Dynavax Reports First Quarter 2022 Financial Results

May 5, 2022

- *First quarter 2022 total revenue of $114.0 million, up 37% from $83.3 million for Q1 2021*
  - *HEPLISAV-B® vaccine net product revenue of $20.8 million, up 151% from $8.3 million for Q1 2021*
  - *CpG 1018® adjuvant net product revenue of $91.5 million, up 23% from $74.6 million for Q1 2021*
- *Guidance reiterated for 2022 CpG 1018 revenue, operating expenses, and other costs*
- *On track for a second consecutive year of profitability*
- *Conference call today at 4:30 p.m. ET/1:30 p.m. PT*

EMERYVILLE, Calif., May 5, 2022 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today reported financial results and provided business updates for the three months ending March 31, 2022.

Ryan Spencer, Chief Executive Officer of Dynavax, commented: "Following a year of record revenue for both HEPLISAV-B vaccine and CpG 1018 adjuvant, 2022 is off to a great start and has the potential to be another pivotal year. In the first quarter, HEPLISAV-B grew 21% compared to the fourth quarter, exceeding the overall hepatitis B market growth of 14%. The first quarter also marked another quarter of significant revenue for CpG 1018 adjuvant supply for COVID-19 vaccines as we continue to demonstrate strong execution across our portfolio of commercial supply agreements. Looking ahead, we are on track to achieve our second consecutive profitable year with continued revenue growth fueled by HEPLISAV-B and our CpG 1018 adjuvant supply business. This year we also expect additional clinical data readouts from both of our Phase 1 pipeline programs for Tdap and shingles."

FIRST-QUARTER CORPORATE HIGHLIGHTS

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

HEPLISAV-B vaccine is the first and only U.S. FDA-approved adult hepatitis B vaccine that enables series completion with only two doses in one month.

- HEPLISAV-B vaccine achieved net product revenue of $20.8 million for the first quarter of 2022, up 151% compared to $8.3 million for the first quarter of 2021.
- Market share in the accounts targeted by the Dynavax field sales team was approximately 33%, with a total market share of approximately 26% in the first quarter of 2022, up from approximately 27% and 14%, respectively, in the first quarter of 2021.
- The CDC's Advisory Committee on Immunization Practices (ACIP) recommendation for hepatitis B vaccination in adults has been published (link), advising that all adults aged 19-59 should be vaccinated against hepatitis B. Dynavax believes this will enable a significantly expanded total market opportunity of up to $800 million in the U.S. by 2027, with HEPLISAV-B well positioned to secure a majority market share over time.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

Dynavax has established a global portfolio of CpG 1018 adjuvant commercial supply agreements currently focused on the development of COVID-19 vaccines across a variety of vaccine platforms.

- CpG 1018 adjuvant revenue for the first quarter of 2022 was $91.5 million, up 23% compared to $74.6 million for the first quarter of 2021.
- The Company continues to expect 2022 full-year CpG 1018 adjuvant COVID-19 supply revenue to be at least $550 million, based on committed adjuvant orders, with full-year gross margin anticipated to be approximately 50%. Revenue and margins are expected to fluctuate quarter to quarter based on customer mix and timing of product delivery.
- CpG 1018 adjuvant supply partner selected recent regulatory updates:
  - Biological E (Bio E) has received Emergency Use Authorization (EUA) from the Drugs Controller General of India (DCGI) for its subunit COVID-19 vaccine candidate, CORBEVAX™ utilizing CpG 1018 adjuvant, for adults (December 2021), for adolescents aged 12 to less than 18 years of age (February 2022) and for use in children ages 5-12 (April 2022).
  - Clover Biopharmaceuticals has reported it is in the process of submitting conditional regulatory approval applications for its protein-based COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) utilizing CpG 1018

adjuvant. Clover anticipates that its submissions are to be completed in mid-2022 for the China NMPA and by the third quarter of 2022 for the WHO and EMA.

