Dynavax Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Full Year 2023 Financial Guidance

February 23, 2023

- *2022 total revenue of $723 million, up 64% from $439 million in 2021*
  - *HEPLISAV-B® vaccine net product revenue of $126 million, representing 104% growth compared to 2021*
  - *CpG 1018® adjuvant vaccine net product revenue of $588 million*
- *2023 HEPLISAV-B net product revenue anticipated to be between $165 million and $185 million, representing year-over-year revenue growth of approximately 30-47%*
- *Increased strength of financial position with year-end cash and investments of $624 million*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, Calif., Feb. 23, 2023 /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 the full year ending December 2022.

"In 2022, our team exceeded our strategic goals, achieving record HEPLISAV-B revenue, advancing our clinical pipeline and delivering orders of CpG 1018 adjuvant for the equivalent of hundreds of millions of COVID-19 vaccine doses," said Ryan Spencer, Chief Executive Officer of Dynavax. "Following a year of successful execution on our strategy, we are excited for 2023 and look forward to continuing our trend of significant and sustainable annual HEPLISAV-B revenue growth and overall advancement of our business focused on protecting patients worldwide from infectious diseases."

2023 FINANCIAL GUIDANCE

Dynavax anticipates full-year 2023 revenue and operating expenses to be in the ranges below:

- 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

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. 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 record annual net product revenue of $125.9 million for 2022, compared to $61.9 million for 2021, representing annual growth of 104%.
- HEPLISAV-B market share in prioritized Integrated Delivery Networks (IDNs) and Clinics increased to approximately 47%, with total market share increasing to approximately 35%, up from approximately 33% and 25%, respectively, at the end of 2021.
- Dynavax believes it has begun to see a positive impact on HEPLISAV-B revenue from the expanded ACIP recommendation for adult hepatitis B vaccination which has the potential to expand the market to over $800 million by 2027 with HEPLISAV-B well-positioned to achieve a majority market-share.

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

- CpG 1018 adjuvant achieved annual net product revenue of $587.7 million for 2022, up 57% compared to $375.2 million for 2021.
- Due to the successful execution on the pandemic commercial supply agreements and the resulting volume of partners' overall stockpile, coupled with unknowns about the trajectory of the COVID-19 pandemic, Dynavax believes it will have minimal to as little as zero CpG 1018 adjuvant net product revenues in 2023.

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 a Phase 1 clinical trial demonstrating the Tdap vaccine candidate was well tolerated without observed 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 2022.
- Data from non-human primate challenge study is anticipated 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, utilizing different regimens of CpG 1018 adjuvant.
- The full Phase 1 data will be submitted for presentation at an upcoming medical meeting in the first half of 2023.
- The Company plans to initiate a Phase 1/2 study in early 2024 to evaluate various dose levels of glycoprotein E (gE).

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 DoD has approved continuing to Part 2 using a bedside mix of CpG 1018 with the alum adjuvanted rF1V plague vaccine.

FOURTH QUARTER AND FULL YEAR FINANCIAL HIGHLIGHTS

Total Revenue.

- Total revenue for the fourth quarter of 2022 was $184.5 million, compared to $195.1 million for the fourth quarter of 2021.
- Total revenue for the full year 2022 was $722.7 million, compared to $439.4 million for the full year 2021.

Product Revenue, Net.
HEPLISAV-B®

- HEPLISAV-B vaccine product revenue, net was $34.9 million for the fourth quarter of 2022, compared to $17.2 million for the fourth quarter of 2021.
- HEPLISAV-B vaccine product revenue, net was $125.9 million for the full year 2022, compared to $61.9 million for the full year 2021, representing annual growth of 104%.

CpG 1018® *Adjuvant Supply for COVID-19 Vaccines*

- CpG 1018 adjuvant product revenue, net was $147.2 million in the fourth quarter of 2022, compared to $177.4 million in the fourth quarter of 2021.
- CpG 1018 adjuvant product revenue, net was $587.7 million for the full year 2022, compared to $375.2 million for the full year 2021.

