

Dynavax Announces Second Quarter 2009 Financial Results

BERKELEY, Calif., Aug 04, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported financial results for the second quarter and six months ended June 30, 2009.

Dynavax reported \$53.0 million in cash, cash equivalents, marketable securities and investments held by Symphony Dynamo, Inc. (SDI), collectively referred to as total cash, at June 30, 2009. This compared to \$60.5 million at March 31, 2009.

Total revenues for the second quarter 2009 were \$15.9 million, compared to \$10.0 million reported for the second quarter in 2008. Total revenues were \$35.2 million for the six months ended June 30, 2009, compared to \$16.3 million for the same period in 2008. The significant increase in revenues for the second quarter and six months ended June 30, 2009 was primarily attributable to the recognition of \$12.9 million and \$28.5 million, respectively, of non-cash deferred revenue that was

accelerated following the announcement of the termination of the Merck & Co., Inc. collaboration for HEPLISAVTM, Dynavax's investigational hepatitis B vaccine. The Company completed the recognition of the non-cash deferred revenue relating to the HEPLISAV collaboration in the second quarter 2009.

On a *pro forma* basis, including collaboration funding from SDI and excluding the non-cash deferred revenue from the Merck collaboration, revenues were \$3.7 million and \$8.3 million, respectively, for the second quarter and six months ended June 30, 2009, compared to \$10.8 million and \$18.0 million for the same period in 2008.

Total operating expenses were \$13.0 million for the second quarter 2009, compared to \$16.6 million for the second quarter 2008. Total operating expenses were \$28.0 million for the six months ended June 30, 2009, compared to \$36.5 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 TOLAMBATM 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 \$12.1 million and \$26.3 million, respectively, for the second quarter and six months ended June 30, 2009, compared to \$15.6 million and \$34.6 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 income of \$4.1 million, or \$0.10 per share, reported for the second quarter 2009 improved from the net loss of \$6.1 million, or \$0.15 per share, for the same period in 2008. The net income of \$9.2 million, or \$0.23 per share, reported for the six months ended June 30, 2009 was also significantly improved compared to the net loss of \$18.5 million, or \$0.47 per share, for the same period in 2008. The improvement in net loss for 2009 is due to the recognition of non-cash deferred revenue and a decrease in total operating expenses.

Program Update

Phase 3 HEPLISAV Hepatitis B Vaccine - As reported in a separate press release today, Dynavax has met with the U.S. Food and Drug Administration (FDA) to discuss its plans to resume clinical development for HEPLISAV.

Clinical-Stage Programs - Dynavax's clinical-stage programs include Phase 1b hepatitis C and hepatitis B therapies.

Hepatitis C Therapy - SD-101 is a second generation TLR-9 agonist being developed for hepatitis C and is entirely funded through the SDI agreement. Phase 1 studies have demonstrated SD-101's safety, tolerability, and antiviral activity and Dynavax is reviewing future development options with Symphony Capital.

Hepatitis B Therapy - DV-601 combines both surface and core HBV antigens and Dynavax is planning to initiate a Phase 1b clinical trial.

Preclinical Programs - Dynavax's preclinical programs include programs partnered with pharmaceutical partners AstraZeneca and GlaxoSmithKline and the Company's Universal Flu vaccine. The vaccine has demonstrated its biological mechanism in a flu model.

2009 Financial Outlook

Dynavax plans to provide its updated financial outlook for 2009 after determining the timing, scope, and funding for HEPLISAV's future development.

Conference Call

Dynavax will webcast a conference call today at 5:00 p.m. ET (2:00 p.m. PT). The live and archived webcast can be accessed by visiting the investor relations section of the Company's Web site at <u>http://investors.dynavax.com/newsevents.cfm</u>.

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 vaccine targeted for individuals who are less responsive to current licensed hepatitis B vaccines. For more information visit <u>www.dynavax.com</u>.

