

DYNAVAX TECHNOLOGIES CORP  
Form 10-Q  
October 30, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2009

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from            to            .

Commission file number: 001-34207

**Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0728374**  
(IRS Employer

Identification No.)

**2929 Seventh Street, Suite 100**

**Berkeley, CA 94710-2753**

**(510) 848-5100**

(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registration was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.:

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of October 28, 2009, the registrant had outstanding 41,279,270 shares of common stock.

**Table of Contents**

**INDEX**

**DYNAVAX TECHNOLOGIES CORPORATION**

|  | <b>Page No.</b> |
|--|-----------------|
| <b><u>PART I FINANCIAL INFORMATION</u></b>   | 4               |
| <b><u>Item 1. Condensed Consolidated Financial Statements</u></b>  | 4               |
| <u>Condensed Consolidated Balance Sheets as of September 30, 2009 and December 31, 2008</u>  | 4               |
| <u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008</u>   | 5               |
| <u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008</u>   | 6               |
| <u>Notes to Condensed Consolidated Financial Statements</u>  | 7               |
| <b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>  | 17              |
| <b><u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>   | 21              |
| <b><u>Item 4. Controls and Procedures</u></b>  | 22              |
| <b><u>PART II OTHER INFORMATION</u></b>  | 23              |
| <b><u>Item 1. Legal Proceedings</u></b>  | 23              |
| <b><u>Item 1A. Risk Factors</u></b>  | 23              |
| <b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>  | 33              |
| <b><u>Item 3. Defaults upon Senior Securities</u></b>  | 33              |
| <b><u>Item 4. Submission of Matters to a Vote of Security Holders</u></b>  | 33              |
| <b><u>Item 5. Other Information</u></b>  | 33              |
| <b><u>Item 6. Exhibits</u></b>   | 33              |
| <b><u>SIGNATURES</u></b>   | 35              |
| <i>This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners.</i> |                 |

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

*This Quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. Our forward-looking statements include discussions regarding our business and financing strategies, future research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development of our products, uncertainty regarding our future operating results and prospects for profitability. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in Item 1A Risk Factors and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.*

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****Dynavax Technologies Corporation****Condensed Consolidated Balance Sheets****(In thousands, except per share amounts)**

|   | <b>September 30,<br/>2009<br/>(unaudited)</b> | <b>December 31,<br/>2008<br/>(Note 1)</b> |
|---|---|---|
| <b>Assets</b>   |   |   |
| Current assets:   |   |   |
| Cash and cash equivalents   | \$ 24,735                                     | \$ 28,103                                 |
| Marketable securities   |   | 15,264                                    |
| Investments held by Symphony Dynamo, Inc. (SDI)   | 21,697  | 25,109                                    |
| Restricted cash   | 677   | 668                                       |
| Accounts receivable   | 1,184   | 6,407                                     |
| Prepaid expenses and other current assets   | 1,008   | 991                                       |
| <b>Total current assets</b>   | <b>49,301</b>                                 | <b>76,542</b>                             |
| Property and equipment, net   | 8,507   | 9,510                                     |
| Goodwill  | 2,312   | 2,312                                     |
| Other intangible assets, net  | 1,524   | 2,259                                     |
| <b>Total assets</b>   | <b>\$ 61,644</b>                              | <b>\$ 90,623</b>                          |
| <b>Liabilities and stockholders' equity</b>   |   |   |
| Current liabilities:  |   |   |
| Accounts payable  | \$ 1,037                                      | \$ 905                                    |
| Accrued liabilities   | 7,356   | 6,816                                     |
| Deferred revenues   | 3,127   | 33,133                                    |
| <b>Total current liabilities</b>  | <b>11,520</b>                                 | <b>40,854</b>                             |
| Deferred revenues, noncurrent   | 17,440  | 18,512                                    |
| Liability from program option exercised under the SDI collaboration   | 15,000  | 15,000                                    |
| Other long-term liabilities   | 160   | 101                                       |
| Commitments and contingencies (Note 7)  |   |   |
| Dynavax stockholders' equity:   |   |   |
| Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at September 30, 2009 and December 31, 2008  |   |   |
| Common stock: \$0.001 par value; 100,000 shares authorized at September 30, 2009 and December 31, 2008; 41,274 and 39,854 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively |   |   |
|   | 41  | 40  |
| Additional paid-in capital  | 267,115                                       | 262,579                                   |
| Accumulated other comprehensive loss:   |   |   |
| Unrealized gain on marketable securities available-for-sale   |   | 49  |
| Cumulative translation adjustment   | (36)  | (403)                                     |
| <b>Accumulated other comprehensive loss</b>   | <b>(36)</b>                                   | <b>(354)</b>                              |

