Dynavax Announces Second Quarter 2020 Financial Results

August 6, 2020

- Second quarter 2020 HEPLISAV-B® net product revenue of $2.4 million
- Multiple new CpG 1018 collaborations established to develop novel adjuvanted vaccine candidates across several indications, including COVID-19
- Initial Phase 1 results from two COVID-19 adjuvanted vaccine collaborations anticipated by September and October of 2020
- Conference call to be held today at 4:30 p.m. ET/1:30 p.m. PT (UPDATED dial in information below)

EMERYVILLE, Calif., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported financial results for the second quarter of 2020.

"Vaccines play a crucial role in protecting people, particularly those at high risk, from infectious diseases," commented Ryan Spencer, Chief Executive Officer of Dynavax. "The current global pandemic highlights the need for continued development of new and improved vaccines. Our first product, HEPLISAV-B, provides adults protection from hepatitis B, a highly infectious deadly virus which, thankfully, can be prevented with effective vaccination. With a demonstrated profile that provides adults higher levels of protection from hepatitis B in one month, compared to other hepatitis B vaccines that require six months, we believe that HEPLISAV-B has the potential to become the standard of care for adult hepatitis B vaccination in the U.S."

Mr. Spencer added, "As expected from the pandemic driven disruption to non-COVID medical care, the adult hepatitis B vaccine market experienced a significant decline early in the second quarter. Despite the short-term impact, we continue to be optimistic about HEPLISAV-B's long-term value, particularly with the global focus on vaccination efforts as a result of the pandemic. Additionally, we see tremendous opportunity for CpG 1018, our advanced vaccine adjuvant. We have entered into numerous collaborations to develop adjuvanted vaccines across multiple indications, including COVID-19, pertussis, and universal flu. Adjuvanted coronavirus vaccines may play a critical role in providing protection to older adults and people with other chronic conditions, who are at greater risk for COVID-19 and have historically been less responsive to vaccinations."

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

- Net product revenue for second quarter 2020 of $2.4 million declined from $8.3 million for the second quarter of 2019, due to the COVID-19 pandemic. Overall adult hepatitis B vaccine utilization declined significantly beginning in late March, reached a low in the middle of the second quarter, and improved in the later part of the quarter.
- Interim data were reported from the ongoing study of HEPLISAV-B in patients on hemodialysis showing HEPLISAV-B was well tolerated with a seroprotection rate of 86.4% in 44 patients.

CpG 1018 proprietary toll-like receptor 9 (TLR9) agonist adjuvant
·Announced collaborations with Sinovac Biotech, Valneva SE, Medicago, Medigen Vaccine Biologics and Mount Sinai to further advance CpG 1018 in adjuvanted vaccines. A summary of CpG 1018 collaborations is provided below:

Indication	Collaborator	Status
	Clover Biopharmaceuticals	Phase 1
	Medicago	Phase 1
COVID-19	Medigen Vaccine Biologics	Preclinical
	Sinovac Biotech	Preclinical
	Valneva SE	Preclinical
Pertussis	Serum Institute of India	Preclinical
Universal Influenza	Mount Sinai	Preclinical

Additional Corporate Updates

- Completed an $80.5 million public offering of common stock
- Appointed Ms. Julie Eastland and Mr. Brent MacGregor to Board of Directors
- Entered into a purchase agreement with TriSalus Lifesciences for SD-101 and related assets for $9 million in cash payments, up to an additional $250 million in development and commercial milestone payments and low double-digit royalties on potential future sales

2020 Milestones

- Final immunogenicity data from the ongoing study of HEPLISAV-B in patients on hemodialysis anticipated in the fourth quarter with publication planned in the first quarter of 2021.
- Completion of safety follow-up for HEPLISAV-B post-marketing studies in the fourth quarter.
- Completion of Phase 1-enabling animal studies and toxicology for an improved pertussis vaccine with CpG 1018 is

planned for the fourth quarter.
- Preliminary safety and immunogenicity results from Phase 1 COVID-19 studies with Clover Biopharmaceuticals and Medicago expected by September and October, respectively.

Financial Results

Product Revenue, Net. Product revenue, net decreased to $2.4 million in the second quarter of 2020 compared to $8.3 million in the same period in 2019, due to lower sales volume caused by the COVID-19 global pandemic. For much of the second quarter, medical centers and physician practices restricted activities at their facilities. This led to a significant decline in adult hepatitis B vaccine utilization, which fell as much as approximately 70% in April. For HEPLISAV-B, product sales to distributors were lower than end user demand as distributors elected to reduce inventory levels during the quarter. With states beginning to reopen, medical centers have gradually expanded their services under strict social distancing rules. Adult hepatitis B vaccine utilization began to increase in mid-June, reached approximately 60% of pre-COVID levels in July and is expected to continue growing as the U.S. returns to more normal conditions.

Cost of Sales - Product. Cost of sales - product for the second quarter 2020 decreased to $1.0 million, compared to $2.1 million for the second quarter of 2019, primarily due to lower sales volume and lower overhead following the May 2019 restructuring, partially offset by higher unit costs as we produce and then sell inventory that reflects the full cost of manufacturing.

Research and Development Expenses. Research and development (R&D) expenses for the second quarter of 2020 decreased to $5.9 million, compared to $16.2 million for the second quarter of 2019 as personnel costs, facilities overhead cost allocations and non-cash stock-based compensation decreased due to lower R&D headcount because of our restructuring in May 2019 and outside services costs decreased with the winding down of our immuno-oncology programs.