- Medigen Vaccine Biologics Corporation received EUA for MVC-COV1901, its COVID-19 vaccine candidate utilizing CpG 1018 adjuvant, from the Taiwan Food and Drug Administration in 2021 and from Paraguay's National Directorate of Health Surveillance (DINAVISA) in February 2022.
- Valneva SE recently announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom has granted Conditional Marketing Authorization (CMA) for its COVID-19 vaccine candidate, VLA2001 utilizing CpG 1018 adjuvant. Valneva also reported that it now expects a decision from CHMP on its recommendation for potential conditional approval by the European Medicines Agency (EMA) in the second quarter of 2022.

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.

- **Tdap vaccine program**: Interim adult data from the ongoing Phase 1 study evaluating a new Tdap vaccine candidate utilizing CpG 1018 adjuvant demonstrated it was safe and well tolerated with immunogenicity data supporting continued advancement. Adolescent data from the same trial is expected in the second half of 2022.
- **Shingles vaccine program:** Topline data from an ongoing Phase 1 study evaluating the safety, tolerability, and immunogenicity in adults compared to Shingrix, the leading marketed shingles vaccine in the U.S., is anticipated by the end of 2022.
- **Plague vaccine Phase 2 study**: In collaboration with, and funded by, the U.S. Department of Defense, the Company plans to initiate a Phase 2 clinical trial in the second half of 2022.

FIRST-QUARTER FINANCIAL HIGHLIGHTS

Total Revenues and Product Revenue, Net.
Total revenues for the first quarter of 2022 were $114.0 million, compared to $83.3 million for the first quarter of 2021.

- HEPLISAV-B vaccine product revenue, net was $20.8 million for the first quarter of 2022, compared to $8.3 million for the first quarter of 2021.
- CpG 1018 adjuvant product revenue, net was $91.5 million in the first quarter of 2022 compared to $74.6 million in the first quarter of 2021.

Cost of Sales - Product. Cost of sales - product for the first quarter of 2022 increased to $40.0 million, compared to $24.6 million for the first quarter of 2021. The increase was primarily due to manufacturing costs for increased volumes of CpG 1018 adjuvant sold to COVID-19 supply partners and increased HEPLISAV-B vaccine sales volume.

Research and Development Expenses (R&D). R&D expenses for the first quarter of 2022 increased to $11.1 million, compared to $7.8 million for the first quarter of 2021. The increase was primarily driven by higher compensation and personnel costs, including non-cash stock-based compensation, associated with higher headcount and higher external costs as the Company continued to invest in its product candidates with 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 first quarter of 2022 increased to $32.2 million, compared to $22.4 million for the first quarter of 2021. The increase was primarily driven by compensation and related personnel costs, including non-cash stock-based compensation, primarily associated with increased headcount as the Company expanded its field sales team to support HEPLISAV-B vaccine commercialization in mid-2021.

Interest Expense. Interest expense was $1.7 million in the first quarter of 2022, a decrease of $3.0 million from $4.7 million in the first quarter of 2021, reflecting a decreased interest rate associated with the Company's convertible senior notes due 2026.

Other income (expense). Other income (expense) includes the change in fair value of warrant liability which is a non-cash adjustment to fair value each reporting period. The change in fair value of warrant liability for the first quarter of 2022 resulted in a gain of $1.8 million, compared to a loss of $25.6 million in the first quarter of 2021 due to the final mark-to-market adjustment from January 1, 2022, through the expiration date of the warrants on February 12, 2022. There were no warrants outstanding as of March 31, 2022.

Net Income. GAAP net income was $32.9 million, or $0.26 per share (basic) and 0.22 per share (diluted) in the first quarter of 2022, compared to GAAP net income of $0.9 million, or $0.01 per share (basic and diluted) in the first quarter of 2021.

