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Dynavax Reports Fourth Quarter and Year End 2016 Financial Results and Company Update

Key outcomes for multiple programs in 2017

BERKELEY, CA -- (Marketwired) -- 03/13/17 --

Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the fourth quarter and year ended December 31, 2016. The net loss for the year ended December 31, 2016 was $112.4 million, or $2.92 per share, compared to $106.8 million, or $3.25 per share, for the year ended December 31, 2015.

The Company had $81.4 million in cash, cash equivalents and marketable securities as of December 31, 2016, compared to $196.1 million at December 31, 2015. In addition, in the first quarter of 2017 the Company received proceeds of $23.3 million from sales of common stock under an at-the-market sales agreement.

"We are pleased with the continued progress of our immuno-oncology portfolio during 2016 and the recent promising clinical results from our combination trial in melanoma," said Eddie Gray, chief executive officer for Dynavax. "With the expansion of SD-101 into Phase 2 in both melanoma and head and neck cancer this quarter, our marketing application for HEPLISAV-B under review by the FDA and our strong cash balance, we are in position to deliver key outcomes for several programs during 2017."

Overview

During the last few years, the company has steadily advanced on its objective to evolve into an immuno-oncology company as it prepared for an anticipated launch of HEPLISAV-B™. Following receipt of the HEPLISAV-B Complete Response Letter (CRL) from the FDA in November 2016, the company was restructured to focus resources on the immuno-oncology portfolio and to enable HEPLISAV-B to advance through the FDA review process to an approval decision.

Recent Progress

SD-101

In early March, Dynavax presented promising clinical data from the dose escalation phase of an ongoing Phase 1b/2 study investigating SD-101 in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy developed by Merck, known as MSD outside the United States and Canada, in patients with metastatic melanoma. Encouraging overall response rates and complete response rates in patients naïve to anti-PD-1 therapy were observed.

Based on the results of the initial dose escalation phase this trial is being expanded into Phase 2 studies in both melanoma and head and neck cancer. Patients will be enrolled in two cohorts, those naïve to anti-PD-1 treatment and patients who have progressive disease on anti-PD-1 therapy. The trial is designed to build on the encouraging results seen in the anti-PD-1 naïve patient group while allowing for continued dose escalation in patients who have progressive disease on anti-PD-1 therapies.

HEPLISAV-B

In February, Dynavax filed its responses to the November 2016 CRL issued by the FDA for HEPLISAV-B, the company's vaccine candidate intended for immunization against hepatitis B infection in adults 18 years of age and older. The FDA has established August 10, 2017 as the Prescription Drug User Fee Act (PDUFA) action date.

As part of the January restructuring, the company suspended manufacturing activities, commercial preparations and other longer term investment related to HEPLISAV-B during the regulatory review period and reduced its global workforce by approximately 40%. If the product is approved, Dynavax plans to satisfy anticipated initial demand from existing stockpiled inventory and to scale up commercial activities based on market demand and investment priorities.

Financials

Total revenues were $7.3 million for the fourth quarter of 2016 and $11.0 million for the full year of 2016 compared to $0.7 million and $4.1 million for the same periods in 2015. The increase was primarily due to recognition of $7.2 million under the research collaboration and license agreement with AstraZeneca related to the initiation of a Phase 2a clinical trial by AstraZeneca.

Research and development expenses were $18.4 million for the fourth quarter of 2016 and $84.5 million for the full year of 2016 compared to $20.9 million and $86.9 million for the same periods in 2015. This decrease was primarily due to a reduction in outside services expense associated with the completion of the HBV-23 clinical study in the fourth quarter of 2015, partially offset by an increase in headcount as well as regulatory and manufacturing activities in preparation for the anticipated commercial launch of HEPLISAV-B.

General and administrative expenses were $8.2 million for the fourth quarter of 2016 and $37.3 million for the full year of 2016 compared to $6.7 million and $22.2 million for the same periods in 2015. This increase was primarily due to costs related to preparation for the anticipated commercial launch of HEPLISAV-B including additional headcount, information technology systems and infrastructure to support commercial development as well as costs related to sourcing a debt financing commitment.

About Dynavax

Dynavax is a clinical-stage immunology company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax is developing product candidates for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. Dynavax's lead product candidates are SD-101, an investigational cancer immunotherapeutic currently in Phase 1/2 studies, and HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. 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 HEPLISAV-B will be approved by the FDA; whether or not FDA will require additional clinical trials; whether there will be a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and if so, what the outcome of the VRBPAC will be and whether it will impact the timing of FDA review or negatively impact the review and approval of the BLA; whether additional studies or manufacturing process enhancements will be required, or other issues will arise that will delay the BLA review or negatively impact the review and decision whether to approve HEPLISAV-B; if approvable, whether the issues will negatively impact the potential scope of the label claims and nature of the label content for 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; 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; and other risks detailed in the "Risk Factors" section of our most recent periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, 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.

DYNAVAX TECHNOLOGIES CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 31,		***Years Ended December 31,***	
	2016	***2015***	***2016***	***2015***
Revenues:				
Collaboration revenue	$ 7,200	$ 535	$ 9,778	$ 2,765
Grant revenue	92	75	381	683
Service and license revenue	-	75	884	602
Total revenues	7,292	685	11,043	4,050

Operating expenses:				
Research and development	18,442	20,932	84,493	86,943
General and administrative	8,171	6,699	37,257	22,180
Total operating expenses	26,613	27,631	121,750	109,123
Loss from operations	(19,321)	(26,946)	(110,707)	(105,073)
Other (expense) income:				
Interest income	140	127	755	205
Interest expense	-	-	-	(572)
Other (expense) income, net	(2,560)	(43)	(2,492)	317
Loss on extinguishment of debt	-	-	-	(1,671)
Net loss	$ (21,741)	$ (26,862)	$ (112,444)	$ (106,794)
Basic and diluted net loss per share	$ (0.56)	$ (0.70)	$ (2.92)	$ (3.25)
Weighted average shares used to compute basic and diluted net loss per share	38,544	38,429	38,506	32,881

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	December 31, 2016	***December 31, 2015***
Assets		
Cash, cash equivalents and marketable securities	$ 81,415	$ 196,125
Property and equipment, net	17,174	13,804
Goodwill	1,971	2,043
Other assets	9,120	4,661
Total assets	$ 109,680	$ 216,633
Liabilities and stockholders' equity		
Deferred revenues	$ -	$ 2,654
Other liabilities	20,479	26,900
Total liabilities	20,479	29,554
Stockholders' equity	89,201	187,079
Total liabilities and stockholders' equity	$ 109,680	$ 216,633

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