
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): 10/27/2011

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware
(State or other jurisdiction of
incorporation)

33-0728374
(IRS Employer
Identification No.)

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(Address of principal executive offices, including zip code)

(510) 848-5100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 2.02. Results of Operations and Financial Condition

On October 27, 2011, Dynavax Technologies Corporation ("Dynavax") issued a press release announcing its financial results for the third quarter ended September 30, 2011. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information with respect to Item 2.02 in this current report and its accompanying exhibit shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in Item 2.02 of this current report and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Dynavax, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events

On October 27, 2011, Dynavax issued two press releases titled "Dynavax Phase 3 Data in Chronic Kidney Disease Demonstrates Superiority of HEPLISAV(TM) vs Engerix-B(R)" and "Dynavax Confirms HEPLISAV(TM) Submission Strategies with U.S. FDA and EMA." Copies of these press releases are attached as Exhibits 99.2 and 99.3, respectively, to this current report and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release, dated October 27, 2011, titled "Dynavax Reports Third Quarter 2011 Financial Results."

99.2 Press Release, dated October 27, 2011, titled "Dynavax Phase 3 Data in Chronic Kidney Disease Demonstrates Superiority of HEPLISAV(TM) vs Engerix-B(R)."

99.3 Press Release, dated October 27, 2011, titled "Dynavax Confirms HEPLISAV(TM) Submission Strategies with U.S. FDA and EMA."

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dynavax Technologies Corporation

Date: October 31, 2011

By: /s/ Jennifer Lew

Jennifer Lew
Vice President, Finance

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, dated October 27, 2011, titled "Dynavax Reports Third Quarter 2011 Financial Results."
EX-99.2	Press Release, dated October 27, 2011, titled "Dynavax Phase 3 Data in Chronic Kidney Disease Demonstrates Superiority of HEPLISAV(TM) vs Engerix-B(R)."
EX-99.3	Press Release, dated October 27, 2011, titled "Dynavax Confirms HEPLISAV(TM) Submission Strategies with U.S. FDA and EMA."

DYNAVAX

DYNAVAX TECHNOLOGIES

2929 Seventh Street, Suite 100

Berkeley, CA 94710

Contacts:

Jennifer Lew
Vice President, Finance
510-665-7217
jlw@dynavax.com

Michael Ostrach
Vice President and Chief Business Officer
510-665-7257
mostrach@dynavax.com

DYNAVAX REPORTS THIRD QUARTER 2011 FINANCIAL RESULTS

BERKELEY, CA – October 27, 2011 – Dynavax Technologies Corporation (NASDAQ: DVAX) today reported financial results for the third quarter ended September 30, 2011, including \$53.2 million in cash, cash equivalents and marketable securities at September 30, 2011. This amount does not include a total of \$8.6 million, consisting of \$6 million in previously announced payments from Dynavax's collaborations with AstraZeneca and GlaxoSmithKline to be made after the close of the quarter and proceeds of \$2.6 million from the sale of common stock to Aspire Capital received after the close of the third quarter.

Dynavax said that, based on developments to date and additional potential payments anticipated to be received or earned by year end under existing arrangements, it expects to end 2011 with approximately \$50 million in cash, cash equivalents and marketable securities.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior 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 regarding our projected net cash usage and cash position. 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 or clinical trial enrollment, whether the studies can support registration for commercialization of HEPLISAV; 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

– more –

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.

– tables to follow –

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Collaboration revenue	\$ 369	\$ 10,402	\$ 7,098	\$ 19,164
Grant revenue	658	1,218	2,437	2,697
Service and license revenue	<u>147</u>	<u>29</u>	<u>652</u>	<u>323</u>
Total revenues	1,174	11,649	10,187	22,184

