Dynavax Reports Third Quarter 2021 Financial Results

November 4, 2021

- Third quarter 2021 total revenue of $108.3 million
-- HEPLISAV-B net product revenue of $22.7 million
-- CpG 1018® adjuvant product revenue of $84.3 million
- Increased 2021 full-year CpG 1018 revenue guidance to be between $375 and $425 million
- ACIP voted unanimously to recommend that all adults 19 to 59 years of age should receive hepatitis B vaccination
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT

EMERYVILLE, Calif., Nov. 4, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the third quarter ended September 30, 2021 and provided a business update.

"This quarter we continued to make strong progress with both our lead commercial vaccine, HEPLISAV-B, and our CpG 1018 vaccine adjuvant platform," commented Ryan Spencer, Chief Executive Officer of Dynavax. "Our belief in the significant value of both assets is reinforced by the continued growth in market share and revenue for HEPLISAV-B along with multiple positive data readouts for adjuvanted COVID-19 vaccine candidates demonstrating the capabilities of CpG 1018 to help drive efficacy and high levels of antibodies while maintaining a favorable tolerability profile. Strong execution on a thoughtful, timely strategy has resulted in $244 million in year-to-date total revenue and $215 million in cash flow from operations, generating approximately $414 million in cash and equivalents at the end of this quarter which further enables our ability to continue to make investments which we believe will drive long-term value."

THIRD QUARTER AND RECENT BUSINESS UPDATE

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

HEPLISAV-B achieved another quarterly high with $22.7 million in revenue during the third quarter of 2021, compared to $11.6 million for the third quarter 2020. This increase was primarily driven by continued success in the field targeted accounts. Market share in the accounts targeted by the field sales team increased to 33.5%, up from 23% in the third quarter of 2020. With a consistent seroprotection rate of over 90% across all patients and the only FDA-approved two-dose hepatitis B vaccine for adults that is completed in one month, in a market where three-dose compliance is known to be a significant challenge, the Company believes HEPLISAV-B can protect more adults against hepatitis B than all other competitor vaccines.

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) at its November 2021 meeting voted unanimously to recommend that all adults 19 to 59 years of age should receive hepatitis B vaccination. This recommendation greatly simplifies the identification of patients who need a hepatitis B vaccine compared to the current risk-based recommendation, and significantly expands the number of adults in the United States who should be vaccinated against hepatitis B.

CpG 1018® (Vaccine Adjuvant)

The Company's strategy to expand the use of its CpG 1018 adjuvant platform and proven technology in multiple modalities of vaccine development continued to generate positive results in the third quarter. Through global partnerships, multiple data read outs for late-stage clinical trials of COVID-19 vaccine candidates adjuvanted with CpG 1018 generated impressive efficacy, immunogenicity and tolerability results. These clinical results enhance the data supporting CpG 1018's ability to help enable new and improved vaccines that are effective and well-tolerated.

Net product revenue for CpG 1018 adjuvant during the third quarter of 2021 was $84.3 million, compared to $1.7 million for the third quarter 2020. The increase was associated with commercial supply agreements for COVID-19 collaborations. With the meaningful progress made across our COVID-19 partnership portfolio, the Company now expects 2021 full-year CpG 1018 revenue to be approximately $375- $425 million.

- In July, Medigen Vaccine Biologics Corporation received Emergency Authorization (EUA) from the Taiwan Food and Drug Administration for MVC-COV1901, their COVID-19 vaccine adjuvanted with CpG 1018, and began vaccinating Taiwan residents in late August.
- In July, Dynavax and Biological E (Bio E) entered into a commercial supply agreement for the use of CpG 1018 adjuvant in the commercial production of Bio E's subunit COVID-19 vaccine candidate, CORBEVAX™. Upon completion of their Phase 2/3 clinical trial in India and subsequent EUA, Bio E stated India's Union Ministry of Health has reserved 300 million doses of CORBEVAX™.
- In September, Clover Biopharmaceuticals reported positive data for their protein-based COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) adjuvanted with Dynavax's CpG 1018, which achieved the primary and secondary efficacy endpoints in SPECTRA, a global pivotal Phase 2/3 clinical trial that enrolled over 30,000 participants. Vaccine efficacy was successfully demonstrated in an environment where 100% of SARS-CoV-2 strains observed in the efficacy analysis were variants. SCB-2019 (CpG 1018/Alum) demonstrated a favorable safety and tolerability profile. Subject to receiving Emergency Use Listing (EUL) from the World Health Organization (WHO), Clover said it plans to supply up to 414 million doses of its COVID-19 vaccine candidate globally through the COVAX Facility.
- In September, Dynavax and the U.S. Department of Defense (DOD) executed an agreement for approximately $22 million

