



## Dynavax Reports Second Quarter 2018 Financial Results

August 6, 2018

*HEPLISAV-B® Launch Progressing as Planned with Key Customer Successes*

*Three abstracts accepted for presentation at European Society for Medical Oncology (ESMO) 2018 Annual Meeting*

*Conference Call to be held at 4:30pm ET/1:30pm PT*

BERKELEY, Calif., Aug. 06, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today reported financial results for the second quarter ended June 30, 2018. The net loss for the quarter was \$39.4 million, or \$0.63 per share, compared to \$20.3 million, or \$0.41 per share, for the quarter ended June 30, 2017. Cash, cash equivalents and marketable securities totaled \$216.0 million at June 30, 2018.

### Recent Highlights

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

- 100% of Medicare-insured lives, 94% of commercially-insured lives, and 73% of lives under state Medicaid plans are covered
- 219 of our largest targeted customers have received P&T committee approval, of whom 91 have progressed to purchase and 24 have implemented the use of HEPLISAV-B throughout their system
- Another 198 target customers have sub-committee or P&T committee review scheduled
- Q2 sales of \$1.3 million compared to \$0.2 million in Q1

### Immuno-oncology

- Encouraging SD-101 Phase 1b/2 advanced melanoma data in combination with KEYTRUDA® in patients naïve to anti PD-1 therapy for 2 mg dose selected for Phase 3:
  - Overall response rate (ORR) of 70%
  - 80% ORR in patients with low PD-L1
  - 6-month progression free survival (PFS) rate of 76%
- AEs related to SD-101 treatment were transient, mild to moderate flu-like symptoms
- End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) scheduled
- Three abstracts accepted for presentation at the European Society for Medical Oncology (ESMO) 2018 Annual Meeting, October 19-23, 2018

"The launch is progressing as planned and I continue to expect HEPLISAV-B will become the standard of care for vaccination of adults against hepatitis B. During my field visits, I have personally witnessed the strength of the product profile and label in motivating customers to switch vaccines," said Eddie Gray, chief executive officer of Dynavax. "Our efforts to date are beginning to pay off with increasing sales, which we expect will accelerate during Q4 and into 2019, when we expect HEPLISAV-B to be cash generative before year end. In addition, we continue to advance our SD-101 clinical program which has shown encouraging results so far in both melanoma and head and neck carcinoma patients. We look forward to updating these data later this year."

### Financial Results

Cash, cash equivalents and marketable securities of \$216.0 million at end of the second quarter, with \$75 million available from the February 2018 term loan agreement

Net product revenue was \$1.3 million for the quarter ended June 30, 2018, which consists of sales of HEPLISAV-B in the U.S. Product revenue from sales is recorded at the net sales price which includes estimates of product returns, chargebacks, discounts and other fees.

Cost of sales, product was \$5.2 million for the quarter ended June 30, 2018 and consists of certain fill, finish and fixed overhead costs for HEPLISAV-B incurred after FDA approval and costs relating to excess capacity at our Dusseldorf manufacturing facility associated with resuming operations after receiving FDA approval of HEPLISAV-B and pre-filled syringes.

Cost of sales, amortization of intangible assets was \$2.3 million for the quarter ended June 30, 2018 and consists of amortization of the intangible asset recorded as a result of milestone and sublicense payments relating to HEPLISAV-B.

Research and development expenses for the quarter ended June 30, 2018 and 2017, were \$16.3 million and \$14.8 million, respectively. The increase in 2018 reflects increased compensation and related personnel costs related to the ongoing development of SD-101, DV281 and earlier stage oncology programs. Additionally, in the current quarter, manufacturing related costs incurred by our Dusseldorf facility that were previously included in research and development expense are now accounted for as excess capacity in our cost of sales, product.

Selling, general and administrative expenses for the quarter ended June 30, 2018 and 2017, were \$15.7 million and \$5.6 million, respectively. The increase is primarily due to an overall increase in HEPLISAV-B sales, marketing and commercial activities, including full-deployment of a contract sales force, post-marketing studies and consultants for commercial development services.