SG&A Expenses. Selling, general and administrative (SG&A) expenses for the second quarter of 2020 were $19.0 million, compared to $17.9 million for the second quarter of 2019 as compensation and related personnel costs decreased due to lower headcount and business travel decreased due to COVID-19 travel restrictions, offset by increased administrative expense, expenses related to the post-marketing studies and facility costs due to higher overhead allocation to SG&A.

Loss from Operations and Net Loss. Loss from operations for the second quarter of 2020 decreased to $23.3 million from $39.0 million in the second quarter of 2019. Net loss for the second quarter of 2020 was $51.6 million, or $0.53 per basic and diluted share, compared to a net loss of $42.7 million, or $0.66 per basic and diluted share, for the second quarter of 2019. The net loss in the quarter ended June 30, 2020 includes expense of $25.7 million due to an increase in the estimated fair value of outstanding warrants.

Cash Position. Cash, cash equivalents and marketable securities totaled $200.7 million at June 30, 2020.

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 800-939-4079 or 212-231-2911 and refer to conference ID 21967375. 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.

Indication and Use
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

Important 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%).

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

About CpG 1018
CpG 1018 is the adjuvant used in HEPLISAV-B®, an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. In pre-clinical and clinical

studies, results demonstrated that the addition of CpG 1018 increases antibody concentrations, stimulates helper (CD4+) and cytotoxic (CD8+) T cell populations and generates robust T and B cell memory responses. Additionally, CpG 1018 strongly favors development of the Th1 subset of helper T cells, the type of helper T cell that is essential for protection from infections with viruses and intracellular bacteria. CpG 1018 targets a single, well defined receptor (TLR9) expressed on only a few key cell types and the mechanisms of action as an adjuvant are quite well understood. CpG 1018 provides a well- developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine. Upon completion of on-going scale up activities, the existing equipment capacity for CpG 1018 will be 600 million to 1.2 billion adjuvant doses annually, depending on final dose selected.

About Dynavax

Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also developing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis 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 the potential for HEPLISAV-B to become the standard of care adult hepatitis B vaccine in the U.S., long-term growth of HEPLISAV-B, the impact of COVID-19 on the utilization of vaccines, including HEPLISAV-B, the timing of enrollment in and completion of clinical studies, the adequacy of current capital, the results of clinical studies and what the results will demonstrate or support, developing an improved pertussis vaccine, a vaccine for COVID-19, a universal flu vaccine, and other vaccines, entering into strategic relationships and expected results of such relationships, and establishing CpG 1018 as a leading 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 the vaccine market and/or the adult hepatitis B market may not grow as expected, the risk that COVID-19 will continue to have a significant negative impact on the use of vaccines, including HEPLISAV-B, until the U.S. returns to more normal conditions, the adverse effects of the recent coronavirus pandemic on our ability to access customers and on customer decision making, adoption and implementation, the risk that HEPLISAV-B may not provide the anticipated benefits and may not become the standard of care adult hepatitis B vaccine in the U.S., the risk that our growth initiatives may not be successful, 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 development and clinical testing of vaccines and whether use of CpG 1018 will prove to be beneficial in other vaccines, and risks related to whether existing or future collaborations will be successful; 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, 2019, 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-report

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Product revenues, net	$ 2,405	$ 8,301	$ 12,919	$ 13,928
Other revenue	263	-	668	146
Total revenues	**2,668**	**8,301**	**13,587**	**14,074**
Operating expenses:				
Cost of sales - product	967	2,141	3,321	3,941
Cost of sales - amortization of intangible assets	202	2,297	2,500	4,570
Research and development	5,884	16,196	10,537	37,402
Selling, general and administrative	18,954	17,861	39,880	36,209
Restructuring	-	8,777	-	8,777
Total operating expenses	**26,007**	**47,272**	**56,238**	**90,899**
Loss from operations	(23,339)	(38,971)	(42,651)	(76,825)

Other income (expense):				
Interest income	331	979	921	1,714
Interest expense	(4,732)	(4,598)	(9,463)	(7,332)
Sublease income	1,927	-	3,853	-
Change in fair value of warrant liability	(25,655)	-	(17,045)	-
Other	(111)	(123)	211	58
Net loss	**$ (51,579)**	**$ (42,713)**	**$ (64,174)**	**$ (82,385)**
Basic and diluted net loss per share	**$ (0.53)**	**$ (0.66)**	**$ (0.70)**	**$ (1.28)**
Weighted average shares used to compute basic and diluted net loss per share	**97,339**	**65,088**	**91,408**	**64,436**

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

	June 30, 2020	**December 31, 2019**
Assets		
Cash, cash equivalents and marketable securities	$ 200,708	$ 151,055
Inventories, net	54,392	41,332
Property and equipment, net	30,476	32,022
Intangible assets, net	-	2,500
Operating lease right-of-use assets	27,871	30,252
Goodwill	2,103	2,081
Other assets	13,764	19,826
Total assets	**$ 329,314**	**$ 279,068**
Liabilities and stockholders' equity		
Total current liabilities	$ 53,222	$ 53,047
Total long-term liabilities	217,797	217,731
Stockholders' equity	58,295	8,290
Total liabilities and stockholders' equity	**$ 329,314**	**$ 279,068**

Source: Dynavax Technologies Corporation