2022 Financial Guidance
Dynavax anticipates 2022 revenues, operating expenses, and other costs to be in the ranges shown below, unchanged from the Company's previous financial guidance provided on February 28, 2022:

- Full-year CpG 1018 adjuvant net product revenues of at least $550 million, with an associated gross margin of approximately 50%
- Research and development expenses to be between approximately $55 - $70 million
- Selling, general and administrative expenses to be between approximately $120 - $140 million
- Interest expense of approximately $7 million

Conference Call and Webcast Information
Dynavax will hold a conference call today 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 http://investors.dynavax.com/events-presentations. Alternatively, participants may dial (866) 420-4066 or (409) 217-8237 and refer to conference ID 4282730. A replay of the webcast will be available for 30 days following the live event.

Please see Important Safety Information below.

For more information about HEPLISAV-B vaccine, visit http://heplisavb.com.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer, and death. The hepatitis B virus is 50 to 100 times more infectious than HIV, [i] and transmission are on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The U.S. Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that adults aged 19–59 years and adults aged ≥60 years with risk factors for hepatitis B should receive HepB vaccines, and that adults aged ≥60 years without known risk factors for hepatitis B may receive HepB vaccines.[iii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults aged 19 to 59 with diabetes as soon as possible after their diagnosis, and for people aged 60 and older with diabetes at their physician's discretion. [iii] Approximately 26 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year. [iv]

About HEPLISAV-B Vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted]
HEPLISAV-B vaccine is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist CpG 1018 adjuvant to enhance the immune response. Dynavax wholly owns HEPLISAV-B.

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 CpG 1018 Adjuvant
Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response with an improved tolerability profile, which has been demonstrated in HEPLISAV-B vaccine and multiple COVID-19 vaccines that have received Emergency Use Authorization outside of the U.S. CpG 1018 adjuvant provides a well-developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of novel or improved vaccines.

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 age 18 years 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 through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, seasonal influenza, universal influenza, plague, shingles and Tdap. 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, including statements regarding financial guidance, establishing CpG 1018 adjuvant as a leading adjuvant, 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, or the timing of our collaborators to seek conditional or emergency use authorization of COVID-19 vaccines containing CpG 1018 adjuvant. 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 conducted by us or our collaborators, risks that our collaborators will not obtain regulatory approval of their vaccine candidates, 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, when and whether 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 Quarterly Report on Form 10-Q for the quarter ended March 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, 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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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/hepatitis/hbv/vaccadults.htm
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Product revenues, net	$ 112,327	$ 82,885
Other revenue	1,665	450
Total revenues	**113,992**	**83,335**
Operating expenses:		
Cost of sales – product	39,962	24,625
Research and development	11,095	7,758
Selling, general and administrative	32,172	22,423
Total operating expenses	**83,229**	**54,806**
Income from operations	30,763	28,529
Other income (expense):		
Interest income	261	47
Interest expense	(1,680)	(4,712)
Sublease income	1,609	2,022
Change in fair value of warrant liability	1,801	(25,552)
Other	105	557
Net income	**$ 32,859**	**891**
Net income per share attributable to common stockholders		
Basic	**$ 0.26**	**$ 0.01**
Diluted	**$ 0.22**	**$ 0.01**
Weighted-average shares used in computing net income per share attributable to common stockholders:		
Basic	**124,555**	**112,035**
Diluted	**149,425**	**113,469**

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

	March 31, 2022	**December 31, 2021**
Assets		
Cash, cash equivalents and marketable securities	$ 503,216	$ 545,950
Inventories, net	79,038	61,335
Property and equipment, net	36,407	35,020
Operating lease right-of-use assets	26,310	25,964
Goodwill	2,082	2,125
Other assets	361,922	368,852
Total assets	**$ 1,008,975**	**$ 1,039,246**
Liabilities and stockholders' equity		
Total current liabilities	$ 466,203	$ 556,402
Total long-term liabilities	255,288	260,470

Stockholders' equity	287,484	222,374
Total liabilities and stockholders' equity	**$ 1,008,975**	**$ 1,039,246**

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