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

|  |           |           |
|--|-----------|-----------|
| Accumulated deficit                        | (249,038) | (248,743) |
| Total Dynavax stockholders' equity         | 18,082    | 13,522    |
| Noncontrolling interest in SDI             | (558)     | 2,634     |
| Total stockholders' equity                 | 17,524    | 16,156    |
| Total liabilities and stockholders' equity | \$ 61,644 | \$ 90,623 |

*See accompanying notes.*

**Table of Contents****Dynavax Technologies Corporation****Condensed Consolidated Statements of Operations****(In thousands, except per share amounts)****(Unaudited)**

|   | <b>Three Months Ended</b> |                   | <b>Nine Months Ended</b> |                    |
|---|---------------------------|-------------------|--------------------------|--------------------|
|   | <b>September 30,</b>      |                   | <b>September 30,</b>     |                    |
|   | <b>2009</b>               | <b>2008</b>       | <b>2009</b>              | <b>2008</b>        |
| <b>Revenues:</b>  |                           |                   |                          |                    |
| 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              |
| <b>Total revenues</b>   | <b>2,901</b>              | <b>8,857</b>      | <b>38,129</b>            | <b>25,149</b>      |
| <b>Operating expenses:</b>  |                           |                   |                          |                    |
| Research and development  | 9,631                     | 10,456            | 29,202                   | 38,522             |
| General and administrative  | 3,736                     | 3,913             | 11,693                   | 11,904             |
| Amortization of intangible assets   | 245                       | 245               | 735                      | 735                |
| <b>Total operating expenses</b>   | <b>13,612</b>             | <b>14,614</b>     | <b>41,630</b>            | <b>51,161</b>      |
| <b>Loss from operations</b>   | <b>(10,711)</b>           | <b>(5,757)</b>    | <b>(3,501)</b>           | <b>(26,012)</b>    |
| 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)                |
| <b>Net loss</b>   | <b>(10,706)</b>           | <b>(7,133)</b>    | <b>(3,487)</b>           | <b>(28,696)</b>    |
| Add: Losses attributable to noncontrolling interest in SDI  | 1,200                     | 1,713             | 3,192                    | 4,768              |
| <b>Net loss attributable to Dynavax</b>   | <b>\$ (9,506)</b>         | <b>\$ (5,420)</b> | <b>\$ (295)</b>          | <b>\$ (23,928)</b> |
| <b>Basic net loss per share attributable to Dynavax common stockholders</b>                             | <b>\$ (0.24)</b>          | <b>\$ (0.14)</b>  | <b>\$ (0.01)</b>         | <b>\$ (0.60)</b>   |
| Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders | 40,153                    | 39,831            | 39,990                   | 39,807             |

*See accompanying notes.*

**Table of Contents****Dynavax Technologies Corporation****Condensed Consolidated Statements of Cash Flows****(In thousands)****(Unaudited)**

