Dynavax Announces Second Quarter 2005 Financial Results

BERKELEY, Calif., July 28 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported financial results for the second quarter 2005.

Total revenues for the quarter ended June 30, 2005 were $1.0 million compared to $5.5 million for the same period in 2004. Revenues in the second quarter 2005 reflect a decrease in collaboration revenue following the March 2005 ending of the allergy collaboration between Dynavax and UCB Farchim (UCB) and the return to Dynavax of full rights to its allergy program. Revenues in the second quarter 2005 were driven by grants awarded by the National Institute of Allergy and Infectious Diseases and by the Alliance for Lupus Research. For the six months ended June 30, 2005, total revenues were $13.7 million, compared to $8.7 million for the same period in 2004. Collaboration revenue of $12.2 million for the six months ended June 30, 2005 included a one-time non-cash amount of $7.0 million resulting from the accelerated recognition of an upfront payment the Company received from UCB in 2004.

Total operating expenses for the quarter ended June 30, 2005 were $10.0 million compared to $8.6 million for the same period in 2004. The increase in operating expenses is primarily due to increased clinical trial and manufacturing activities related to the Company's ragweed allergy and hepatitis B vaccine programs, as well as overall organizational growth and expenses incurred to support public company compliance requirements. Total operating expenses for the six months ended June 30, 2005 were $18.0 million, compared to $15.8 million for the same period in 2004.

Net loss for the quarter ended June 30, 2005 was $8.6 million, or $0.35 per diluted share, compared to a net loss of $2.9 million, or $0.12 per diluted share for the same period in 2004. The increase in net loss was primarily driven by the decline in collaboration revenue. Net loss for the six months ended June 30, 2005 was $3.5 million or $0.14 per diluted share, compared to net loss of $6.8 million, or $0.38 per diluted share for the same period in 2004. The decrease in net loss for the six months ended June 30, 2005 resulted primarily from the one-time non-cash impact to collaboration revenue of $7.0 million.

As of June 30, 2005, cash, cash equivalents and marketable securities totaled $58.2 million compared to $65.8 million at December 31, 2004. The cash balance at June 30, 2005 includes cash proceeds that Dynavax received from UCB in April 2005.

"We believe that Dynavax delivered a strong first-half 2005 performance, highlighted by progress in advancing our lead clinical programs in ragweed allergy immunotherapy and HBV prophylaxis," said Dino Dina, MD, president and chief executive officer. "Enrollment in our AIC trial in ragweed allergic children exceeded our expectations, due to the enthusiastic efforts of our clinical investigators, and the second season booster phase in our two-year Phase 2/3 AIC trial has been completed. Our first pivotal HBV vaccine clinical trial is well underway, and we are on track to initiate the second pivotal trial in early 2006."

Continued Dr. Dina: "In anticipation of sustaining this rapid pace of development, we are continuing to sharpen our commercial strategies for both lead programs and believe that our AIC ragweed immunotherapy and our HBV vaccine represent significant commercial opportunities for Dynavax. We are pleased with our overall progress and anticipate a productive second half of 2005."

Second Quarter 2005 Highlights
-- Dynavax announced positive data from the primary endpoint analysis of its hepatitis B vaccine Phase 2/3 clinical trial. The data showed statistically significant superiority in protective antibody response and robustness of protective effect after three vaccinations when compared to GlaxoSmithKline's Engerix-B® vaccine in an older adult population that is difficult to immunize with conventional vaccine. The primary endpoint of the ongoing Phase 2/3 trial is seroprotection four weeks after administration of the third dose. The results of the primary endpoint analysis of the Phase 2/3 trial will be presented in a poster at the 45th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), to be held September 21-24, in New Orleans, Louisiana. The title of the poster is "Recombinant Hepatitis B Surface Antigen (rHBsAg) Co-administered with an Immunostimulatory Phosphorothioate Oligonucleotide (1018 ISS) Provides Superior Protection in Older Subjects."
-- Dynavax initiated a pivotal Phase 3 clinical trial of its hepatitis B vaccine. The pivotal Phase 3 trial is designed to compare the effectiveness of Dynavax's HBV vaccine to GlaxoSmithKline's Engerix-B HBV vaccine in an older adult population that is more difficult to immunize with conventional vaccine. The Phase 3 trial will enroll more than 400 seronegative adults (with no detectable HBV antibodies), aged 40-70, and is being conducted at study sites in Singapore, Taiwan, Korea and the Philippines. The trial is one-to-one randomized and double-blinded. The primary endpoint is seroprotection four weeks after the third vaccination (at month seven). Study subjects will also be followed for an additional five months. The trial is anticipated to be completed in the second half of 2006.
-- Dynavax announced that enrollment in the Company's clinical trial of its AIC (Amb a 1 immunostimulatory conjugate) ragweed

