

Dynavax Announces Third Quarter 2009 Financial Results

- To Host Webcast of Conference Call Today at 4:30 pm EDT -

BERKELEY, Calif., Oct 22, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) today reported financial results for the third quarter and nine months ended September 30, 2009.

Dynavax reported \$46.4 million in cash, cash equivalents, marketable securities and investments held by Symphony Dynamo, Inc. (SDI), collectively referred to as total cash, at September 30, 2009. This compared to \$53.0 million at June 30, 2009.

"During the third quarter, we began the first of two planned Phase 3 registration trials for our lead product HEPLISAVTM and our goal is to complete these trials within 24 months," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "With our commercialization strategy focused on directly serving high-value markets in the U.S. and a partnering strategy to expand into broader market segments and internationally, HEPLISAV can become a company-building product for Dynavax."

Total revenues for the third quarter 2009 were \$2.9 million, compared to \$8.9 million reported for the third quarter in 2008. The decline in total revenues for the third quarter was primarily due to a decrease in collaboration revenue following the termination of the Merck & Co., Inc. collaboration for HEPLISAV. Total revenues were \$38.1 million for the nine months ended September 30, 2009, compared to \$25.1 million for the same period in 2008. The increase in revenues for the nine months ended September 30, 2009 was primarily attributable to the recognition of \$28.5 million of non-cash deferred revenue that was accelerated upon the termination of the Merck collaboration.

On a *pro forma* basis, including collaboration funding from SDI and excluding the non-cash deferred revenue from the Merck collaboration, revenues were \$3.9 million and \$12.2 million, respectively, for the third quarter and nine months ended September 30, 2009, compared to \$9.9 million and \$27.9 million for the same period in 2008.

Total operating expenses were \$13.6 million for the third quarter 2009, compared to \$14.6 million for the third quarter 2008. Total operating expenses were \$41.6 million for the nine months ended September 30, 2009, compared to \$51.2 million for the same period in 2008. The decrease in operating expenses for 2009 was primarily due to a reduction in clinical development costs associated with HEPLISAV and the discontinuation of development for the TOLAMBA ragweed allergy program in May 2008.

On a *pro forma* basis, excluding the non-cash charges for stock-based compensation and amortization of intangible assets, operating expenses were \$12.5 million and \$38.8 million, respectively, for the third quarter and nine months ended September 30, 2009, compared to \$13.3 million and \$47.9 million for the same periods in 2008.

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.

The net loss of \$9.5 million, or \$0.24 per share, reported for the third quarter 2009 increased from the net loss of \$5.4 million, or \$0.14 per share, for the same period in 2008. The increase in net loss for third quarter is due to a decrease in collaboration revenue partially offset by a decrease in total operating expenses. The net loss of \$0.3 million, or \$0.01 per share, reported for the nine months ended September 30, 2009 significantly improved compared to the net loss of \$23.9 million, or \$0.60 per share, for the same period in 2008. The improvement in net loss for the nine months ended September 30, 2009 is due to the recognition of non-cash deferred revenue and a decrease in total operating expenses.

HEPLISAV Phase 3 Hepatitis B Vaccine - In a previously completed pivotal Phase 3 trial, HEPLISAV provided increased, rapid protection with fewer doses than current licensed vaccines. To complete the registration trials for HEPLISAV, Dynavax has begun vaccinating chronic kidney disease patients in a Phase 3 trial and expects to begin a Phase 3 lot-to-lot consistency trial in adults over 40 years of age in early 2010. Dynavax will present chronic kidney disease patient data for HEPLISAV at the Infectious Disease Society of America (IDSA) meeting in Philadelphia, Pennsylvania, October 29 through November 1, 2009.

Phase 1b Hepatitis C Therapy - SD-101 is a second generation TLR-9 agonist which is being developed in an ongoing Phase 1b trial funded through the SDI agreement. Dynavax and Symphony Capital are evaluating future development options for this hepatitis C therapy.

Phase 1b Hepatitis B Therapy - In 2009, Dynavax plans to begin a Phase 1b trial of DV-601, the first hepatitis B therapy to combine both surface and core HBV antigens.

Preclinical Programs - Dynavax's preclinical programs include a unique Universal Flu vaccine and programs partnered with pharmaceutical partners AstraZeneca and GlaxoSmithKline.

Conference Call

Dynavax will webcast a conference call today at 4:30 p.m. EDT (1:30 p.m. PDT). The live and archived webcast can be accessed by visiting the investor relations section of the Company's Web site at http://investors.dynavax.com/newsevents.cfm.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide more rapid and increased protection with fewer doses than current licensed vaccines. 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 relating to planned clinical trials and our commercialization strategy for HEPLISAV. 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 successful clinical and regulatory development and approval of HEPLISAV can occur in a timely manner or without significant additional studies or difficulties or delays in development, whether the studies can support registration for commercialization of HEPLISAV, initiation and completion of clinical trials of the Company's other 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; the Company's ability to obtain additional financing to support the development and commercialization of HEPLISAV and its other operations, possible claims against the Company based on the patent rights of others; and other risks detailed in the "Risk Factors" section of our current periodic reports with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Information on Dynavax's website at www.dynavax.com is not incorporated by reference in the Company's current periodic reports with the SEC.

