Dynavax Reports First Quarter 2023 Financial Results

May 2, 2023

- *HEPLISAV-B® vaccine net product revenue increased 109% year-over-year to $43.5 million in the first quarter of 2023*
- *Reaffirming HEPLISAV-B net product revenue guidance for full year 2023 of between $165–$185 million, representing annual revenue growth of 30-47%*
- *Strengthened balance sheet with cash and investments of $652 million at quarter end and expects positive free cash flow in 2023*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, Calif., May 2, 2023 /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 March 31, 2023.

"We are excited to once again post record quarterly net product revenue for HEPLISAV-B, which exceeded our expectations. We are encouraged by the continued expansion of the total hepatitis B vaccination market, along with the continued market share gains of HEPLISAV-B, driven in part from the expanded ACIP recommendation for adult hepatitis B vaccination," said Ryan Spencer, Chief Executive Officer of Dynavax. "We expect these tailwinds driving HEPLISAV-B growth to further improve this year, while we also advance our clinical pipeline and continue to evaluate strategic opportunities to accelerate growth through disciplined use of our strong capital position."

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 net product revenue of $43.5 million for the first quarter of 2023, an increase of 109% compared to $20.8 million for the first quarter of 2022.
- HEPLISAV-B total market share increased to approximately 37%, compared to approximately 26% at the end of the first quarter of 2022.
- HEPLISAV-B market share in Integrated Delivery Networks (IDNs) and Clinics increased to approximately 49%, compared to approximately 33% at the end of the first quarter of 2022.
- HEPLISAV-B market share in the retail segment grew to 49% at the end of the first quarter of 2023, up from 28% at end of the first quarter of 2022.
- Dynavax continues to see a positive impact on HEPLISAV-B revenue from the Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP) universal recommendation for adult hepatitis B vaccination, which we believe has the potential to expand the market to over $800 million by 2027 with HEPLISAV-B well-positioned to achieve a majority market-share.
- In February, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) granted Marketing Authorization in Great Britain for HEPLISAV-B.
- In April, Dynavax submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for HEPLISAV-B vaccination of adults on hemodialysis.

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:

- The Company has completed a Phase 1 clinical trial evaluating its Tdap vaccine candidate adjuvanted with CpG 1018. Adult and adolescent safety data from the trial demonstrated that the Tdap vaccine candidate was well tolerated without observed safety concerns. Immunogenicity results in adults were 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 2022.
- Data from a non-human primate challenge study is anticipated in mid-2023.
- The Company plans to initiate a human challenge study by the end of 2023.

Shingles vaccine program:

- In January 2023, the Company reported top line results from the Phase 1 clinical trial designed to evaluate an investigational shingles vaccine, Z-1018, utilizing different regimens of CpG 1018 adjuvant.
- An abstract featuring Phase 1 data results has been accepted for oral presentation at the National Foundation for Infectious Diseases' online 2023 Annual Conference on Vaccinology Research on June 6, 2023.
- Based on these initial data, the Company plans to initiate a Phase 1/2 study in early 2024 to evaluate various dose levels of glycoprotein E (gE) plus CpG 1018 adjuvant.

Plague vaccine candidate funded by the Defense Department (DoD):

- Part 1 of the Phase 2 clinical trial evaluating the immunogenicity, safety, and tolerability in adults of a plague (rF1V) vaccine candidate adjuvanted with CpG 1018 was successfully completed in January 2023.
- Both CpG 1018 adjuvanted arms met the Part 1 primary endpoint and demonstrated a greater than two-fold increase in antibodies over the alum adjuvanted control arm after two doses.
- The Company recently completed enrollment in Part 2 of the Phase 2 clinical trial, with top line data anticipated in 2024.

FIRST QUARTER 2023 FINANCIAL HIGHLIGHTS

Total Revenues and Product Revenue, Net.

- Total revenues for the first quarter of 2023 were $46.9 million, compared to $114.0 million for the first quarter of 2022.
- HEPLISAV-B vaccine product revenue, net was $43.5 million for the first quarter of 2023, compared to $20.8 million for the first quarter of 2022, representing year-over-year growth of 109%.
- Other revenue was $3.5 million for the first quarter of 2023, compared to $1.7 million in the same period of 2022, primarily consisting of revenue related to the plague vaccine program in collaboration with and fully funded by the U.S. Department of Defense.
- No CpG 1018 adjuvant product revenue was recorded in the first quarter of 2023, compared to $91.5 million in the first quarter of 2022, due to completion of all obligations and product delivery under the Company's CpG 1018 adjuvant COVID-19 collaboration agreements as of December 31, 2022.