over two and a half years to develop a recombinant plague vaccine adjuvanted with CpG 1018. Enrollment for the Phase 2 clinical trial is expected to commence in 2022.
- In October, Valneva SE reported positive topline data for their inactivated whole virus COVID-19 vaccine candidate, VLA2001, adjuvanted with Dynavax's CpG 1018, in Cov-Compare, a comparative immunogenicity Phase 3 trial in approximately 4,000 adults. The trial successfully met both co-primary endpoints of superior neutralizing antibody titer levels compared to the active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S), and neutralizing antibody seroconversion rate above 95%. VLA2001 was well-tolerated, demonstrating a statistically significant better tolerability profile compared to AZD1222.

Corporate Updates

- In October, Scott Myers was appointed to Board of Director and elected Chairman.

Upcoming Milestones

- Multiple CpG 1018 COVID-19 collaboration partners' regulatory submissions for emergency or conditional use authorization are expected by the end of 2021 and may provide additional revenue opportunity in 2022.
- Data from Tdap-1018 in the ongoing Phase 1 clinical trial for an improved tetanus, diphtheria, and acellular pertussis booster vaccine candidate adjuvanted with CpG 1018 are expected in the first quarter of 2022.

Financial Results for the Third Quarter

Product Revenue, Net.

Total revenue for the third quarter of 2021 was $108.3 million.

- HEPLISAV-B product revenue, net was $22.7 million in the third quarter of 2021 compared to $11.6 million in the same period in 2020.
- CpG 1018 product revenue, net was $84.3 million in the third quarter of 2021 compared to $1.7 million in the same period in 2020. As CpG 1018 revenues are generally recorded upon shipment to a customer, there may be fluctuations in revenues between quarters, as shipments often consist of large-sized batches.

Cost of Sales - Product. Cost of sales - product for the third quarter 2021 increased to $60.1 million, compared to $4.0 million for the third quarter of 2020. The increase was primarily due to manufacturing costs for increased volumes of CpG 1018 and HEPLISAV-B sold to customers.

Research and Development Expenses (R&D). R&D expenses for the third quarter of 2021 decreased to $6.2 million, compared to $8.5 million for the third quarter of 2020. The decrease is primarily associated with certain non-recurring expenses incurred in the third quarter of 2020 associated with the wind-down of the Company's legacy immuno-oncology business.

Selling, General and Administrative Expenses (SG&A). SG&A expenses for the third quarter of 2021 increased to $26.9 million, compared to $21.5 million for the third quarter of 2020. This increase is primarily driven by compensation and related personnel costs, including non-cash stock-based compensation, associated with higher headcount.

Income (loss) from Operations and Net Income (loss). Income from operations for the third quarter of 2021 was $16.1 million compared to a loss from operations of $13.8 million in the third quarter of 2020. Net loss for the third quarter of 2021 was $28.4 million compared to net income of $4.4 million for the third quarter of 2020.

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 third quarter of 2021 resulted in a loss of $45.1 million, compared to a gain of $21.2 million in the third quarter of 2020.

Earnings per share. Basic and diluted net loss per share were ($0.24), for the third quarter of 2021, compared to basic net income per share of $0.04 and diluted net loss per share of ($0.15) in the third quarter of 2020.

