Dynavax Announces Fourth Quarter and Year-End 2008 Financial Results

Provides Corporate Update and 2009 Financial Outlook

BERKELEY, Calif., Mar 02, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported financial results for the fourth quarter and year ended December 31, 2008 and provided a corporate update and financial outlook for 2009.

"We are making progress in our discussions with the regulatory authorities in the United States and Europe regarding the development of HEPLISAV™, our Phase 3 hepatitis B vaccine that has demonstrated significant clinical benefits based on our trials," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "Our pharmaceutical partnerships, funding agreements, and stringent management of our cash provide Dynavax with the resources to reach several value inflection points for our diversified pipeline of products over the next 12 to 24 months."

Dynavax reported $68.5 million in cash, cash equivalents, marketable securities and investments held by Symphony Dynamo, Inc. (SDI), cumulatively referred to as total cash, at December 31, 2008. This compared to $64.3 million at September 30, 2008 and $88.2 million at December 31, 2007. Total cash at December 31, 2008 included an initial payment of $10 million from GlaxoSmithKline as part of a worldwide strategic alliance.

Total revenues were $11.9 million for the fourth quarter 2008, compared to $9.3 million for the fourth quarter 2007. Total revenues were $37.1 million for the year ended December 31, 2008, compared to $14.1 million for the same period of 2007. The significant increase in revenues for the fourth quarter and full year 2008 primarily was attributable to research and development funding for HEPLISAV and to a lesser extent the recognition of non-cash deferred revenue following the December 2008 termination of the Merck & Co., Inc. collaboration for HEPLISAV.

On a *pro forma* basis, including collaboration funding from SDI, revenues were $12.7 million for the fourth quarter 2008, compared to $11.4 million for the fourth quarter 2007, and $42.4 million for the full year 2008, compared to $24.7 million for the full year 2007.

Total operating expenses were $10.1 million for the fourth quarter 2008, compared to $23.3 million for the fourth quarter 2007. Total operating expenses were $61.2 million for the year ended December 31, 2008, compared to $85.2 million for the same period of 2007. The decrease in operating expenses for the fourth quarter and full year 2008 was primarily due to a reduction in clinical development costs associated with HEPLISAV and the discontinuation of clinical development for the TOLAMBA ragweed allergy program. Total operating expenses for 2007 also included a one-time payment for a license to certain patent rights for the commercialization of HEPLISAV.

On a *pro forma* basis, excluding the one-time and other non-cash charges for stock-based compensation and amortization of intangible assets, operating expenses were $9.1 million for the fourth quarter 2008, compared to $22.0 million for the fourth quarter 2007, and $57.0 million for the full year 2008, compared to $75.7 million for the full year 2007.

The tables included as part of this press release provide a reconciliation of GAAP revenues and operating expenses to *pro forma* revenues and operating expenses.

Net income was $3.1 million, or $0.08 per share, for the fourth quarter 2008, compared to a net loss of $12.1 million, or $0.30 per share, for the fourth quarter 2007. Net loss for the year ended December 31, 2008 was $20.8 million, or $0.52 per share, compared to a net loss of $60.0 million, or $1.51 per share, for the same period of 2007. The net income for the fourth quarter and improvement in net loss for the full year 2008 reflected the increase in revenues from the Company's collaboration agreements and decrease in operating expenses. The net income for the fourth quarter 2008 is due to revenue recognized from non-recurring events and Dynavax does not expect to report quarterly net income during 2009.

Corporate Update

Phase 3 HEPLISAV hepatitis B vaccine - Dynavax is seeking clarification of the remaining regulatory requirements for development and licensure of HEPLISAV in the United States and Europe and expects to have sufficient information in the first half of 2009 to determine a path forward, if any. Concurrently, Dynavax is pursing potential pharmaceutical partnerships and financing arrangements to complete clinical development if the regulatory feedback is positive. Dynavax also expects to report complete Phase 3 PHAST clinical study data from healthy adults in the second quarter of 2009.

