Dynavax Announces Fourth Quarter and Year-End 2004 Financial Results and 2005 Outlook

BERKELEY, Calif., Feb 15, 2005 /PRNewswire-FirstCall via COMTEX/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported financial results for the fourth quarter and year-end 2004. The Company's financial results reflect an increase in clinical development activity as Phase 2/3 programs in ragweed allergy immunotherapy and in hepatitis B prophylaxis advanced, as well as activity related to earlier stage preclinical programs, which are in line with the Company's goals and expectations.

As of December 31, 2004, Dynavax reported that cash, cash equivalents and marketable securities totaled $65.8 million compared to $71.5 million at September 30, 2004 and $29.1 million at December 31, 2003. The increase in cash from 2003 to 2004 is due primarily to proceeds from the Company's February 2004 initial public offering.

Net loss for the fourth quarter ended December 31, 2004 was $5.2 million, or $0.21 per share, compared to a net loss of $5.2 million, or $2.83 per share for the same period in 2003. For the year ended December 31, 2004, net loss was $16.0 million or $0.75 per share compared to $18.0 million or $10.04 per share for the comparable period in 2003. The net loss per share for the fourth quarter and year ended December 31, 2004 reflects the increase in common shares outstanding as a result of the Company's initial public offering in February 2004.

Revenue for the fourth quarter ended December 31, 2004 was $2.5 million compared to $0.7 million for the same period in 2003. For the year ended December 31, 2004, total revenues were $14.8 million, compared to $0.8 million for the comparable period of 2003. The increase in revenue is due to the Company's collaborative agreement with UCB Pharma in ragweed and grass allergies, which was initiated in 2004, and biodefense grants awarded by the National Institute of Allergy and Infectious Diseases.

Total operating expenses were $8.0 million for the fourth quarter 2004 compared to $5.3 million for the same period in 2003. Operating expenses for the year ended December 31, 2004 totaled $31.7 million as compared to $18.6 million in the comparable period of 2003. The increase in operating expenses is primarily due to increased clinical trial activities in the Company's ragweed allergy and hepatitis B vaccine programs, as well as preclinical work associated with government grants for biodefense programs. This increase also reflects higher expenses associated primarily with the expansion of our management team and additional requirements associated with being a public company.

"We believe that 2004 was a year of achievement, maturation and validation for Dynavax," said Dino Dina, MD, president and chief executive officer. "Our lead clinical programs in ragweed allergy immunotherapy, hepatitis B prophylaxis and asthma continue to advance and our robust preclinical pipeline in allergy, infectious disease and chronic inflammatory diseases is maturing. We believe that our ISS-based approach has been clinically validated and that our development programs represent large market opportunities for our Company. Our balance sheet is strong, our commercial strategies are taking shape, and we are confident that our management team possesses the breadth of expertise and experience to lead Dynavax through its next stages of development."

2004 Highlights

- Dynavax's hepatitis B vaccine induced significantly more rapid and more durable protective antibody responses than GlaxoSmithKline's Engerix-B™ in a Phase 2 trial in younger adults.
- Interim results from the hepatitis B vaccine Phase 2/3 trial in the older adult, more difficult to immunize population showed statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B™. The primary endpoint of the ongoing Phase 2/3 trial is seroprotection four weeks after administration of the third dose.
- The one-year interim analysis of the company's two-year Phase 2/3 clinical trial of AIC ragweed allergy immunotherapeutic showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season.
- Dynavax established a collaboration with the Riken Institute in Japan for development of ISS-based cedar tree allergy therapeutics. The

incidence of cedar allergy is at least 12-13% in Japan's population, but it can be as high as 26% in some areas, and has been directly linked to a significant reduction in health status, quality of life and productivity.

-- Dynavax presented preclinical data from studies in mice and in human cellular assays showing that the company's ISS-based peanut immunotherapy demonstrated potent inhibition of harmful allergic responses and induction of therapeutic immune responses to peanut allergen. Dynavax's peanut allergy product candidate consists of ISS linked to the peanut allergen, Ara h 2.

-- Dynavax introduced a new approach to treating autoimmune disease based upon a novel class of oligonucleotides, named immunoregulatory sequences (IRS), that specifically inhibit the toll-like receptor (TLR)-induced inflammatory response implicated in disease progression. Dynavax is exploring development of an IRS-based treatment for autoimmune disease, including systemic lupus erythematosus (SLE or lupus).