|   | <b>Nine Months Ended<br/>September 30,</b> |                 |
|---|--|-----------------|
|   | <b>2009</b>                                | <b>2008</b>     |
| <b>Operating activities</b>   |  |                 |
| Net loss attributable to Dynavax  | \$ (295)                                   | \$ (23,928)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |                 |
| Depreciation and amortization   | 1,435                                      | 1,361           |
| Amount attributed to noncontrolling interest in SDI                         | (3,192)                                    | (4,768)         |
| Amortization of intangible assets   | 735  | 735             |
| Loss on the disposal of assets  |  | 25              |
| Accretion and amortization on marketable securities                         | 4  | (621)           |
| Interest associated with Deerfield financing agreement                      | 84   | 9,089           |
| Loan forgiveness  |  | (5,000)         |
| Stock-based compensation expense  | 2,102                                      | 2,488           |
| Changes in operating assets and liabilities:                                |  |                 |
| Accounts receivable   | 5,223                                      | 1,018           |
| Prepaid expenses and other current assets                                   | (17)                                       | 1,173           |
| Restricted cash and other assets  | (9)  | (85)            |
| Accounts payable  | 132  | (3,288)         |
| Accrued liabilities and other long term liabilities                         | 615  | (968)           |
| Deferred revenues   | (31,078)                                   | 1,753           |
| <b>Net cash used in operating activities</b>                                | <b>(24,261)</b>                            | <b>(21,016)</b> |
| <b>Investing activities</b>   |  |                 |
| Change in investments held by SDI   | 3,412                                      | 4,946           |
| Purchases of marketable securities  | (14,289)                                   | (23,082)        |
| Proceeds from maturities of marketable securities                           | 29,500                                     | 46,900          |
| Proceeds from sales of marketable securities                                |  | 4,046           |
| Purchases of property and equipment, net                                    | (448)                                      | (4,328)         |
| <b>Net cash provided by investing activities</b>                            | <b>18,175</b>                              | <b>28,482</b>   |
| <b>Financing activities</b>   |  |                 |
| Proceeds from notes payable issued to Deerfield                             |  | 2,000           |
| Repayment of notes payable issued to Deerfield                              |  | (817)           |
| Proceeds from issuance of common stock, net of issuance costs               | 2,275                                      |                 |
| Proceeds from employee stock purchase plan                                  | 72   | 204             |
| Proceeds from exercise of stock options                                     | 4  | 5               |
| <b>Net cash provided by financing activities</b>                            | <b>2,351</b>                               | <b>1,392</b>    |
| Effect of exchange rate on cash and cash equivalents                        | 367  | (533)           |
| <b>Net increase (decrease) in cash and cash equivalents</b>                 | <b>(3,368)</b>                             | <b>8,325</b>    |



Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

|   |           |           |
|---|-----------|-----------|
| Cash and cash equivalents at beginning of period        | 28,103    | 14,293    |
| Cash and cash equivalents at end of period              | \$ 24,735 | \$ 22,618 |
| <b>Supplemental disclosure of cash flow information</b> |           |           |
| Disposal of fully depreciated property and equipment    | \$ 907    | \$        |

*See accompanying notes.*

---

**Table of Contents**

**Dynavax Technologies Corporation**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

Dynavax Technologies Corporation ( Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. Our lead product candidate is HEPLISAV™, a Phase 3 investigational adult hepatitis B vaccine. We originally incorporated in California on August 29, 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware on March 26, 2001.

***Basis of Presentation***

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2008 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles ( GAAP ) for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission ( SEC ).

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiary, Rhein Biotech GmbH ( Rhein or Dynavax Europe ), as well as the accounts of a variable interest entity, Symphony Dynamo, Inc. ( SDI ), which we consolidate pursuant to the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification related to consolidation. All significant intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products. We have evaluated all subsequent events through October 30, 2009, the date the financial statements were filed with the SEC.

In June 2009, the FASB released the *FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles* ( the Codification ), which has become the source of authoritative U.S. generally accepted accounting principles ( GAAP ) recognized by the FASB to be applied by nongovernmental entities. The Codification superseded all existing non-SEC accounting and reporting standards. The GAAP hierarchy was modified to include only two levels of GAAP: authoritative and non-authoritative. Rules and interpretive releases of the SEC under authority of federal securities laws are sources of authoritative GAAP for SEC registrants. All other non-grandfathered non-SEC accounting literature not included in the Codification became non-authoritative. The Codification was effective for financial statements issued for interim and annual periods ending after September 15, 2009, and was adopted by us in the third fiscal quarter of 2009. There was no impact to our consolidated financial position, results of operations and cash flows as a result of adoption of this pronouncement.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results may differ from these estimates.

***Significant Accounting Policies***

The Company believes that there have been no significant changes in its critical accounting policies during the nine months ended September 30, 2009 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2008, except as discussed below.

In December 2007, the FASB established accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The FASB also established disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. The new accounting and reporting standards regarding noncontrolling interests became effective on January 1, 2009. The Company adopted the new accounting and reporting standards regarding noncontrolling interests and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI was reclassified to equity.