Operating expenses:					
Research and development		11,777	14,204	39,706	40,729
General and administrative		4,217	3,951	13,025	12,694
Amortization of intangible assets		—	245	299	735
		<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total operating expenses		15,994	18,400	53,030	54,158
		<u> </u>	<u> </u>	<u> </u>	<u> </u>
Loss from operations		(14,820)	(6,751)	(42,843)	(31,974)
Interest income		18	12	74	53
Interest expense		(485)	(399)	(1,462)	(1,229)
Other income (expense)		58	2,140	(99)	(9,036)
		<u> </u>	<u> </u>	<u> </u>	<u> </u>
Net loss	\$	<u>(15,229)</u>	\$ <u>(4,998)</u>	\$ <u>(44,330)</u>	\$ <u>(42,186)</u>
Basic and diluted net loss per share	\$	<u>(0.12)</u>	\$ <u>(0.06)</u>	\$ <u>(0.37)</u>	\$ <u>(0.57)</u>
Shares used to compute basic net loss per share		<u>124,069</u>	<u>86,826</u>	<u>119,244</u>	<u>74,519</u>

– more –

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
GAAP revenues	\$ 1,174	\$ 11,649	\$ 10,187	\$ 22,184
LESS:				
Deferred revenue from collaborations	=	<u>10,000</u>	=	<u>10,000</u>
<i>Pro forma</i> revenues (1)	<u>\$ 1,174</u>	<u>\$ 1,649</u>	<u>\$ 10,187</u>	<u>\$ 12,184</u>

(1) These pro forma amounts are intended to illustrate the Company's revenues excluding certain items for which cash was received in a prior period. 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)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
GAAP operating expenses	\$ 15,994	\$ 18,400	\$ 53,030	\$ 54,158
LESS:				
Stock-based compensation expense	1,287	586	3,934	1,552
Amortization of intangible assets	—	245	299	735
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<i>Pro forma</i> operating expenses (2)	<u>\$ 14,707</u>	<u>\$ 17,569</u>	<u>\$ 48,797</u>	<u>\$ 51,871</u>

(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)
(Unaudited)

	September 30,	December 31,
	<u>2011</u>	<u>2010</u>
Assets		
Cash and cash equivalents and marketable securities	\$ 53,221	\$ 72,154
Property and equipment, net	6,127	6,404
Goodwill	2,312	2,312
Other intangible assets, net	—	299
Other assets	3,059	3,080
	<hr/>	<hr/>
Total assets	\$ 64,719	\$ 84,249
	<hr/>	<hr/>
Liabilities and stockholders' equity		
Accounts payable	\$ 1,313	\$ 2,329
Accrued and other liabilities	8,823	11,786
Current portion of deferred revenue	1,429	1,429
Noncurrent portion of deferred revenue	4,583	5,655
Long-term note payable to Holdings	12,342	10,939
Stockholders' equity	36,229	52,111
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 64,719	\$ 84,249
	<hr/>	<hr/>

###

DYNAVAX TECHNOLOGIES
2929 Seventh Street, Suite 100
Berkeley, CA 94710

Contact:

Michael Ostrach
 Vice President and Chief Business Officer
 510-665-7257
mostrach@dynavax.com

DYNAVAX PHASE 3 DATA IN CHRONIC KIDNEY DISEASE DEMONSTRATES SUPERIORITY OF HEPLISAV™ VS ENGERIX-B®

Detailed Phase 3 Data to Be Presented at Kidney Week

Berkeley, CA – October 27, 2011– Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the company has unblinded its Phase 3 primary endpoint immunogenicity data in subjects with chronic kidney disease and that the data achieved statistical significance demonstrating both the superiority and non-inferiority of HEPLISAV as compared to Engerix-B. A partial safety analysis also showed a similar safety profile for the two vaccines, with the incidence of post-injection reactions and adverse events similar in both groups. This Phase 3 multi-center trial evaluated 507 subjects with chronic kidney disease, as defined by a modified intent-to-treat analysis, and compared three doses of HEPLISAV given at months 0, 1 and 6 with eight doses of Engerix-B given as double-doses at months 0, 1, 2 and 6. Detailed results of the trial will be presented in November at the American Society of Nephrology Kidney Week meeting in Philadelphia.

Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said, "The demonstrated superiority of HEPLISAV in chronic kidney disease patients who are at high risk of HBV infection and hypo-responsive to hepatitis B vaccine adds to the growing body of evidence of HEPLISAV's advantages in a well known hypo-responsive patient population already being vaccinated against hepatitis B infection. These results, with three doses of HEPLISAV compared to eight doses of Engerix-B, provide the data necessary to support an indication and specific treatment regimen for HEPLISAV in persons with chronic kidney disease."

The observer-blinded trial was conducted among 507 patients 18-75 years of age with chronic kidney disease (GFR 45 mL/min/1.73 m²). Subjects were recruited at 69 sites in the U.S., Canada, and Germany and were randomized 1:1 to receive HEPLISAV or Engerix-B. The primary objective was to determine if HEPLISAV is non-inferior to Engerix-B by comparing seroprotection rates (anti-HBs 10mIU/mL) one month after the last dose of vaccine (Month 7) and if non-inferior, to determine if HEPLISAV was superior to Engerix-B.

– more –

Engerix-B® is a registered trademark of GlaxoSmithKline

The Advisory Committee on Immunization Practices (ACIP) and other public health authorities recommend vaccination for all persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients. Specific regimens or formulations are recommended for both of the currently available hepatitis B vaccines due to the hypo-responsiveness of chronic kidney disease patients. For immunocompromised persons, including dialysis patients, it is also recommended that additional vaccine be administered as needed to retain seroprotective levels of antibody against hepatitis B.

There are 750,000 persons with end-stage kidney disease in the United States and the five major European markets and an annual incidence of 150,000 new diagnoses and entry onto dialysis. Dialysis patients typically receive dialysis treatments, vaccination and monitoring of antibody levels through a network of dialysis centers that include approximately 5,000 sites in the United States.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. In earlier Phase 3 trials, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV and is developing the vaccine for large, high-value populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known as ISS to enhance the immune response.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior 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," including those relating to the timing of presentation of results and the data necessary to support an indication and regimen for chronic kidney disease, 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 successful clinical and regulatory development and approval of HEPLISAV and our process for its manufacture can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether our studies can support registration for commercialization of HEPLISAV; 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, including the outcome of pre-filing discussions with regulatory authorities; 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
2929 Seventh Street, Suite 100
Berkeley, CA 94710

Contact:

Michael Ostrach
Vice President and Chief Business Officer
510-665-7257
mostrach@dynavax.com

DYNAVAX CONFIRMS HEPLISAV™ SUBMISSION STRATEGIES WITH U.S. FDA AND EMA

Berkeley, CA – October 27 – Dynavax Technologies Corporation (NASDAQ: DVAX) today said that the U.S. Food and Drug Administration (FDA) had concurred with the company's plan to submit a Biologics License Application (BLA) for HEPLISAV for persons over 40 years of age, followed by a supplemental BLA for licensure of a specific regimen for vaccinating chronic kidney disease (CKD) patients against hepatitis B infection at the time the initial application is approved. Dynavax also updated its timeline for the company's first BLA submission saying it expected to submit in the first quarter of 2012.

Dynavax also said that the European Medicines Agency (EMA) has advised the company it could submit the primary endpoint immunogenicity data and associated safety data for the over-40 population as well as the CKD indication as part of the initial Marketing Authorization Application (MAA) and that the outstanding CKD data can be submitted in the course of the application's review. Dynavax confirmed its plan to submit the MAA for European approval after the submission of its BLA in the U.S.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. In earlier Phase 3 trials, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV and is developing the vaccine for large, high-value populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known as ISS to enhance the immune response.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

– more –

Forward-Looking Statements

This press release contains "forward-looking statements," including those relating to our plans for the HEPLISAV BLA and MAA and the timing of the submissions, 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 successful clinical and regulatory development and approval of HEPLISAV and our process for its manufacture can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether our studies can support registration for commercialization of HEPLISAV; 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, including the outcome of pre-filing discussions with regulatory authorities; 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.

###