Phase 1b SD-101 hepatitis C therapy - In mid-year 2009, Dynavax expects to report top-line data from an ongoing Phase 1b trial for SD-101 therapy for hepatitis C virus (HCV). This trial is being funded entirely under the SDI arrangement.

Phase 1b DV-601 hepatitis B therapy - In mid-year 2009, Dynavax expects to begin enrolling patients in a Phase 1b trial for DV-601 therapy for hepatitis B virus (HBV).

Phase 1a studies - In the second half of 2009, Dynavax expects phase 1a studies will be initiated for AZD1419 for asthma, under a partnership with AstraZeneca, and DV1079 for autoimmune and inflammatory diseases, under a partnership with GlaxoSmithKline. In the first half of 2010, the Company plans to initiate a Phase 1a study for its Universal Flu vaccine, which is under a supply and option agreement with Novartis.

2009 Financial Outlook

The following statements are forward-looking and are based on current expectations as of the date of this press release. Actual results may differ materially and Dynavax undertakes no duty to update these statements.

The Company's total cash is projected to be approximately $50 million at December 31, 2009, compared to $68.5 million at December 31, 2008. These projections do not include the potential impact of any new collaborations or other transactions that may be closed or entered into after March 2, 2009.

Total *pro forma* revenues for 2009 are expected to be in the range of $48 to $56 million, compared to $42.6 million for 2008. The *pro forma* revenues for 2009 include approximately $28 million of non-cash deferred revenue to be recognized following the termination of the HEPLISAV collaboration.

Total *pro forma* operating expenses for 2009 are projected to be in the range of $52 to $60 million, compared to $57.0 million for 2008.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) based product candidates. Based on Dynavax's proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax has partnerships with leading pharmaceutical companies such as GlaxoSmithKline, AstraZeneca AB, and Novartis as well as funding from Symphony Dynamo, Inc. and the National Institutes of Health. For more information visit www.dynavax.com.

Forward Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements related to the nature and timing of communications with the FDA regarding the current HEPLISAV clinical hold, planned initiation and completion of other clinical trials, and our projected cash position and operating results. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether the provision of additional information requested by the FDA is found to be satisfactory, whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies and difficulties or delays in development, initiation and completion of clinical trials of our product candidates, the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process; obtaining regulatory approval for HEPLISAV; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K and our Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

DYNAVAX TECHNOLOGIES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2008	2007	2008	2007

Revenues:				
Collaboration revenue	$ 10,231	$ 7,097	$ 31,666	$ 9,315
Grant revenue	972	1,198	2,999	3,046
Service and license revenue	742	1,000	2,429	1,732
Total revenues	11,945	9,295	37,094	14,093
Operating expenses:				
Research and development (1)	6,249	18,183	44,771	65,888
General and administrative (2)	3,559	4,879	15,463	18,293
Amortization of intangible assets	245	250	980	1,004
Total operating expenses (3)	10,053	23,312	61,214	85,185
Income (loss) from operations	1,892	(14,017)	(24,120)	(71,092)
Interest and other income, net	284	1,571	1,741	4,165
Loan forgiveness	--	--	5,000	--
Interest expense	(16)	(1,631)	(9,157)	(1,719)
Income (loss) including noncontrolling interest in SDI.	2,160	(14,077)	(26,536)	(68,646)
Amount attributed to noncontrolling interest in SDI	939	2,001	5,707	8,675
Net income (loss)	$ 3,099	$ (12,076)	$ (20,829)	$ (59,971)
Basic and diluted net income (loss) per share	$ 0.08	$ (0.30)	$ (0.52)	$ (1.51)
Shares used to compute basic and diluted net income (loss) per share	39,854	39,765	39,819	39,746

(1) Research and development expenses included non-cash stock-based compensation charges of $0.4 million and $1.4 million for the fourth quarter and year ended December 31, 2008, respectively. Research and development expenses included non-cash stock-based compensation charges of $0.3 million and $1.1 million for the fourth quarter and year ended December 31, 2007, respectively.