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

Consolidated net income or loss was adjusted to include the net income or loss attributed to the noncontrolling interest in SDI.

Consolidated comprehensive income or loss was adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

The Company must disclose for each reporting period the amounts of consolidated income or loss attributed to the Company and to the noncontrolling interest in SDI. In addition, for each reporting period the Company must present a reconciliation at the beginning and end of the period of the carrying amount of total equity and equity attributable to the Company and to the noncontrolling interest in SDI.

***Recent Accounting Pronouncements***

In June 2009, the FASB changed the consolidation guidance applicable to a variable interest entity ( VIE ). The FASB also amended the guidance governing the determination of whether an enterprise is the primary beneficiary of a VIE, and is therefore required to consolidate a VIE, by requiring a qualitative analysis rather than a quantitative analysis. The qualitative analysis will include, among other things, consideration of who has the power to direct the activities of the entity that most significantly impact the entity's economic performance and who has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE. This standard also requires continuous reassessments of whether an enterprise is the primary beneficiary of a VIE. Previously, the FASB required reconsideration of whether an enterprise was the primary beneficiary of a VIE only when specific events had occurred. Qualifying Special Purpose Entities, which were previously exempt from the application of this standard, will be subject to the provisions of this standard when it becomes effective. The FASB also requires enhanced disclosures about an enterprise's involvement with a VIE. The new consolidation guidance regarding a VIE will be effective for the first annual reporting periods that begin after November 15, 2009 and will be adopted by the Company in the first quarter of fiscal 2010. We do not expect the adoption of the new guidance regarding the consolidation of a VIE to have a material effect on our consolidated results of operations and financial condition.

**2. Fair Value Measurements**

The FASB has established a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 - Quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents the fair value hierarchy for our financial assets (cash equivalents and marketable securities) and investments held by SDI measured at fair value on a recurring basis as of September 30, 2009 (in thousands):

|                                   | Level 1   | Level 2  | Level 3 | Total     |
|-----------------------------------|-----------|----------|---------|-----------|
| Money market funds                | \$ 39,859 | \$       | \$      | \$ 39,859 |
| U.S. Government agency securities |           | 2,000    |         | 2,000     |
| Total                             | \$ 39,859 | \$ 2,000 | \$      | \$ 41,859 |

### 3. Available-for-Sale Securities

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Management determines the appropriate classification of marketable securities at the time of purchase. We invest in short-term money market funds, government agency securities and corporate obligations, some of which are government-secured. We believe these types of investments are subject to minimal credit and market risk. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

We have classified our entire investment portfolio as available-for-sale. We view our available-for-sale portfolio as available for use in current operations, and accordingly, have classified all investments as short-term. As of September 30, 2009 the stated maturity of our investments is within one year of the current balance sheet date. Available-for-sale securities are carried at fair value based on quoted market prices, with unrealized gains and losses included in accumulated other comprehensive income in stockholders' equity. Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are included in interest income or expense. The cost of securities sold is based on the specific identification method. Management assesses whether declines in the fair value of investment securities are other than temporary. In determining whether a decline is other than temporary, management considers the following factors:

Length of the time and the extent to which the market value has been less than cost;

The financial condition and near-term prospects of the issuer; and

Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

To date, there have been no declines in fair value that have been identified as other than temporary. The following is a summary of available-for-sale securities included in cash and cash equivalents and investments held by SDI and restricted cash as of September 30, 2009 (in thousands):

|  | Amortized<br>Cost | Unrealized<br>Gains | Unrealized<br>Losses | Aggregated<br>Fair Value |
|--|-------------------|---------------------|----------------------|--------------------------|
| <b>September 30, 2009:</b>                     |                   |                     |                      |                          |
| Certificates of deposit and money market funds | \$ 40,701         | \$                  | \$                   | \$ 40,701                |
| U.S. Government agency securities              | 1,999             | 1                   |                      | 2,000                    |
| <b>Total</b>                                   | <b>\$ 42,700</b>  | <b>\$ 1</b>         | <b>\$</b>            | <b>\$ 42,701</b>         |