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

· ·	Three Months Ended <u>September 30.</u>				Nine Months Ended <u>September 30,</u>			
		<u> 2009</u>		<u>2008</u>		<u> 2009</u>		<u>2008</u>
Revenues:								
Collaboration revenue	\$	1,791	\$	7,960	\$	34,079	\$	21,435
Grant revenue		887		581		2,921		2,027
Service and license revenue		223		316		1,129		1,687
Total revenues		2,901	_	8,857		38,129		25,149
Operating expenses:								
Research and development (1)		9,631		10,456		29,202		38,522
General and administrative (2)		3,736		3,913		11,693		11,904
Amortization of intangible assets		245		245		735		735
Total operating expenses (3)		13,612	_	14,614	_	41,630		51,161
Loss from operations		(10,711)		(5,757)		(3,501)		(26,012)
Interest income		18		313		174		1,461
Loan Forgiveness				5,000				5,000
Interest expense		(93)		(6,457)		(120)		(9,141)
Other income (expense)		80	_	(232)	_	(40)		(4)
Net loss.		(10,706)		(7,133)		(3,487)		(28,696)
Add: Losses attributed to noncontrolling interest in SDI		1,200		1,713		3,192		4,768
Net loss attributable to Dynavax	\$	(9,506)	\$	(5,420)	\$	(295)	\$	(23,928)

Basic and diluted net loss per share	\$ (0.24)	\$ (0.14)	\$ (0.01)	\$ (0.60)
Shares used to compute basic and diluted net loss per	 			
share	40,153	39,831	39,990	39,807

- (1) Research and development expenses included non-cash stock-based compensation charges of \$0.4 million and \$0.8 million for the three and nine months ended September 30, 2009, respectively. Research and development expenses included non-cash stock-based compensation charges of \$0.5 million and \$1.0 million for the three and nine months ended September 30, 2008, respectively.
- (2) General and administrative expenses included non-cash stock-based compensation charges of \$0.5 million and \$1.3 million for the three and nine months ended September 30, 2009, respectively. General and administrative expenses included non-cash stock-based compensation charges of \$0.6 million and \$1.4 million for the three and nine months ended September 30, 2008, respectively.
- (3) Total operating expenses excluding non-cash stock-based compensation charges were \$12.7 million and \$39.5 million for the three and nine months ended September 30, 2009, respectively. Total operating expenses excluding non-cash stock-based compensation charges were \$13.6 million and \$48.7 million for the three and nine months ended September 30, 2008, respectively.

DYNAVAX TECHNOLOGIES CORPORATION RECONCILIATION OF GAAP REVENUES TO PRO FORMA REVENUES (In thousands)

(Unaudited)

	Three Months Septembe		Nine Months Ended September 30,			
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>		
GAAP revenues ADD:	\$ 2,901	\$ 8,857	\$ 38,129	\$ 25,149		
Collaboration funding incurred under SDI programs LESS:	1,009	1,642	2,551	4,605		
Non-cash deferred revenue from Merck collaboration		596	28,485	1,879		
Pro forma revenues (1)	\$ 3,910	\$ 9,903	\$ 12,195	\$ 27,875		

(1) These pro forma amounts are intended to illustrate the Company's revenues including collaboration funding provided for the SDI programs and excluding certain non-cash items. 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 operating programs. 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 September 30,			Nine Months Ended <u>September 30,</u>			
		<u>2009</u>		<u>2008</u>	<u>2009</u>		<u>2008</u>
GAAP operating expenses	\$	13,612	\$	14,614	\$ 41,630	\$	51,161
LESS:							
Stock-based compensation expense		916		1,052	2,102		2,488
Amortization of intangible assets		245		245	735		735
Pro forma operating expenses (2)	\$	12,451	\$	13,317	\$ 38,793	\$	47,938

(2) These pro forma amounts are intended to illustrate the Company's operating expenses excluding certain 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)

	September 3 <u>2009</u>	0, Ε	December 31, <u>2008</u>
Assets	(unaudited)		
Cash and cash equivalents and marketable securities (1)	\$ 46	5,432 \$	68,476

Property and equipment, net Goodwill Other intangible assets, net	8,507 2,312 1,524	9,510 2,312 2,259
Other assets	2,869	8,066
Total assets	\$ 61,644	\$ 90,623
Liabilities and stockholders'equity		
Accounts payable	\$ 1,037	\$ 905
Accrued liabilities	7,356	6,816
Current portion of deferred revenue	3,127	33,133
Noncurrent portion of deferred revenue	17,440	18,512
Liability from Program Option exercised under the SDI collaboration	15,000	15,000
Other long-term liabilities	160	101
Stockholders' equity	17,524	16,156
Total liabilities and stockholders' equity	\$ 61,644	\$ 90,623

⁽¹⁾ These amounts also included investments held by SDI of \$21.7 million and \$25.1 million as of September 30, 2009 and December 31, 2008, respectively.

SOURCE: Dynavax Technologies Corporation

Dynavax Technologies Corporation
Jennifer Lew, 510-665-7217
Vice President, Finance
jlew@dynavax.com
Amy Figueroa, 510-665-7211
Investor Relations & Corporate Communications
afigueroa@dynavax.com

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