

# **Dynavax Reports First Quarter 2016 Financial Results**

BERKELEY, CA -- (Marketwired) -- 05/09/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the first quarter ended March 31, 2016.

The Company had \$166.8 million in cash, cash equivalents and marketable securities as of March 31, 2016, compared to \$196.1 million at December 31, 2015. The net loss for the first quarter of 2016 was \$27.0 million, compared to \$26.2 million for the first quarter of 2015.

#### First Quarter Financials

Total revenues for the three months ended March 31, 2016 increased by \$0.3 million, or 50%, compared to the same period in 2015.

Research and development expenses for the first quarter decreased by \$2.2 million, or 10%, compared to the same period in 2015, reflecting an increase in employee headcount and activities in preparation for the anticipated commercial launch of HEPLISAV-B<sup>™</sup> and a reduction in outside services expense due to lower activity related to HBV-23 following its completion in

the fourth quarter of 2015.

General and administrative expenses for the three months ended March 31, 2016, increased by \$3.3 million, or 68%, compared to the same period in 2015, as we added headcount and addressed information technology systems and other infrastructure needs in preparation for the anticipated commercial launch of HEPLISAV-B.

The net loss for the quarter ended March 31, 2016 was \$27.0 million, or \$0.70 per basic and diluted share compared to \$26.2 million, or \$0.97 per basic and diluted share for the quarter ended March 31, 2015.

#### **Recent Progress**

At the end of the quarter, the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for HEPLISAV-B, the company's vaccine for immunization against hepatitis B infection in adults 18 years of age and older. The FDA has established December 15th as the Prescription Drug User Fee Act (PDUFA) action date for the BLA.

"We are focused on working with the FDA to obtain approval of HEPLISAV-B before year end and on preparing for launch, including preparation for an advisory panel in case one is called, hiring of key commercial personnel, market and pricing research and manufacturing of launch inventory," said Dynavax Chief Executive Officer, Eddie Gray.

In April, we reported additional details from the HBV-23 pivotal Phase 3 HEPLISAV-B trial at the National Foundation for Infectious Diseases' (NFID) 19th Annual Conference on Vaccine Research (ACVR).

Also in April, we presented encouraging additional data from Part 1 of the Phase 1/2 study evaluating our lead immunotherapy product candidate, SD-101, in lymphoma patients. The clinical data, along with preclinical SD-101 data, were presented at the American Association for Cancer Research (AACR) Annual Meeting.

#### About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, uses TLR biology to discover and develop novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information visit <u>www.dynavax.com</u>.

#### Forward Looking Statements

This release contains forward-looking statements, including statements regarding anticipated approval and launch of HEPLISAV-B. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether there will be the need for additional studies, further manufacturing enhancements or other

activities, or other issues will arise that will negatively impact the review, duration of review and approval of the BLA by the FDA; whether we will successfully launch the product, possible claims against us, including enjoining sales of HEPLISAV-B based on the patent rights of others, and the potential size and value of approved indications addressable with HEPLISAV-B; initiation and completion of pre-clinical studies and clinical trials of our other product candidates, including SD-101, in a timely manner; 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; our ability to execute on our commercial strategies; whether our financial resources will be adequate without the need to obtain additional financing and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this release. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available.

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

	Three Months Ended March 31,				
				2015	
Revenues:					
Collaboration revenue	\$	895	\$	471	
Grant revenue		39		148	
Service and license revenue		8		8	
Total revenues		942		627	
Operating expenses:					
Research and development		20,067		22,220	
General and administrative		8,169		4,859	
Total operating expenses		28,236		27,079	
Loss from operations		(27,294)		(26,452)	
Interest income		225		27	
Interest expense		-		(247)	
Other income, net		46		455	
Net loss	\$	(27,023)	\$	(26,217)	
Basic and diluted net loss per share	\$	(0.70)	\$	(0.97)	
Weighted average shares used to compute basic and diluted net loss per share		38,472		27,065	

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

(Unaudited)

	March 31, 2016		December 31, 2015	
Assets				
Cash, cash equivalents and marketable securities	\$	166,847	\$	196,125
Property and equipment, net		15,894		13,804
Goodwill		2,127		2,043

Other assets	4,776	4,661
Total assets	\$ 189,644	\$ 216,633
Liabilities and stockholders ' equity		
Deferred revenues	\$ 1,759	\$ 2,654
Other liabilities	23,454	26,900
Total liabilities	 25,213	 29,554
Stockholders' equity	 164,431	 187,079
Total liabilities and stockholders' equity	\$ 189,644	\$ 216,633

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