There were no realized gains or losses from the sale of marketable securities for the three and nine months ended September 30, 2009. We recognized immaterial realized gains and no realized losses for the three and nine months ended September 30, 2008. Additionally, there was no other-than-temporary impairment recognized for the three and nine months ended September 30, 2009 and 2008. As of September 30, 2009, all of our investments have a stated maturity date that is within one year of the current balance sheet date. All of our investments are classified as short-term and available-for-sale, as we may not hold our investments until maturity. As of September 30, 2009, our marketable securities had the following maturities (in thousands):

| Maturities:   | Amortized<br>Cost | Aggregated<br>Fair Value |
|---------------|-------------------|--------------------------|
| Within 1 year | \$ 42,700         | \$ 42,701                |
| Total         | \$ 42,700         | \$ 42,701                |

**4. Intangible Assets**

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Intangible assets consist primarily of the manufacturing process and customer relationships. The manufacturing process derives from the methods for making proteins in *Hansenula* yeast, which is a key component in the production of hepatitis B vaccine. The customer relationships derive from Rhein's ability to sell existing, in-process and future products to its existing customers. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following tables present details of the purchased intangible assets at September 30, 2009 (in thousands, except years):

|                        | Original Estimated<br>Useful Life<br>(in Years) | Gross           | Accumulated<br>Amortization | Net             |
|------------------------|---|-----------------|-----------------------------|-----------------|
| Manufacturing process  | 5   | \$ 3,670        | \$ (2,529)                  | \$ 1,141        |
| Customer relationships | 5   | 1,230           | (847)                       | 383             |
| <b>Total</b>           | <b>5</b>  | <b>\$ 4,900</b> | <b>\$ (3,376)</b>           | <b>\$ 1,524</b> |

The estimated future amortization expense of purchased intangible assets is as follows (in thousands):

| <b>Year ending December 31,</b> |                 |
|---------------------------------|-----------------|
| 2009 (remaining three months)   | \$ 245          |
| 2010                            | 980             |
| 2011                            | 299             |
| <b>Total</b>                    | <b>\$ 1,524</b> |

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

**5. Symphony Dynamo, Inc.**

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP and certain of its affiliates ( Symphony ) to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development (the Development Programs ). The material agreements included:

the Amended and Restated Limited Liability Corporation Agreement of Symphony Dynamo Holdings LLC (the LLC Agreement );

the Funding Agreement by and among Dynavax Technologies Corporation, Symphony Capital Partners LP, Symphony Dynamo Holdings LLC, and Symphony Dynamo Investors LLC (the Funding Agreement );

the Amended and Restated Research and Development Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (the R&D Agreement );

the Novated and Restated Technology License Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc. (the License Agreement );

the Purchase Option Agreement among Dynavax Technologies Corporation, Symphony Dynamo Holdings LLC and Symphony Dynamo, Inc.;

the Registration Rights Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC; and

the Warrant Purchase Agreement between Dynavax Technologies Corporation and Symphony Dynamo Holdings LLC (the Warrant Agreement ).

The LLC Agreement provided for the formation of Symphony Dynamo Holdings LLC ( Holdings ) and its wholly-owned subsidiary, SDI. Pursuant to the Funding Agreement, Symphony invested \$50 million in Holdings (\$20 million at closing and an additional \$30 million in April 2007), which was invested into SDI to fund the Development Programs. Pursuant to the License Agreement, we licensed to Holdings our intellectual property rights related to the Development Programs, which were assigned to SDI. Pursuant to the R&D Agreement, which was also assigned to SDI, we are primarily responsible for performing the work required to proceed with the Development Programs unless we determine that certain work should be undertaken by third party contractors retained by SDI. As a result of these agreements, Symphony owns 100% of the equity of Holdings, which owns 100% of the equity of SDI.

Pursuant to the Warrant Agreement, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock, which Holdings distributed to Symphony, at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share if either of two events occurs: (a) we enter into a collaboration agreement with a third party for a specified oncology program; or (b) the Purchase Option (as defined below) is terminated or expires unexercised. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant, issued upon closing, was assigned a value of



## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

\$5.6 million using the Black-Scholes valuation model and was recorded in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option (the Purchase Option ) to acquire the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices that range from \$100.7 million as of September 30, 2009, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (the Program Option ) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The current terms provide that the intellectual property rights to the remaining cancer and hepatitis C therapy programs, if not purchased through the exercise of the Purchase Option, will remain with SDI.

