Dynavax Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Full Year 2022 Financial Guidance

February 28, 2022

Record 2021 total revenue of $439 million, up from $47 million for 2020
Record full year HEPLISAV-B net product revenue of $62 million
Record full year CpG 1018® adjuvant net product revenue of $375 million, meeting previously announced 2021 guidance
2021 GAAP Net Income of $77 million, achieving first profitable year Ended 2021 with $546 million cash, cash equivalents and marketable securities
Full Year 2022 CpG 1018 adjuvant revenue anticipated to be at least $550 million
Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., Feb. 28, 2022 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial stage biopharmaceutical company developing and commercializing innovative vaccines, reported record 2021 total revenue of $439.4 million for the full year of 2021, marking a significant increase compared to $46.6 million for 2020.

"The Company's strong performance throughout 2021 is a testament to the strategy, hard work and dedication of the Dynavax team. This past year we made tremendous progress across our three strategic focus areas – HEPLISAV-B commercialization, execution of CpG 1018 adjuvant supply for COVID-19 vaccines, and advancement of our clinical pipeline - driving 72% year-over-year growth in HEPLISAV-B sales and $375 million in CpG 1018 adjuvant supply revenue," commented Ryan Spencer, Chief Executive Officer of Dynavax. "With approximately $546 million in cash and investments at year-end, we are able to make thoughtful investments into our pipeline leveraging our proven adjuvant. In 2022, we expect continued growth with HEPLISAV-B and our CpG 1018 adjuvant supply business, generating another profitable year with record total revenue, as well as initial clinical data that we anticipate will support meaningful differentiation to establish our high value pipeline designed to produce best-in-class products targeting large markets."

2021 CORPORATE AND FINANCIAL HIGHLIGHTS

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

- HEPLISAV-B achieved record annual revenue of $61.9 million for 2021, compared to $36.0 million for 2020, despite the disruptions to the healthcare system from the COVID-19 pandemic.
- Market share in the accounts targeted by the field sales team grew to approximately 34%, up from approximately 26% at the end of 2020.
- With a proven clinical profile and strong commercial execution, the Company expects further market share gains and revenue growth in 2022.
- Recent recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP) advise that all adults aged 19-59 should be vaccinated against Hepatitis-B, creating a significantly expanded market opportunity, which the company estimates to be $800 million in the U.S. by 2027. The Company believes that HEPLISAV-B is well-positioned to secure majority market share.

CpG 1018® Adjuvant Supply for COVID-19 Vaccines

- Dynavax has established a portfolio of global CpG 1018 adjuvant commercial supply agreements leveraging its adjuvant in the development of COVID-19 vaccines across a variety of vaccine platforms.
- CpG 1018 adjuvant revenue for 2021 of $375.2 million, compared to $3.3 million 2020.
- The Company expects 2022 full-year CpG 1018 adjuvant COVID-19 supply revenue to be at least $550 million, based on committed adjuvant orders, with gross margin of approximately 50%.
- CpG 1018 adjuvant supply partner status:
    - Biological E (Bio E) received Emergency Use Authorization (EUA) from the Drugs Controller General of India (DCGI) for their subunit COVID-19 vaccine candidate, CORBEVAX™ adjuvanted with CpG 1018, for adults in December 2021. In February 2022, Bio E received EUA for adolescents aged 12 to less than 18 years of age by the DCGI.
    - Clover Biopharmaceuticals 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 our CpG 1018 adjuvant, to China's National Medical Products Administration, the European Medicines Agency (EMA) and the World Health

Organization (WHO).
  - Medigen Vaccine Biologics Corporation received EUA for MVC-COV1901, its COVID-19 vaccine utilizing our 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 reported it is continuing to provide data to the European Medicines Agency (EMA), the UK Medicines and Healthcare products Regulatory Agency, and the National Health Regulatory Authority in Bahrain (NHRA) as part of the rolling submissions process for initial approval of VLA2001.
  - CpG 1018 adjuvant supply partners have ongoing clinical trials evaluating the immunogenicity or efficacy of their vaccine candidates for global use, homologous and heterologous boosters, as well as additional indications including pediatrics.

Clinical Pipeline

- The Company is advancing its clinical pipeline leveraging its CpG 1018 adjuvant to develop improved vaccines in indications with unmet medical need.
- CpG 1018 adjuvant has demonstrated its ability to enhance immune responses with a favorable tolerability profile established through a wide range of clinical trials and real-world commercial use.
- The Company is currently advancing three clinical-stage programs with important milestones in 2022:
  - Topline data is expected in the first half of 2022 from the Company's ongoing Tdap Phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity in adults, with adolescent data expected in the second half of 2022.
  - In January 2022, the first patient was dosed in a Phase 1 clinical trial evaluating the safety, tolerability, and immunogenicity in the Company's investigational shingles vaccine program utilizing CpG 1018 adjuvant. Topline data from the trial is expected by the end of 2022.
  - In collaboration with, and funded by, the U.S. Department of Defense, the Company will conduct a Phase 2 clinical trial for a plague vaccine utilizing CpG 1018 adjuvant with trial initiation anticipated in the second half of 2022.