Outlook for 2005

"Our perspective on 2005 is optimistic," said Dr. Dina. "We anticipate initiating a broad pivotal Phase 3 program for our hepatitis B vaccine in multiple age groups. We plan to complete the current Phase 2/3 AIC ragweed allergy trial and initiate a supportive AIC trial in a pediatric indication, and we anticipate initiating a Phase 2b asthma trial. We also plan to develop commercialization strategies for our AIC and hepatitis B vaccine programs, which we believe represent large commercial opportunities for the company. We look forward to an expeditious completion of the review of our collaboration with UCB Pharma concerning our seasonal allergy program and anticipate a mutually favorable resolution."

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 December 31, 2004.

We anticipate that the Company's cash, cash equivalents and marketable securities should be in the range of $30 million to $33 million at the end of 2005.

We anticipate that operating expenses for 2005, excluding non-cash stock-based compensation expense, should be in the range of $39 million to $43 million, driven primarily by the increase in clinical development activities related to the company's anticipated supportive Phase 3 ragweed allergy trial, Phase 3 hepatitis B vaccine trial and Phase 2b asthma trial.

We anticipate that revenue for 2005 will be in the range of $7 million to $9 million. The difference between revenue in 2004 and 2005 primarily reflects collaboration revenue recorded in 2004 for start-up of the Phase 2/3 AIC clinical trial.

Dynavax will hold a conference call to discuss fourth quarter and year-end 2004 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 February 22, 2005 by dialing 888-286-8010, conference identification number 12744711. International callers can dial 617-801-6888, conference identification number 12744711.

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. ISS are being developed in three initial indications: a ragweed allergy immunotherapeutic, currently in a Phase 2/3 clinical trial; a hepatitis B vaccine that is currently in a Phase 2/3 clinical trial; and an asthma immunotherapeutic that has completed a Phase 2 exploratory 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, hepatitis B and asthma, and demonstrate the potential of its ISS technology. 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; expectations concerning achievement of a mutually favorable outcome following completion of the review of the seasonal allergy development and commercialization collaboration between Dynavax and UCB Pharma; 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 30, 2004, and in the section titled "Additional Factors That May Affect Future Results" within Dynavax's quarterly report on Form 10-Q filed on November 8, 2004. 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

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2004	2003	2004	2003
Revenues:				
Collaboration revenue	$2,138	$--	$13,782	$--
Grant revenue	317	707	1,030	826
Total revenues	2,455	707	14,812	826
Operating expenses:				
Research and development (1)	5,420	4,258	23,129	13,786
General and administrative (2)	2,530	1,072	8,543	4,804
Total operating expenses	7,950	5,330	31,672	18,590
Loss from operations	(5,495)	(4,623)	(16,860)	(17,764)
Interest income, net	332	83	889	412
Net loss	(5,163)	(4,540)	(15,971)	(17,352)
Deemed dividend upon issuance of ordinary shares of Dynavax Asia	--	(633)	--	(633)
Net loss attributable to common stockholders	$(5,163)	$(5,173)	$(15,971)	$(17,985)
Basic and diluted net loss per share attributable to common stockholders	$(0.21)	$(2.83)	$(0.75)	$(10.04)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	24,622	1,827	21,187	1,791

(1) Research and development expenses included non-cash stock-based compensation charges of $0.2 million and $0.5 million for the fourth quarter of 2004 and 2003, respectively, and $1.3 million for each of the years ended December 31, 2004 and 2003.

(2) General and administrative expenses included non-cash stock-based compensation charges of $0.6 million and $0.1 million for the fourth quarter of 2004 and 2003, respectively, and $1.5 million and $0.5 million for the years ended December 31, 2004 and 2003, respectively.

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

(Unaudited)

	December 31,	
	2004	2003
Cash, cash equivalents and marketable securities	$65,844	$29,097
Total assets	$73,646	$31,585
Minority interest in Dynavax Asia	$--	$14,733

Convertible preferred stock	$--	$83,635
Total stockholders' equity (net capital deficiency)	$59,876	$(71,932)

SOURCE Dynavax Technologies Corporation

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