We have determined that SDI is a variable interest entity and we are its primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements from the date of formation on April 18, 2006.

At September 30, 2009, the investments held by SDI were \$21.7 million. The investments held by SDI in the consolidated balance sheet include the aggregate \$50 million of funding, less funds spent on the Development Programs as of the end of each reporting period.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

At September 30, 2009, the noncontrolling interest was a deficit balance of \$0.6 million. The noncontrolling interest in SDI in the consolidated balance sheet represents Symphony's equity investment in SDI of \$50 million, reduced by the \$5.6 million fair value of the warrants we issued and \$2.6 million of fees we paid to Symphony upon the transaction's closing, and the losses attributed to the noncontrolling interest since its inception in April 2006. The noncontrolling interest was further reduced when we recorded the \$15 million liability upon our exercise of the Program Option in April 2007, as that amount will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option.

Net losses incurred by SDI and charged to the noncontrolling interest were \$3.2 million and \$4.8 million for the nine months ended September 30, 2009 and 2008, respectively. We have attributed net loss to Dynavax and the noncontrolling interest in SDI in our consolidated statements of operations.

**6. Financing Agreements**

On August 17, 2009 the Company entered into an equity distribution agreement (the "Agreement") with Wedbush Morgan Securities, Inc. ("Wedbush") pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the quarter ended September 30, 2009, we sold 1,281,100 shares of common stock under the Agreement with Wedbush as our sales agent for aggregate net proceeds of \$2.3 million after deducting commissions paid to Wedbush and offering expenses. As of September 30, 2009, we could offer and sell from time to time through Wedbush up to an additional \$12.2 million in aggregate offering price of our common stock under the Agreement.

On August 26, 2008, Dynavax and Deerfield Management, a healthcare investment fund, and its affiliates ("Deerfield") entered into a Settlement Agreement and Mutual General Release (the "Settlement Agreement") under which the parties agreed to terminate the Loan Agreement dated July 18, 2007 (the "Loan Agreement") and also to provide for an amendment of the warrants previously issued to Deerfield pursuant to the Loan Agreement. The Settlement Agreement terminated any further obligations under the Loan Agreement.

Under the Loan Agreement, Deerfield agreed to advance to Dynavax loans that could be drawn down over a three-year period in the aggregate principal amount of up to \$30 million, subject to achievement of specific milestones in relation to the development of certain products in Dynavax's allergy franchise. Repayment of a portion of the loans to Deerfield was contingent upon the positive outcome of studies related to TOLAMBA, Dynavax's product candidate for the treatment of ragweed allergy. If the TOLAMBA program was discontinued, Dynavax would have had no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal was slated to be due in July 2010. Deerfield received an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the volume weighted average price in the 15-day period prior to achievement of certain milestones.

Under the Loan Agreement, through August 26, 2008 (the date of termination), we had received \$7.5 million in cash from Deerfield, which was recorded as a long-term liability in our consolidated balance sheet. Additionally, we paid and recognized as interest expense \$1.7 million of commitment fees and we issued to Deerfield warrants to purchase up to 3,550,000 shares of our common stock. The warrants were valued on the issuance date using the Black-Scholes valuation model. The original warrants issued and their related assumptions under the Black-Scholes option valuation model are as follows (in thousands, except for Black-Scholes Assumptions):

| Warrant Issuance Date | Black-Scholes Assumptions |                         |                          |            |         | Exercise Price per Share | Assigned Value using Black-Scholes |
|-----------------------|---------------------------|-------------------------|--------------------------|------------|---------|--------------------------|------------------------------------|
|                       | Shares Issued             | Risk-Free Interest Rate | Expected Life (in years) | Volatility |         |                          |                                    |
| July 18, 2007         | 1,250                     | 4.9%                    | 5.5                      | 0.7        | \$ 5.13 | \$ 3,350                 |                                    |

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

|                   |       |      |     |     |         |          |
|-------------------|-------|------|-----|-----|---------|----------|
| October 18, 2007  | 1,300 | 4.2% | 5.5 | 0.7 | \$ 5.75 | 3,700    |
| December 27, 2007 | 1,000 | 3.6% | 5.5 | 0.7 | \$ 5.65 | 2,746    |
| Total             | 3,550 |      |     |     |         | \$ 9,796 |