Forward Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties. 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 and when the FDA will remove the clinical hold for HEPLISAV, whether HEPLISAV can be further developed, financed or commercialized, or even if further development is permitted, that successful clinical development and regulatory approval can occur in a timely manner or without significant additional studies and difficulties or delays in development; 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 its operations, possible claims against the Company based on the patent rights of others; and other risks detailed in the "Risk Factors" section of the Company's current periodic reports with the SEC. The Company undertakes 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 <u>www.dynavax.com</u> 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>June 30,</u>			Six Months Ended June 30,			
		<u>2009</u>		<u>2008</u>		<u>2009</u>		<u>2008</u>
Revenues:								
Collaboration revenue	\$	14,596	\$	7,701	\$	32,288	\$	13,475
Grant revenue		895		1,122		2,034		1,446
Service and license revenue		393		1,155		906		1,371
Total revenues		15,884		9,978		35,228		16,292
Operating expenses:								
Research and development (1)		9,239		12,946		19,571		28,066
General and administrative (2)		3,533		3,420		7,957		7,991
Amortization of intangible assets		245		245		490		490
Total operating expenses (3)	_	13,017		16,611	_	28,018	_	36,547
Income (loss) from operations		2,867		(6,633)		7,210		(20,255)
Interest income		46		439		156		1,148
Interest expense		(12)		(1,340)		(27)		(2,684)
Other income (expense)		226		(34)		(120)		228
Net income (loss)		3,127		(7,568)		7,219		(21,563)
Add: Losses attributed to noncontrolling interest in SDI		983		1,489		1,992		3,055
Net income (loss) attributable to Dynavax	\$	4,110	\$	(6,079)	\$	9,211	\$	(18,508)
Basic net income (loss) per share	\$	0.10	\$	(0.15)	\$	0.23	\$	(0.47)
Shares used to compute basic net income (loss) per								

share	_	39,923	_	39,806		39,906	 39,795
Diluted net income (loss) per share	\$	0.10	\$	(0.15)	\$	0.23	\$ (0.47)
Shares used to compute diluted net income (loss) per							
share		40,064		39,806	_	39,906	 39,795

(1) Research and development expenses included non-cash stock-based compensation charges of \$0.3 million and \$0.4 million for the three and six months ended June 30, 2009, respectively. Research and development expenses included non-cash stock-based compensation charges of \$0.4 million and \$0.6 million for the three and six months ended June 30, 2008, respectively.

(2) General and administrative expenses included non-cash stock-based compensation charges of \$0.3 million and \$0.8 million for the three and six months ended June 30, 2009, respectively. General and administrative expenses included non-cash stock-based compensation charges of \$0.4 million and \$0.9 million for the three and six months ended June 30, 2008, respectively.

(3) Total operating expenses excluding non-cash stock-based compensation charges are \$12.4 million and \$26.8 million for the three and six months ended June 30, 2009, respectively. Total operating expenses excluding non-cash stock-based compensation charges are \$15.8 million and \$35.1 million for the three and six months ended June 30, 2008, respectively.

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

(Unaudited)

	·	Three Months Ended June 30,				Six Months Ended June 30,			
		<u>2009</u>		<u>2008</u>		<u>2009</u>		<u>2008</u>	
GAAP revenues ADD:	\$	15,884	\$	9,978	\$	35,228	\$	16,292	
Collaboration funding incurred under SDI programs LESS:		795		1,432		1,542		2,963	
Non-cash deferred revenue from Merck						~~ ~~ ~			
collaboration		12,948		619		28,485		1,283	
Pro forma revenues (1)	\$	3,731	\$	10,791	\$	8,285	\$	17,972	

(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)

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		Three Mon <u>June</u>	Six Months Ended June 30,				
		<u>2009</u>	<u>2008</u>		<u>2009</u>		<u>2008</u>
GAAP operating expenses LESS:	\$	13,017	\$ 16,611	\$	28,018	\$	36,547
Stock-based compensation expense		667	775		1,186		1,436
Amortization of intangible assets		245	245		490		490
Pro forma operating expenses (2)	\$	12,105	\$ 15,591	\$	26,342	\$	34,621

(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)

		<u>2009</u>	<u>2008</u>
Assets	(un	audited)	
Cash and cash equivalents and marketable securities (1)	\$	53,040	\$ 68,476
Property and equipment, net		8,610	9,510
Goodwill		2,312	2,312
Other intangible assets, net		1,769	2,259
Other assets		3,417	 8,066
Total assets	\$	69,148	\$ 90,623
Liabilities and stockholders'equity			
Accounts payable	\$	1,222	\$ 905
Accrued liabilities		6,682	6,816
Current portion of deferred revenue		3,672	33,133
Noncurrent portion of deferred revenue		17,798	18,512
Liability from Program Option exercised under the SDI collaboration		15,000	15,000
Other long-term liabilities		166	101
Stockholders' equity		24,608	16,156
Total liabilities and stockholders' equity	\$	69,148	\$ 90,623

(1) These amounts also included investments held by SDI of \$22.8 million and \$25.1 million as of June 30, 2009 and December 31, 2008, respectively.

SOURCE: Dynavax Technologies Corporation

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