## Conference Call and Webcast Information

Dynavax will hold a conference call today at 4:30pm ET/1:30pm PT. To access the call, participants must dial (800) 239-9838 in the U.S. or (323) 794-2551 internationally, and use the conference ID 2303066. The live call will be webcast and can be accessed in the "Investors and Media" section of the company's website at [www.dynavax.com](http://www.dynavax.com). A replay of the webcast will be available for 30 days following the live event.

A replay of the conference call will be available for two weeks and can be accessed by dialing (844) 512-2921 in the U.S. or (412) 317-6671 internationally. The conference ID for the replay will be 2303066.

## 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,<sup>i</sup> and transmission is on the rise. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.<sup>ii</sup> 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 CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.<sup>iii</sup> 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.<sup>iv</sup> Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.<sup>v</sup>

## 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 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

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

## About SD-101

SD-101, the Company's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in several clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy, in patients with advanced melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. Dynavax maintains all commercial rights to SD-101.

## About Dynavax

Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], was approved by the United States Food and Drug Administration in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit [www.dynavax.com](http://www.dynavax.com).

## Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding the commercialization of HEPLISAV-B, conduct of clinical trials of SD-101, including results from the Phase 1b/2 trial, planned optimal dosage for the Phase 3 trial, and potential value of SD-101 across multiple tumor types. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether we are able to continue to build the commercial infrastructure required to increase adoption of HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether prescribers and other key decision-makers will switch to HEPLISAV-B; whether we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101; and whether or not Dynavax and parties with whom we are collaborating may reach any future agreement on further studies or a more extensive collaboration beyond the clinical trials contemplated under the existing agreements, 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, 2017 and in Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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<sup>i</sup> CDC. <https://www.cdc.gov/hepatitis/hbv/bfaq.htm>.

<sup>ii</sup> CDC. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8>. Fig 3.2

<sup>iii</sup> CDC. <https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>.

<sup>iv</sup> CDC. [https://www.cdc.gov/diabetes/pubs/pdf/hepb\\_vaccination.pdf](https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf).

<sup>v</sup> 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		Six Months Ended	
	June 30,	2017	June 30,	2017
	2018		2018	
Revenues:				
Product revenues, net	\$ 1,254	\$ -	\$ 1,419	\$ -
Grant revenue	-	105	-	253
<b>Total revenues</b>	<b>1,254</b>	<b>105</b>	<b>1,419</b>	<b>253</b>
Operating expenses:				
Cost of sales - product	5,177	-	5,382	-
Cost of sales - amortization of intangible assets	2,298	-	4,715	-
Research and development	16,273	14,814	35,239	31,159
Selling, general and administrative	15,653	5,612	32,544	12,084
Restructuring	-	-	-	2,783
<b>Total operating expenses</b>	<b>39,401</b>	<b>20,426</b>	<b>77,880</b>	<b>46,026</b>
Loss from operations	(38,147 )	(20,321 )	(76,461 )	(45,773 )
Other income (expense):				
Interest income	1,153	235	1,893	380
Interest expense	(2,691 )	-	(3,852 )	-
Other income (expense), net	241	(232 )	18	(212 )
<b>Net loss</b>	<b>\$ (39,444 )</b>	<b>\$ (20,318 )</b>	<b>\$ (78,402 )</b>	<b>\$ (45,605 )</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.63 )</b>	<b>\$ (0.41 )</b>	<b>\$ (1.26 )</b>	<b>\$ (1.00 )</b>
<b>Weighted average shares used to compute basic and diluted net loss per share</b>	<b>62,346</b>	<b>49,700</b>	<b>62,047</b>	<b>45,787</b>

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

	June 30,	December 31,
	2018	2017
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 216,043	\$ 191,854
Inventories	5,112	312
Property and equipment, net	16,240	16,619
Intangible assets, net	16,364	1,306
Goodwill	2,189	2,244
Other assets	7,915	6,450
<b>Total assets</b>	<b>\$ 263,863</b>	<b>\$ 218,785</b>
<b>Liabilities and stockholders' equity</b>		
Total current liabilities	\$ 25,522	\$ 18,593
Total long-term liabilities	107,028	643
Stockholders' equity	131,313	199,549
<b>Total liabilities and stockholders' equity</b>	<b>\$ 263,863</b>	<b>\$ 218,785</b>

 [Primary Logo](#)