Board of Directors Additions

- In October, Scott Myers was appointed to the Board of Directors and elected Chairman.
- In December, Elaine Sun was appointed to the Board of Directors.

FOURTH QUARTER AND FULL YEAR 2021 FINANCIAL HIGHLIGHTS

Total Revenues and Product Revenue, Net.
Total revenues for the fourth quarter of 2021 were $195.1 million, compared to $19.6 million for 2020.

- HEPLISAV-B product revenue, net was $17.2 million for the fourth quarter of 2021 compared to $11.5 million for the fourth quarter of 2020.
- CpG 1018 product revenue, net was $177.4 million in the fourth quarter of 2021 compared to $1.6 million in the fourth quarter of 2020.

Total revenues for the full year 2021 were $439.4 million, compared to $46.6 million for the full year 2020.

- HEPLISAV-B product revenue, net increased 72% to $61.9 million for 2021 compared to $36.0 million for the full year 2020.
- CpG 1018 product revenue, net was $375.2 million for 2021 compared to $3.3 million for the full year 2020.

Cost of Sales - Product. Cost of sales - product for the fourth quarter of 2021 increased to $74.0 million, compared to $4.1 million for the fourth quarter of 2020. Full year 2021 cost of sales - product was $173.6 million compared to $11.4 million for the full year of 2020. The increase was primarily due to manufacturing costs for increased volumes of CpG 1018 sold to COVID-19 supply partners, and HEPLISAV-B sales, coupled with approximately $4.8 million in excess capacity charges in connection with an expansion project at the Company's manufacturing facility in Dusseldorf and $2.6 million write-off of HEPLISAV-B inventory that had been manufactured prior to the beginning of the COVID-19 pandemic and not expected to be sold due to the prolonged impact of the pandemic.

Research and Development Expenses (R&D). R&D expenses for the fourth quarter of 2021 increased to $11.1 million, compared to $9.5 million for the fourth quarter of 2020. Full year 2021 R&D expenses were $32.2 million compared to $28.6 million for the full year 2020. The increase in both periods was primarily driven by higher compensation and personnel costs, including non-cash stock-based compensation, associated with higher headcount and external costs as the Company advances 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 fourth quarter of 2021 increased to $29.2 million, compared to $17.8 million for the fourth quarter of 2020. Full year 2021 SG&A expenses were $100.2 million compared to $79.3 million for the full year 2020. The increase in both periods was primarily driven by compensation and related personnel costs, including non-cash stock-based compensation, associated with higher headcount as the Company expanded its field sales team to increase HEPLISAV-B market share.

Interest Expense. Interest expense was $1.7 million in the fourth quarter of 2021 and $11.2 million for the full year 2021, primarily in connection with the 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 fourth quarter of 2021 resulted in a gain of $19.2 million, compared to a loss of $0.1 million in the fourth quarter of 2020.

Income Tax Expense. Income tax expense was $0.8 million for the full year 2021 and the Company's effective tax rate was 1.03%. No income tax expense was recorded for the full year 2020. The increase in income tax expense and the effective tax rate are both due to achieving the Company's first profitable year with GAAP net income of $76.7 million.

Net Income (Loss). GAAP net income was $99.8 million, or $0.80 per share (basic) and 0.55 per share (diluted) in the fourth quarter of 2021, compared to GAAP net loss in the fourth quarter of $15.5 million, or $0.14 per share (basic) and $0.14 per share (diluted) in the fourth quarter of 2020. GAAP net income was $76.7 million, or $0.62 per share (basic) and $0.57 per share (diluted) for the full year 2021, compared to GAAP net loss of $75.2 million, or $0.75 per share (basic) and $0.78 per share (diluted) for the full year 2020.

Cash Flow Statement and Balance Sheet Highlights

- Dynavax ended 2021 with $546 million in cash, cash equivalents and marketable securities, compared to $165 million at the end of 2020.
- Dynavax generated $120.5 million in cash from operations in the fourth quarter of 2021, compared to cash used in operations of $15.7 million in the fourth quarter of 2020. The Company generated $335.5 million in cash from operations for the full year 2021, compared to cash used in operations of $92.3 million for the full year 2020.

