

# Dynavax Announces First Quarter 2006 Financial Results and Outlook

BERKELEY, Calif., April 27 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported financial results for the first quarter 2006.

Total revenues for the first quarter ended March 31, 2006 were \$0.3 million compared to \$12.7 million for the same period in 2005. Revenues in the first quarter 2006 consist of grants awarded by the National Institute of Allergy and Infectious Diseases and by the Alliance for Lupus Research. Collaboration revenue for the quarter ended March 31, 2005 included accelerated recognition of \$7.0 million in deferred revenue following the end of Dynavax's collaboration with UCB Farchim in March 2005.

Total operating expenses were \$9.2 million for the first quarter 2006 compared to \$8.0 million for the same period in 2005. The increase in operating expenses is primarily due to increased clinical trial and manufacturing activities related to TOLAMBA™, the Company's ragweed allergy immunotherapy, and its HEPLISAV™ hepatitis B vaccine, as well as overall organizational growth.

Net loss for the first quarter ended March 31, 2006 was \$8.2 million, or \$0.27 per diluted share, compared to net income of \$5.1 million, or \$0.20 per diluted share for the same period in 2005. The net loss for the quarter ended March 31, 2006 resulted primarily from a decrease in collaboration revenue and increased operating expenses associated with the Company's clinical programs. The net loss per diluted share for the quarter ended March 31, 2006 reflects the completion of an underwritten public offering of 5,720,000 shares of the Company's common stock on November 10, 2005.

As of March 31, 2006, Dynavax reported that cash, cash equivalents and marketable securities totaled \$67.5 million compared to \$75.1 million at December 31, 2005.

"In the first quarter of 2006, we made substantial progress in advancing our lead clinical programs, TOLAMBA and HEPLISAV, as well as in implementing important strategic initiatives that strengthened our overall business," said Dino Dina, MD, president and chief executive officer. "As previously reported, we presented statistically significant results from the Phase 2/3 clinical trial of TOLAMBA at a major medical conference. We also announced the acquisition of Rhein Biotech GmbH, which expands our hepatitis B vaccine pipeline and secures GMP manufacturing assets for our growing vaccine franchise. We recently completed the formation of Symphony Dynamo through a collaborative financing arrangement with Symphony Capital Partners to support advancement of our second-generation TLR-agonist pipeline. We believe that these achievements have added significant depth and breadth to our development and commercial capabilities and enhanced our leadership in the TLR-agonist space."

## Major Safety & Efficacy TOLAMBA Trial Initiated

In the second quarter 2006, Dynavax initiated a major safety and efficacy trial for TOLAMBA. The Dynavax Allergic Rhinitis TOLAMBA Trial, or DARTT, is a multi-center, well-controlled study in up to 700 ragweed allergic subjects, aged 18 to 55 years, randomized into three arms: prior dosing regimen, high-intensity dosing regimen, and placebo.

- -- The prior dosing regimen consists of six injections over six weeks in a dose escalation of 1.2 micrograms (mcg), 3 mcg, 6 mcg, 15 mcg, 21 mcg and 30 mcg.
- -- The high intensity regimen consists of six injections over six weeks in a dose escalation of 3 mcg, 9 mcg, 30 mcg, 30 mcg, 30 mcg and 30 mcg.
- -- The primary endpoint is reduction in total nasal symptom scores (TNSS) in the high-intensity dosing arm compared to placebo after the second (2007) ragweed season.

By early 2007, the Company anticipates having a large and substantial data set for TOLAMBA. The key components will be: the one-year and the two-year safety and efficacy data from the recently completed Phase 2/3 trial; data derived from following subjects in the Phase 2/3 trial for an additional third (2006) year; the primary endpoint data from the trial in ragweed allergic children, which is currently underway; and one-year data from the 2006 ragweed season in the DARTT study. Dynavax anticipates that in early 2007, this expanded data base, which could potentially include approximately 1,000 treated subjects, could provide a foundation for determining the potential timeline to registration.

## **HEPLISAV Strategy Update**

The Company intends to focus its development activities and resources on exploiting the potential of HEPLISAV's demonstrated superiority over conventional hepatitis B vaccine in both the younger and older adult populations, and its potential in the

worldwide dialysis market. The Company intends to continue development of SUPERVAX as a two-dose vaccine for commercialization in developing countries.

The Company plans to initiate large-scale, Phase 3 safety and efficacy trials for HEPLISAV in the second half of 2006 in the younger adult population (under 40 years of age). These trials are planned for implementation in the US, Europe and Canada. The Company's Phase 1 trial in dialysis patients is ongoing, and in the second half of 2006, the Company anticipates initiating a Phase 2 trial in the dialysis population that would be conducted in Europe and/or Canada. The Phase 3 trial being conducted in Asia in the older adult population is also ongoing. Assuming the successful implementation of this broad development plan, the Company anticipates that its first regulatory filing for HEPLISAV could be accomplished in the first half of 2008.

#### Financial Outlook for 2006

The following statements are forward-looking and are based on current expectations. Actual results may differ materially. Except as expressly set forth below, these statements do not include the potential impact of any equity offerings, business collaborations or other transactions that may be closed or entered into after March 31, 2006.

We anticipate that total revenues for 2006 should be in the range of \$5 to \$7 million deriving from the Company's existing grants and anticipated service contract revenue from Rhein Biotech GmbH.