Cost of Sales - Product. Total cost of sales – product for the first quarter of 2023 decreased to $14.7 million, compared to $40.0 million in the first quarter of 2022. The decrease is due to no CpG 1018 adjuvant cost of sales – product for the first quarter of 2023 compared to $34.0 million in the first quarter of 2022. Cost of sales - product for HEPLISAV-B in the first quarter of 2023 increased to $14.7 million, compared to $6.0 million for the first quarter of 2022. The increase was due to higher sales volume driven by continued improvement in HEPLISAV-B market share and utilization, as well as certain one-time charges in connection with improvement projects, and an inspection-related expense, at the Düsseldorf manufacturing facility.

Research and Development Expenses (R&D). R&D expenses for the first quarter of 2023 increased to $13.6 million, compared to $11.1 million for the first quarter of 2022. The increase was primarily driven by continued investments in our product candidates utilizing CpG 1018 adjuvant through preclinical and clinical collaborations and additional discovery efforts.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the first quarter of 2023 increased to $36.5 million, compared to $32.2 million for the first quarter of 2022. The increase was primarily driven by higher compensation and related personnel costs and an overall increase in targeted commercial and marketing efforts to increase market share and maximize the ACIP's universal recommendation.

Bad Debt Expense. During the first quarter of 2023, the Company recognized a bad debt expense of $12.3 million to reflect uncollectible receivables from its customer, Biological E, in connection with the CEPI Arrangement for Biological E supply of CORBEVAX® to the Government of India. Among other factors, the credit profile of Biological E has been negatively impacted by its reliance on future cash collections from the Government of India, which have been significantly reduced and delayed in connection with decreased demand for CORBEVAX in India. In April 2023, Dynavax entered into an amendment with Biological E to resolve remaining outstanding payables from Biological E as well as an agreement with CEPI to fully forgive the corresponding advance payments associated with Biological E supply of CpG 1018.

Net loss. GAAP net loss was $24.3 million, or $0.19 per share (basic and diluted) in the first quarter of 2023, compared to GAAP net income of $32.9 million, or $0.26 per share (basic) and $0.22 per share (diluted) in the first quarter of 2022.

Cash and Marketable Securities. Cash, cash equivalents and marketable securities were $652.0 million as of March 31, 2023.

2023 FINANCIAL GUIDANCE

Full year 2023 financial guidance is reiterated and consists of the following expectations:

- HEPLISAV-B net product revenue between approximately $165 - $185 million
- Research and development expenses between approximately $55 - $70 million
- Selling, general and administrative expenses between approximately $135 - $155 million

Conference Call and Webcast Information

Dynavax will host a conference call and live audio webcast on Tuesday, May 2, 2023, 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 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 and follow Dynavax on LinkedIn and Twitter.

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, planned clinical trials, 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 Annual Report on Form 10-K for the year ended December 31, 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 TECHNOLOGIES CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Product revenues, net	$ 43,451	$ 112,327
Other revenue	3,474	1,665
Total revenues	**46,925**	**113,992**

Operating expenses:		
Cost of sales – product	14,712	39,962
Research and development	13,605	11,095
Selling, general and administrative	36,543	32,172
Bad debt expense	12,313	-
Total operating expenses	**77,173**	**83,229**
(Loss) income from operations	(30,248)	30,763
Other income (expense):		
Interest income	6,597	261
Interest expense	(1,686)	(1,680)
Sublease income	1,598	1,609
Change in fair value of warrant liability	-	1,801
Other	23	105
Net (loss) income before income taxes	(23,716)	32,859
Provision for income taxes	(616)	-
Net (loss) income	**$ (24,332)**	**$ 32,859**
Net (loss) income per share attributable to common stockholders:		
Basic	**$ (0.19)**	**$ 0.26**
Diluted	**$ (0.19)**	**$ 0.22**
Weighted-average shares used in computing net (loss) income per share attributable to common stockholders:		
Basic	**127,921**	**124,555**
Diluted	**127,921**	**149,425**

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

	March 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 651,956	$ 624,395
Inventories, net	57,693	59,446
Other current assets	120,492	233,144
Total current assets	**830,141**	**916,985**
Total non-current assets	139,781	68,865
Total assets	**$ 969,922**	**$ 985,850**
Liabilities and stockholders' equity		
Total current liabilities	$ 91,515	$ 150,074
Total long-term liabilities	314,675	254,763
Stockholders' equity	563,732	581,013
Total liabilities and stockholders' equity	**$ 969,922**	**$ 985,850**

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