2022 Financial Guidance
In 2022, Dynavax anticipates:

- Full year CpG 1018 adjuvant net product revenues of at least $550 million, with associated gross margin of approximately 50%
- Selling, general and administrative expenses to be between approximately $120 - $140 million
- Research and development expenses to be between approximately $55 - $70 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 4678925. 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, 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 is 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 (CDC) recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 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
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist CpG 1018 to enhance the immune response. Dynavax wholly owns HEPLISAV-B.

Important U.S. Product Information
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

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 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%).

Important EU/EEA Product Information
HEPLISAV B is indicated for active immunization against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

The use of HEPLISAV B should be in accordance with official recommendations.
It can be expected that hepatitis D will also be prevented by immunization with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

For full EU/EEA. Prescribing Information for HEPLISAV-B, click here.

Important EU/EEA Safety information
Do not receive HEPLISAV B if you have had a sudden life-threatening, allergic reaction after receiving HEPLISAV B in the past, or if you are allergic to any of components of this vaccine, including yeast. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.

Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reactions following the administration of the vaccine.
The administration of HEPLISAV B should be postponed in subjects suffering from acute severe febrile illness.

Immunocompromised persons may have a diminished immune response to HEPLISAV B.
Because of the long incubation period of hepatitis B, it is possible for unrecognized HBV infection to be present at the time of immunization. HEPLISAV B may not prevent HBV infection in such cases.
There are very limited data on the immune response to HEPLISAV B in individuals who did not mount a protective immune response to another hepatitis B vaccine.

As a precautionary measure, it is preferable to avoid the use of HEPLISAV B during pregnancy. Vaccination during pregnancy should only be performed if the risk-benefit ratio at the individual level outweighs possible risks for the fetus.

The most common patient-reported side effects reported within 7 days of vaccination were pain, swelling or redness at the injection site, feeling tired, headache, muscle aches, feeling unwell and fever.

About CpG 1018 Adjuvant
Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response with improved tolerability profile, which has been demonstrated in HEPLISAV-B and two COVID-19 vaccines that have received Emergency Use Authorization. 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 novel vaccines to help protect the world against infectious diseases. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. and the European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, plague, shingles, Tdap, seasonal influenza and universal influenza. For more information, visit www.dynavax.com and follow the company 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 by us or by our collaborators, potential future sales of CpG 1018 adjuvant or HEPLISAV-B, 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 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 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 fiscal year ended December 31, 2021 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/diabetes/pubs/pdf/hepb_vaccination.pdf.
[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 December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenues, net	$ 194,541	$ 13,112	$ 437,099	$ 39,307
Other revenue	529	6,438	2,343	7,244
Total revenues	**195,070**	**19,550**	**439,442**	**46,551**
Operating expenses:				
Cost of sales – product	74,012	4,058	173,572	11,410
Cost of sales - amortization of intangible assets	-	-	-	2,500
Research and development	11,117	9,549	32,228	28,607
Selling, general and administrative	29,224	17,838	100,156	79,256
Gain on sale of assets	-	-	(1,000)	(6,851)
Total operating expenses	**114,353**	**31,445**	**304,956**	**114,922**
Income (loss) from operations	80,717	(11,895)	134,486	(68,371)
Other income (expense):				
Interest income	6	70	140	1,260
Interest expense	(1,679)	(4,805)	(11,176)	(19,062)
Sublease income	2,021	1,927	7,735	7,706
Loss on debt extinguishment	-	-	(5,232)	-
Change in fair value of warrant liability	19,222	(76)	(49,354)	4,124
Other	300	(688)	922	(897)
Net income (loss) before provision for income taxes	100,587	(15,467)	77,521	(75,240)
Provision for income taxes	(808)	-	(808)	-
Net income (loss)	**$ 99,779**	**(15,467)**	**$ 76,713**	**$ (75,240)**
Net income (loss) per share attributable to common stockholders				
Basic	**$ 0.80**	**$ (0.14)**	**$ 0.62**	**$ (0.75)**
Diluted	**$ 0.55**	**$ (0.14)**	**$ 0.57**	**$ (0.78)**
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	**121,380**	**110,176**	**116,264**	**100,753**
Diluted	**149,744**	**110,176**	**133,006**	**101,504**

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

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 545,950	$ 165,036
Inventories, net	61,335	63,689
Property and equipment, net	35,020	30,567
Operating lease right-of-use assets	25,964	26,583
Goodwill	2,125	2,297
Other assets	368,852	65,100
Total assets	**$ 1,039,246**	**$ 353,272**
Liabilities and stockholders' equity		
Total current liabilities	$ 556,402	$ 77,411
Total long-term liabilities	260,470	217,168
Stockholders' equity	222,374	58,693
Total liabilities and stockholders' equity	**$ 1,039,246**	**$ 353,272**

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SOURCE Dynavax Technologies