(2) General and administrative expenses included non-cash stock-based compensation charges of $0.4 million and $1.8 million for the fourth quarter and year ended December 31, 2008, respectively. General and administrative expenses included non-cash stock-based compensation charges of $0.7 million and $2.4 million for the fourth quarter and year ended December 31, 2007, respectively.

(3) Total operating expenses excluding non-cash stock-based compensation charges were $9.3 million and $58.0 million for the fourth quarter and year ended December 31, 2008, respectively. Total operating expenses excluding non-cash stock-based compensation charges were $22.3 million and $81.7 million for the fourth quarter and year ended December 31, 2007, respectively.

DYNAVAX TECHNOLOGIES CORPORATION

RECONCILIATION OF GAAP REVENUES TO PRO FORMA REVENUES

(In thousands)

(Unaudited)

	Three Months Ended		**Year Ended**	
	December 31,		**December 31,**	
	2008	**2007**	**2008**	**2007**
GAAP revenues	$ 11,945	$ 9,295	$ 37,094	$ 14,093
ADD:				
Collaboration funding incurred under SDI programs	744	2,115	5,349	10,602
Pro forma revenues (1)	$ 12,689	$ 11,410	$ 42,443	$ 24,695

(1) These *pro forma* amounts are intended to illustrate the company's revenues to be inclusive of collaboration funding provided for the SDI programs. The collaboration funding is reflected in the amount attributed to the noncontrolling interest in SDI in the company's consolidated statement of operations, but would have been reported as revenue if SDI's results of operations were not consolidated with those of the company. Management of the company believes the *pro forma* results are a more useful measure of the company's revenues because it provides investors the ability to evaluate the company's operations in the manner that management uses to assess the continued progress of programs funded under the SDI arrangement. These *pro forma* results are not in accordance with, or an alternative for, generally accepted accounting principles and may be different from *pro forma* measures used by other companies.

DYNAVAX TECHNOLOGIES CORPORATION

RECONCILIATION OF GAAP OPERATING EXPENSES TO PRO FORMA OPERATING EXPENSES

(In thousands)

(Unaudited)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2008	2007	2008	2007
GAAP operating expenses	$ 10,053	$ 23,312	$ 61,214	$ 85,185
LESS:				
Licensing fee	--	--	--	5,000
Stock-based compensation expense	717	1,050	3,205	3,531
Amortization of intangible assets	245	250	980	1,004
Pro forma operating expenses (2)	$ 9,091	$ 22,012	$ 57,029	$ 75,650

(2) These pro forma amounts are intended to illustrate the company's operating expenses excluding certain one-time and non-cash charges in accordance with the financial statements that management uses to evaluate the company's operations. These pro forma results are not in accordance with, or an alternative for, generally accepted accounting principles and may be different from pro forma measures used by other companies.

DYNAVAX TECHNOLOGIES CORPORATION

SELECTED BALANCE SHEET DATA

(In thousands)

	December 31, 2008	December 31, 2007
Assets	(unaudited)	(audited)
Cash and cash equivalents and marketable securities (1)	$ 68,476	$ 88,248
Property and equipment, net	9,510	7,314
Goodwill	2,312	2,312
Other intangible assets, net	2,259	3,239
Other assets	8,066	19,336
Total assets	$ 90,623	$ 120,449
Liabilities, noncontrolling interest and stockholders'equity		
Accounts payable	$ 905	$ 4,418
Accrued liabilities	6,816	12,059
Current portion of deferred revenue	33,133	3,427
Noncurrent portion of deferred revenue	18,512	40,792
Liability from Program Option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	101	5,622
Noncontrolling interest in SDI	2,634	8,341
Stockholders' equity	13,522	30,790
Total liabilities, noncontrolling interest and stockholders' equity	$ 90,623	$ 120,449

(1) These amounts also include investments held by SDI of $25.1 million and $31.6 million as of December 31, 2008 and 2007, respectively.

SOURCE: Dynavax Technologies Corporation

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