allergy immunotherapy in ragweed allergic children has exceeded expectations relative to speed of enrollment and number of study subjects. A total of 315 subjects aged six to 15 years have been enrolled in the 19- center trial in less than two and one-half months, exceeding the original expectation of 280 subjects. The Company attributes the rapid, expanded enrollment to strong investigator and subject interest in AIC due to its demonstrated tolerability and its potential to offer a more effective and convenient therapy for ragweed allergic children. This clinical trial is designed to be supportive of the Company's pivotal AIC Phase 3 trial, anticipated to begin in the first half of 2006.
-- AIC is currently being evaluated in a 462-patient, multi-site Phase 2/3 clinical trial. The Company announced that the re-enrollment rate for the second season of this two-year trial was also very high -- more than 86% of the initial patient population has remained in the study. Results from this trial are anticipated in the first quarter 2006.
-- Dynavax presented data from preclinical studies showing that the Company's ISS-based flu vaccine induces an immune response potentially capable of eradicating cells infected by highly divergent influenza viruses. It also has the potential to augment the protective antibody response generated by standard flu vaccine. These combined responses may provide effective immunity against multiple strains of the flu virus and may represent a potent new vaccine approach against divergent or pandemic strains of the flu virus. The data were presented at the Eighth Annual Conference on Vaccine Research in Baltimore, Maryland, in a poster entitled, "Influenza Nucleoprotein Conjugated to Immunostimulatory DNA as a Potential Vaccine Against Pandemic Influenza."

Dynavax will hold a conference call to discuss second quarter 2005 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 webcast 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 August 4, 2005 by dialing 888.286.8010, access code: 95875176. International callers can dial 617.801.6888, access code: 95875176.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative 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: a ragweed allergy immunotherapeutic, currently in a large-scale Phase 2/3 clinical trial, and in a supportive clinical trial in ragweed allergic children; a hepatitis B vaccine that is currently in a pivotal Phase 3 clinical trial; a cancer therapy currently in a Phase 2 clinical trial; and an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical trial.

Dynavax cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements, including without limitation all statements related to plans to advance its clinical programs in ragweed allergy and hepatitis B and the commercial opportunities for those programs, and the potential of its ISS technology in providing immunity against the flu virus. 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 anticipated Phase 3 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 18, 2005 and Dynavax's quarterly report on Form 10-Q filed on May 9, 2005. 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.

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,	
	2005	2004	2005	2004
Revenues:				
Collaboration revenue	$--	$5,131	$12,199	$7,875

Grant revenue	953	361	1,452	822
Total revenues	953	5,492	13,651	8,697
Operating expenses:				
Research and development(1)	7,493	6,510	13,148	11,781
General and administrative(2)	2,473	2,077	4,813	3,996
Total operating expenses	9,966	8,587	17,961	15,777
Loss from operations	(9,013)	(3,095)	(4,310)	(7,080)
Interest income, net	434	186	801	305
Net loss	$(8,579)	$(2,909)	$(3,509)	$(6,775)
Basic and diluted net loss per share	$(0.35)	$(0.12)	$(0.14)	$(0.38)
Shares used to compute basic and diluted net loss per share	24,745	24,594	24,734	17,720

(1) Research and development expenses included non-cash stock-based compensation charges of $0.1 million and $0.3 million for the three and six months ended June 30, 2005, respectively, and $0.3 million and $0.7 million for the three and six months ended June 30, 2004, respectively.

(2) General and administrative expenses included non-cash stock-based compensation charges of $0.2 million and $0.4 million for the three and six months ended June 30, 2005, respectively, and $0.2 million and $0.5 million for the three and six months ended June 30, 2004, respectively.

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

	June 30, 2005	December 31, 2004
Cash, cash equivalents and marketable securities	$58,234	$65,844
Total assets	$64,339	$73,646
Total stockholders' equity	$57,150	$59,876

SOURCE Dynavax Technologies Corporation
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