We anticipate that total operating expenses for 2006, including approximately \$3 million of non-cash stock compensation, should be in the range of \$49 to \$53 million, driven primarily by costs associated with advancing our clinical programs in ragweed allergy and hepatitis B vaccines which are expected to increase in the second half of 2006. We therefore anticipate that our loss from operations for 2006 should be in the range of \$41 to \$47 million. This excludes operating expenses incurred by Symphony Dynamo.

In the second quarter of 2006, we anticipate recording one-time cash-based charges of approximately \$17 million due to the Rhein Biotech GmbH acquisition and the structuring fees associated with the formation of Symphony Dynamo, including associated legal expenses and banking fees for both transactions.

The Company believes that Symphony Dynamo will be treated as a variable interest entity under FASB interpretation no. 46, "Consolidation of Variable Interest Entities," resulting in the consolidation of Symphony Dynamo's operating activities within Dynavax's financial statements. Symphony Dynamo's expenses are expected to be principally included in the Company's R&D expense. Accordingly, the portion of the Company's net loss attributed to Symphony Dynamo will be separately identified to reflect the losses borne by Symphony Dynamo's investors.

We anticipate that the Company's consolidated cash, cash equivalents and marketable securities should be approximately \$20 million at the end of 2006. This includes the impact of the aforementioned \$17 million in one-time transaction charges. Investments held by Symphony Dynamo are in addition to the Company's cash and are expected to include the balance of cash net of program expenses plus any additional capital contributions made during 2006.

## Conference Call Today

Dynavax will hold a conference call to discuss first quarter 2006 financial results today at 5:00 p.m. Eastern. Interested parties may listen to the webcast live at http://www.dynavax.com by clicking on the "Events" tab under the heading, "Investors." The webcast is also being distributed over CCBN's Investor Distribution Network to both institutional and individual investors. Individual investors can listen to the call through CCBN's individual investor center at http://www.fulldisclosure.com or by visiting any of the investor sites in CCBN's Individual Investor Network. Institutional investors can access the call via CCBN's password-protected event management site, StreetEvents, at http://www.streetevents.com. A telephonic replay will be available through May 4, 2006 by dialing 888-286-8010, access code: 62341632. International callers can dial 617-801-6888, access code: 62341632.

## **About Dynavax**

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR-9 agonist-based products to treat and prevent allergies, infectious diseases, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. Dynavax's pipeline includes: TOLAMBA, a ragweed allergy immunotherapeutic, for which a major safety and efficacy trial is currently underway, and that is in a supportive clinical trial in ragweed allergic children; HEPLISAV, a hepatitis B vaccine that is currently in a Phase 3 clinical trial; SUPERVAX, a hepatitis B vaccine; a cancer therapy currently in a Phase 2 clinical trial and anticipated to enter clinical trials in solid tumors; an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical trial; and preclinical programs in hepatitis B and hepatitis C therapy.

Dynavax cautions you that statements included in this press release that are not a description of historical facts are forwardlooking statements, including without limitation all statements regarding progress in the Company's clinical programs; implementation of strategies that strengthen the Company's business; the Company's revenue, operating expenses, loss from operations and cash balance estimates for 2006; statements regarding the accounting treatment of Symphony Dynamo by the Company: statements related to the potential for determining the potential timeline to registration for TOLAMBA: statements concerning the anticipated development plan for HEPLISAV and SUPERVAX; and statements related to plans to advance its clinical programs in ragweed allergy, hepatitis B, cancer, hepatitis B and hepatitis C therapy and the commercial opportunities for those programs. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Dynavax that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Dynavax's business including, without limitation, risks relating to: the progress and timing of its current and anticipated clinical trials in ragweed allergy and hepatitis B; difficulties or delays in developing, testing, obtaining regulatory approval of, producing and marketing its products; the scope and validity of patent protection for its products; competition from other pharmaceutical or biotechnology companies; its ability to obtain additional financing to support its operations; its ability to maintain effective financial planning and internal controls; and other risks detailed in the "Risk Factors" section of Dynavax's Annual Report on Form 10-K filed on March 16, 2006. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Dynavax undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

Three Months Ended

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

	March 31,	
	2006	2005
Revenues:		
Collaboration revenue	\$	\$12,199
Grant revenue	288	499
Total revenues	288	12,698
Operating expenses:		
Research and development (1)	6,592	5,655
General and administrative (2)	2,603	2,340
Total operating expenses	9,195	7,995
Income (loss) from operations	(8,907)	4,703
Interest income, net	735	367
Net income (loss)	\$(8,172)	\$5,070
Basic net income (loss) per share	\$(0.27)	\$0.21
Shares used to compute basic net income		
(loss) per share	30,487	24,722
Diluted net income (loss) per share	\$(0.27)	\$0.20
Shares used to compute diluted net income		
(loss) per share	30,487	25,580

- (1) Research and development expenses included non-cash stock-based compensation charges of \$0.3 million and \$0.1 million for the three months ended March 31, 2006 and 2005, respectively.
- (2) General and administrative expenses included non-cash stock-based compensation charges of \$0.4 million and \$0.2 million for the three months ended March 31, 2006 and 2005, respectively.

DYNAVAX TECHNOLOGIES CORPORATION SELECTED BALANCE SHEET DATA (In thousands)

(Unaudited)

	March 31, 2006	December 31, 2005
Cash, cash equivalents and		
marketable securities	\$67,491	\$75,110
Total assets	\$73,471	\$80,093
Total stockholders' equity	\$66,946	\$74,363

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