 2023, compared to approximately 47% at the end of 2022.
- A supplemental Biologic License Application (sBLA) for HEPLISAV-B vaccination of adults on hemodialysis is currently under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) action date planned for May 13, 2024.
- Driven by the Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP) universal recommendation for adult hepatitis B vaccination, the hepatitis B vaccine market continues to expand in the U.S. and Dynavax believes the U.S. market has the potential to grow to approximately $800 million by 2027, with HEPLISAV-B well-positioned to achieve a majority 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.

Shingles vaccine program:

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

- Dynavax recently submitted an Investigational New Drug Application (IND) to the U.S. FDA to support initiation of a Phase 1/2 trial of Z-1018 in the first half of 2024.

Tdap vaccine program:

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

- Dynavax plans to submit an IND to the U.S. FDA to support the initiation of a Phase 2 human challenge study of Tdap-1018 in the second half of 2024, upon completion of the independent study conducted by the Canadian Center for Vaccinology to establish the human challenge dose.

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 top line data for the randomized, active-controlled Phase 2 clinical trial evaluating immunogenicity, safety, and tolerability of the plague vaccine candidate in 2024.

FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL HIGHLIGHTS

Total Revenues and Net Product Revenue.

- HEPLISAV-B vaccine net product revenue was $51.1 million for the fourth quarter of 2023, compared to $34.9 million for the fourth quarter of 2022, and $213.3 million for the full year 2023, compared to $125.9 million for the full year 2022.
- Other revenue was $4.5 million for the fourth quarter of 2023, compared to $2.3 million for the fourth quarter of 2022, and $19.0 million for the full year 2023, compared to $9.0 million for the full year 2022. Other revenue primarily includes revenue from the plague vaccine agreement with the U.S. Department of Defense. The increase was primarily driven by the advancement into a nonhuman primate challenge study.
- No CpG 1018 adjuvant product revenue was recorded in the fourth quarter and full year 2023, compared to $147.2 million and $587.7 million in the same periods of 2022, respectively, due to completion of all obligations and product delivery under the Company's CpG 1018 adjuvant COVID-19 collaboration agreements as of the end of 2022.
- Total revenues for the fourth quarter of 2023 were $55.6 million, compared to $184.5 million for the fourth quarter of 2022, and $232.3 million for the full year 2023, compared to $722.7 million for the full year 2022.

Cost of Sales - Product. Cost of sales - product for HEPLISAV-B the fourth quarter of 2023 decreased to $8.7 million, compared to $12.4 million for the fourth quarter of 2022, and $50.2 million for the full year 2023, compared to $40.1 million for the full year 2022.

Research and Development Expenses (R&D). R&D expenses for the fourth quarter of 2023 increased to $14.1 million, compared to $12.9 million for the fourth quarter of 2022, and $54.9 million for the full year 2023, compared to $46.6 million for the full year 2022. The increase was primarily driven by continued investments in advancing our clinical and preclinical development programs and collaborations.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the fourth quarter of 2023 increased to $41.3 million, compared to $31.0 million for the fourth quarter of 2022, and $152.9 million for the full year 2023, compared to $131.4 million for the full year 2022. The increase was primarily driven by higher compensation and related personnel costs and an overall increase in targeted commercial and marketing efforts designed to increase HEPLISAV-B market share and maximize the opportunities presented by the ACIP's universal recommendation.

Net Income. GAAP net income was $0.2 million, or less than $0.01 per share (basic and diluted) in the fourth quarter of 2023, compared to GAAP net income of $67.7 million, or $0.53 per share (basic) and $0.45 per share (diluted) in the fourth quarter of 2022. GAAP net loss was $6.4 million, or $0.05 per share (basic and diluted) for the full year 2023, compared to GAAP net income of $293.2 million, or $2.32 per share (basic) and $1.97 per share (diluted) for the full year 2022.

Cash and Marketable Securities. Cash, cash equivalents and marketable securities were $742.3 million as of December 31, 2023.

2024 FINANCIAL GUIDANCE

Dynavax is providing the following 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 agreement with Bavarian Nordic in Germany
- HEPLISAV-B gross margin of approximately 80% for full year 2024
- Research and development expenses between approximately $60 - $75 million
- Selling, general and administrative expenses between approximately $160 - $180 million
- Expect to be cash flow positive for full year ended December 31, 2024

Conference Call and Webcast Information

Dynavax will host a conference call and live audio webcast on Thursday, February 22, 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 adjuvant as a premier vaccine adjuvant with adjuvanted vaccine clinical programs for shingles and Tdap, and through 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 and quarter ended December 31, 2024, expectations regarding future growth and market share, and the timing of IND filings, initiation and completion of clinical studies, the publication of results, 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 Annual Report on Form 10-K for the year ended December 31, 2023 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 TECHNOLOGIES CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
HEPLISAV-B product revenue, net	$ 51,086	$ 34,939	$ 213,295	$ 125,937
CpG 1018 adjuvant product revenue, net	-	147,244	-	587,708
Other revenue	4,510	2,309	18,989	9,038
Total revenues	**55,596**	**184,492**	**232,284**	**722,683**
Operating expenses:				

HEPLISAV-B cost of sales – product	8,689	12,391	50,167	40,131
CpG 1018 cost of sales – product	-	65,097	-	222,022
Research and development	14,119	12,854	54,886	46,600
Selling, general and administrative	41,279	31,015	152,946	131,408
Gain on sale of assets	-	-	(1,000)	(1,000)
Bad debt expense	-	-	12,313	-
Total operating expenses	**64,087**	**121,357**	**269,312**	**439,161**
(Loss) income from operations	(8,491)	63,135	(37,028)	283,522
Other income (expense):				
Interest income	9,556	4,324	31,993	7,912
Interest expense	(1,692)	(1,684)	(6,757)	(6,732)
Sublease income	1,993	2,025	7,577	7,685
Change in fair value of warrant liability	-	-	-	1,801
Other	(370)	174	(152)	111
Net income (loss) before income taxes	996	67,974	(4,367)	294,299
Provision for income taxes	(777)	(241)	(2,022)	(1,143)
Net income (loss)	**$ 219**	**$ 67,733**	**$ (6,389)**	**$ 293,156**
Net income (loss) per share attributable to common stockholders:				
Basic (*)	**$ 0.00**	**$ 0.53**	**$ (0.05)**	**$ 2.32**
Diluted (*)	**$ 0.00**	**$ 0.45**	**$ (0.05)**	**$ 1.97**
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	**129,381**	**127,589**	**128,733**	**126,398**
Diluted	**133,278**	**151,728**	**128,733**	**150,797**

(*) GAAP net income per share (basic and diluted) was less than $0.01 for the fourth quarter of 2023.

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

	December 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 742,302	$ 624,395
Inventories	53,290	59,446
Other current assets	63,528	233,144
Total current assets	**859,120**	**916,985**
Total non-current assets	137,976	68,865
Total assets	**$ 997,096**	**$ 985,850**
Liabilities and stockholders' equity		
Total current liabilities	$ 62,195	$ 150,074
Total long-term liabilities	312,829	254,763
Stockholders' equity	622,072	581,013
Total liabilities and stockholders' equity	**$ 997,096**	**$ 985,850**

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