August 5, 2016

Dynavax Reports Second Quarter 2016 Financial Results

BERKELEY, CA -- (Marketwired) -- 08/05/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the second quarter and six months ended June 30, 2016.

The Company had $139.0 million in cash, cash equivalents and marketable securities as of June 30, 2016, compared to $196.1 million at December 31, 2015. The net loss for the second quarter of 2016 was $29.0 million, or $0.75 per basic and diluted share, compared to $23.6 million, or $0.80 per basic and diluted share, for the second quarter of 2015.

Recent Progress

During the quarter, the U.S. Food and Drug Administration (FDA) established December 15, 2016 as the Prescription Drug User Fee Act (PDUFA) action date for its review of the Biologics License Application (BLA) for HEPLISAV-B™, the company's investigational vaccine for immunization against hepatitis B infection in adults 18 years of age and older. In August, the FDA informed the Company that its Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to discuss HEPLISAV-B at its meeting on November 16, 2016. The FDA has indicated it will communicate questions for the VRBPAC to address closer in time to the meeting date.

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

In June, we reported additional details from the HBV-23 pivotal Phase 3 HEPLISAV-B trial at the 76th Annual Scientific Sessions of the American Diabetes Association (ADA).

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 in April at the American Association for Cancer Research (AACR) Annual Meeting. Recently our collaborator, Merck, initiated a Phase 1 study of SD-101 in combination with its immunomodulator MK-1966 in cancer patients.

Financials

Total revenues for the second quarter of 2016 were $2.6 million compared to $1.6 million for the same period in 2015. Revenue primarily reflects research and development revenues from our collaboration with AstraZeneca.

Research and development expenses for the second quarter of 2016 were $22.8 million compared to $19.7 for the same period in 2015. This $3.1 million increase was primarily due to an increase in employee headcount and regulatory and manufacturing activities in preparation for the anticipated commercial launch of HEPLISAV-B, partially offset by a reduction in outside services expense associated with the completion of HBV-23 in the fourth quarter of 2015.

General and administrative expenses for the second quarter of 2016 were $9.2 million compared to $5.1 for the same period in 2015. This $4.1 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 second quarter of 2016 was $29.0 million, or $0.75 per basic and diluted share, compared to $23.6 million, or $0.80 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, 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Collaboration revenue	$ 1,683	$ 930	$ 2,578	$ 1,401
Grant revenue	88	101	127	249
Service and license revenue	876	519	884	527
Total revenues	2,647	1,550	3,589	2,177
Operating expenses:				
Research and development	22,750	19,686	42,817	41,906
General and administrative	9,151	5,098	17,320	9,957
Total operating expenses	31,901	24,784	60,137	51,863
Loss from operations	(29,254)	(23,234)	(56,548)	(49,686)
Interest income	220	18	445	45
Interest expense	-	(263)	-	(510)
Other income (expense), net	48	(112)	94	343
Net loss	$ (28,986)	$ (23,591)	$ (56,009)	$ (49,808)
Basic and diluted net loss per share	$ (0.75)	$ (0.80)	$ (1.46)	$ (1.70)
Weighted average shares used to compute basic and diluted net loss per share	38,496	29,335	38,491	29,230

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

	June 30, 2016	December 31, 2015
Assets		
Cash, cash equivalents and marketable securities	$ 138,989	$ 196,125
Property and equipment, net	17,448	13,804
Goodwill	2,080	2,043
Other assets	9,096	4,661
Total assets	$ 167,613	$ 216,633
Liabilities and stockholders ' equity		
Deferred revenues	$ -	$ 2,654
Other liabilities	28,843	26,900

Total liabilities	28,843	29,554
Stockholders' equity	138,770	187,079
Total liabilities and stockholders' equity	$ 167,613	$ 216,633

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Source: Dynavax Technologies