November 7, 2016

Dynavax Reports Third Quarter 2016 Financial Results and Company Update

BERKELEY, CA -- (Marketwired) -- 11/07/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the third quarter and nine months ended September 30, 2016.

The Company had $109.6 million in cash, cash equivalents and marketable securities as of September 30, 2016, compared to $196.1 million at December 31, 2015. The net loss for the third quarter of 2016 was $34.7 million, compared to $30.1 million for the third quarter of 2015.

Recent Progress

HEPLISAV-B. In late August, the U.S. Food and Drug Administration (FDA) cancelled its previously scheduled Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to review the Biologics License Application (BLA) for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)]. The FDA indicated that remaining questions on the BLA will be addressed between Dynavax and the FDA review team. The Company has since provided responses to information requests by the FDA related to remaining questions. The FDA also confirmed in August that it will not include in its review of the BLA the immunogenicity data submitted by the Company related to sub-populations, including results in individuals with diabetes. The Company plans to submit these data as a supplemental BLA.

The Prescription Drug User Fee Act (PDUFA) date for the HEPLISAV-B BLA is December 15, 2016.

In late October, we reported sub-group results from HBV-23, demonstrating that HEPLISAV-B, when administered as two doses over one month, induced significantly higher seroprotection rates than the approved hepatitis B vaccine Engerix-B®, when administered as three doses over six months. This result was observed in all prespecified groups of study participants, including those with characteristics that are known to have a reduced immune response to currently licensed hepatitis B vaccines, including older age, high body mass index, diabetes mellitus, male gender and persons who smoke. In the total Phase 3 trial population, the rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups. The data were presented at the Infectious Diseases Society of America's (IDSA) annual IDWeek 2016 meeting in New Orleans.

Preparations for launch of HEPLISAV-B are continuing, including pre-commercial activities, manufacturing of launch inventory and continued infrastructure spending related to commercial development and information technology capabilities and related increases in headcount.

Immuno-oncology. In October we announced at the European Society of Medical Oncology (ESMO) Annual Congress 2016 the first presentation of findings from an ongoing Phase 1/2 study evaluating SD-101, Dynavax's intratumoral TLR9 agonist, in combination with Keytruda® (pembrolizumab), Merck's anti-PD-1 treatment. Early results evaluating five patients with metastatic melanoma for efficacy and 16 patients for safety were reported. In patients naïve to anti-PD-1 treatment objective responses were observed in three out of four (75%) including one complete response (CR) and two partial responses (PR's). One patient with progressive disease while receiving anti-PD-1 therapy was observed to have stable disease (SD). The drug combination was well-tolerated. No dose-limiting toxicities of the combination were observed in any dose cohort, and a maximum tolerated dose (MTD) was not identified. No immune-related adverse events were reported. Additional results from this study will be presented at future scientific meetings.

Financial. In late October we secured a $100 million loan commitment from Deerfield upon FDA approval of HEPLISAV-B and satisfaction of other conditions. We intend to use the net proceeds for general corporate purposes, including the commercialization of HEPLISAV-B.

Financials

Total revenues for the third quarter of 2016 were $0.2 million compared to $1.2 million for the same period in 2015. The $1.0 million decrease was due to the conclusion of our work under the research collaboration and license agreement with AstraZeneca for the clinical development of AZD 1419.

Research and development expenses for the third quarter of 2016 were $23.2 million compared to $24.1 million for the same period in 2015. This $0.9 million decrease was primarily due to reduction in outside services expense associated with the completion of HBV-23 in the fourth quarter of 2015, partially offset by an increase in employee headcount and

regulatory and manufacturing activities in preparation for the anticipated commercial launch of HEPLISAV-B.

General and administrative expenses for the third quarter of 2016 were $11.8 million compared to $5.5 million for the same period in 2015. This $6.3 million increase reflects expenses related to preparation for the commercial launch of HEPLISAV-B including additional headcount, information technology systems and infrastructure to support commercial development.

The net loss for the third quarter of 2016 was $34.7 million, or $0.90 per basic and diluted share, compared to $30.1 million, or $0.82 per basic and diluted share, for the same period in 2015.

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 www.dynavax.com.

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, a VRBPAC will be scheduled, whether the FDA will find our responses to their questions to be sufficient, 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; whether we will satisfy the conditions to the Deerfield loan; 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Collaboration revenue	$ -	$ 829	$ 2,578	$ 2,230
Grant revenue	162	359	289	608
Service and license revenue	-	-	884	527
Total revenues	162	1,188	3,751	3,365
Operating expenses:				
Research and development	23,234	24,105	66,051	66,011
General and administrative	11,766	5,524	29,086	15,481
Total operating expenses	35,000	29,629	95,137	81,492
Loss from operations	(34,838)	(28,441)	(91,386)	(78,127)
Interest income	170	33	615	78
Interest expense	-	(62)	-	(572)
Other (expense) income, net	(26)	17	68	360
Loss on extinguishment of debt	-	(1,671)	-	(1,671)
Net loss	$ (34,694)	$ (30,124)	$ (90,703)	$ (79,932)
Basic and diluted net loss per share	$ (0.90)	$ (0.82)	$ (2.36)	$ (2.43)
Weighted average shares used to compute basic and				

diluted net loss per share	38,512	36,532	38,493	32,880

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

	September 30, 2016	***December 31, 2015***
Assets		
Cash, cash equivalents and marketable securities	$ 109,551	$ 196,125
Property and equipment, net	18,739	13,804
Goodwill	2,100	2,043
Other assets	8,908	4,661
Total assets	$ 139,298	$ 216,633
Liabilities and stockholders' equity		
Deferred revenues	$ -	$ 2,654
Other liabilities	31,026	26,900
Total liabilities	31,026	29,554
Stockholders' equity	108,272	187,079
Total liabilities and stockholders' equity	$ 139,298	$ 216,633

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Source: Dynavax Technologies