Cost of Sales - Product. Cost of sales - product for the fourth quarter of 2022 increased to $77.5 million, compared to $74.0 million for the fourth quarter of 2021. Full year 2022 cost of sales - product was $262.2 million compared to $173.6 million for the full year 2021. The increase was due to higher sales volume for HEPLISAV-B and CpG 1018 adjuvant in 2022.

Research and Development Expenses (R&D). R&D expenses for the fourth quarter of 2022 increased to $12.9 million, compared to $11.1 million for the fourth quarter of 2021. Full year 2022 R&D expenses were $46.6 million compared to $32.2 million for the full year 2021. The increase was primarily driven by continued investments in our product candidates utilizing CpG 1018 adjuvant through pre-clinical and clinical collaborations and additional discovery efforts.

Selling, General, and Administrative Expenses (SG&A). SG&A expenses for the fourth quarter of 2022 increased to $31.0 million, compared to $29.2 million for the fourth quarter of 2021. Full year 2022 SG&A expenses were $131.4 million compared to $100.2 million for the full year 2021. 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 Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP) universal recommendation.

Net Income. GAAP net income was $67.7 million, or $0.53 per share (basic) and $0.45 per share (diluted) in the fourth quarter of 2022, compared to GAAP net income of $99.8 million, or $0.80 per share (basic) and $0.55 per share (diluted) in the fourth quarter of 2021. GAAP net income was $293.2 million, or $2.32 per share (basic) and $1.97 per share (diluted) for the full year 2022, compared to GAAP net income was $76.7 million, or $0.62 per

share (basic) and $0.57 per share (diluted) for the full year 2021.

Cash and Marketable Securities. Cash and marketable securities were $624.4 million as of December 31, 2022.

Conference Call and Webcast Information

Dynavax will host a conference call and live audio webcast on Thursday, February 23, 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. 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 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.

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 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	Year Ended

	December 31, 2022	December 31, 2021	December 31, 2022	December 31, 2021
Revenues:				
Product revenues, net	$ 182,183	$ 194,541	$ 713,645	$ 437,099
Other revenue	2,309	529	9,038	2,343
Total revenues	**184,492**	**195,070**	**722,683**	**439,442**
Operating expenses:				
Cost of sales – product	77,488	74,012	262,153	173,572
Research and development	12,854	11,117	46,600	32,228
Selling, general and administrative	31,015	29,224	131,408	100,156
Gain on sale of assets	-	-	(1,000)	(1,000)
Total operating expenses	**121,357**	**114,353**	**439,161**	**304,956**
Income from operations	64,135	80,717	283,522	134,486
Other income (expense):				
Interest income	4,324	6	7,912	140
Interest expense	(1,684)	(1,679)	(6,732)	(11,176)
Sublease income	2,025	2,021	7,685	7,735
Loss on debt extinguishment	-	-	-	(5,232)
Change in fair value of warrant liability	-	19,222	1,801	(49,354)
Other	174	300	111	922
Net income before income taxes	67,974	100,587	294,299	77,521
Provision for income taxes	(241)	(808)	(1,143)	(808)
Net income	**$ 67,733**	**$ 99,779**	**$ 293,156**	**$ 76,713**
Net income per share attributable to common stockholders:				
Basic	**$ 0.53**	**$ 0.80**	**$ 2.32**	**$ 0.62**
Diluted	**$ 0.45**	**$ 0.55**	**$ 1.97**	**$ 0.57**
Weighted-average shares used in computing net income per share attributable to common stockholders:				
Basic	**127,589**	**121,380**	**126,398**	**116,264**
Diluted	**151,728**	**149,744**	**150,797**	**133,006**

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

	December 31, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 624,395	$ 545,950
Inventories, net	59,446	61,335
Property and equipment, net	37,596	35,020
Operating lease right-of-use assets	25,745	25,964
Goodwill	2,006	2,125
Other assets	236,662	368,852
Total assets	**$ 985,850**	**$ 1,039,246**
Liabilities and stockholders' equity		
Total current liabilities	$ 150,074	$ 556,402
Total long-term liabilities	254,763	260,470
Stockholders' equity	581,013	222,374
Total liabilities and stockholders' equity	**$ 985,850**	**$ 1,039,246**

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