Cash Position and cash flow from operations. Cash, cash equivalents and marketable securities totaled $414.2 million on September 30, 2021. Cash flow from operations for the nine months ended September 30, 2021 was approximately $215.0 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 www.dynavax.com. Alternatively, participants may dial (866) 420-4066 or (409) 217-8237 and refer to conference ID 5994808. 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 20 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 has worldwide commercial rights to 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 immunisation 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 unrecognised HBV infection to be present at the time of immunisation. 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

CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. 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. 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,

TDaP, 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 as a leading adjuvant, the development and potential approval of vaccines containing CpG 1018 by us or by our collaborators and potential future sales of CpG 1018 or HEPLISAV-B, the timing of initiation and completion of clinical studies and the publication of results, the timing of our collaborators seeking conditional or emergency use authorization of COVID-19 vaccines containing CpG 1018 adjuvant, our ability to scale manufacturing capacity, the expected demand for our products, our efforts to develop an improved pertussis vaccine and a seasonal flu vaccine, our collaboration partners' efforts to develop and commercialize a vaccine for COVID-19 and a universal flu vaccine, entering into strategic relationships and expected results of such relationships, the potential for CpG 1018 to accelerate development and large scale manufacturing of COVID-19 or other vaccines and sales potential under certain agreements. 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 HEPLISAV-B may not become the standard of care adult hepatitis B vaccine in the U.S., risks related to whether and when prescribers and other key decision-makers at potential purchasing entities will make the decision to switch to HEPLISAV-B, and the timing and quantity of actual purchases, risks related to the timing and result of the ACIP vote on a universal hepatitis B recommendation, 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, and whether use of CpG 1018 will prove to be beneficial in these vaccines, risks related to whether, when and the quantity of CpG 1018 actually purchased by vaccine companies, risks related to the use of contract manufacturers to timely supply CpG 1018 and financial commitments made to them, 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, 2020 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. 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-r

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenues, net	$ 106,996	$ 13,276	$ 242,558	$ 26,195
Other revenue	1,274	138	1,814	806
Total revenues	**108,270**	**13,414**	**244,372**	**27,001**
Operating expenses:				
Cost of sales – product	60,090	4,031	99,560	7,352
Cost of sales - amortization of intangible assets	-	-	-	2,500
Research and development	6,186	8,521	21,111	19,058
Selling, general and administrative	26,926	21,538	70,932	61,418
Gain on sale of assets	(1,000)	(6,851)	(1,000)	(6,851)
Total operating expenses	**92,202**	**27,239**	**190,603**	**83,477**
Income (loss) from operations	16,068	(13,825)	53,769	(56,476)
Other income (expense):				
Interest income	39	269	134	1,190
Interest expense	(1,676)	(4,794)	(9,497)	(14,257)
Sublease income	2,022	1,926	5,714	5,779
Loss on debt extinguishment	-	-	(5,232)	-
Change in fair value of warrant liability	(45,121)	21,245	(68,576)	(4,200)
Other	238	(420)	622	(209)
Net (loss) income	**$ (28,430)**	**$ 4,401**	**$ (23,066)**	**$ (59,773)**
Net (loss) income per share – basic	**$ (0.24)**	**$ 0.04**	**$ (0.20)**	**$ (0.61)**

Weighted average shares used to compute basic net (loss) income per share	**116,903**	**109,816**	**114,540**	**97,589**
Net loss per share – diluted	**$ (0.24)**	**$ (0.15)**	**$ (0.20)**	**$ (0.65)**
Weighted average shares used to compute diluted net loss per share	**116,903**	**111,973**	**114,540**	**98,577**

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

	September 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 414,155	$ 165,036
Inventories, net	67,297	63,689
Property and equipment, net	34,251	30,567
Operating lease right-of-use assets	26,772	26,583
Goodwill	2,171	2,297
Other assets	375,065	65,100
Total assets	**$ 919,711**	**$ 353,272**
Liabilities and stockholders' equity		
Total current liabilities	$ 528,935	$ 77,411
Total long-term liabilities	323,200	217,168
Stockholders' equity	67,576	58,693
Total liabilities and stockholders' equity	**$ 919,711**	**$ 353,272**

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