At the date of each issuance, the warrant valuation was recorded as a deferred transaction cost in other assets and an increase in additional paid in capital. The deferred transaction cost was amortized on a straight-line basis and recognized as interest expense through the termination of the Loan Agreement. We amortized zero and \$1.8 million of deferred transaction cost in interest expense for the nine months ended September 30, 2009 and 2008, respectively.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

Under the Settlement Agreement, \$5.0 million of funds received for the TOLAMBA program were forgiven, resulting in loan forgiveness in the statement of operations and a reduction in long-term liabilities as of and for the fiscal year ended December 31, 2008. All commitment fees paid to date, which totaled \$1.7 million, were applied to the loan, resulting in a reduction in interest expense and long-term liabilities as of and for the fiscal year ended December 31, 2008. We paid the remaining loan balance of \$0.8 million in cash to Deerfield. In addition, the warrants previously issued to Deerfield were amended as follows:

| <b>Warrant Issuance Date</b>     | <b>Shares Issued<br/>(in thousands)</b> | <b>Expiration<br/>Date</b> | <b>Exercise Price<br/>per Share</b> |
|----------------------------------|---|----------------------------|-------------------------------------|
| July 18, 2007                    | 1,250                                   | 2/26/2014                  | \$ 5.13                             |
| October 18, 2007                 | 1,300                                   | 2/26/2014                  | \$ 1.68                             |
| December 27, 2007                | 300                                     | 2/26/2014                  | \$ 5.65                             |
| December 27, 2007 <sup>(1)</sup> | 700                                     | 2/26/2014                  | \$ 1.68                             |
| <b>Total</b>                     | <b>3,550</b>                            |                            |                                     |

- (1) Pursuant to the Settlement Agreement, the warrants to purchase an aggregate of 700,000 shares of our common stock issued on December 27, 2007 were amended on August 26, 2008 to provide for a termination date of February 26, 2014 at the existing exercise price of \$5.65 and were further amended on August 26, 2009 to provide for a new exercise price of \$1.68, which is equal to the VWAP over the 15 trading days prior to August 26, 2009.

The amendments to the warrants resulted in a re-measurement of the fair value based on the amended terms and current period assumptions and were accounted for as modifications to equity awards under the provisions of Topic 718, *Compensation-Stock Compensation*. We recorded interest expense and an increase of additional paid in capital of \$0.1 million and \$0.9 million for the nine months ended September 30, 2009 due to these modifications.

**7. Commitments and Contingencies**

We lease our facilities in Berkeley, California (the *Berkeley Lease* ) and Düsseldorf, Germany (the *Düsseldorf Lease* ) under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated in February 2011 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of September 30, 2009 and December 31, 2008. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2014. Total net rent expense related to our operating leases was \$1.9 million for each of the years ended September 30, 2009 and 2008. Deferred rent was \$0.9 million as of September 30, 2009.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$58 thousand in 2009 and \$40 thousand in 2010. The sublease rental income is offset against rent expense.

Future minimum payments under the non-cancelable portion of our operating leases at September 30, 2009, excluding payments from the sublease agreement, are as follows (in thousands):

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

| Year ending December 31,      |                  |
|-------------------------------|------------------|
| 2009 (remaining three months) | \$ 652           |
| 2010                          | 2,626            |
| 2011                          | 2,683            |
| 2012                          | 2,743            |
| 2013                          | 2,787            |
| Thereafter                    | 7,124            |
| <b>Total</b>                  | <b>\$ 18,615</b> |

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of September 30, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2009 and December 31, 2008. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of September 30, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of September 30, 2009.

---

**Table of Contents**

**Dynavax Technologies Corporation**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2009, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$8.3 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Under the terms of our license agreements, we could be expected to pay approximately \$0.3 million in 2009 related to such fees and milestone payments to the Regents.

**8. Collaborative Research and Development Agreements**

***GlaxoSmithKline***

In December 2008, we entered into a worldwide strategic alliance with GlaxoSmithKline ( GSK ) to discover, develop, and commercialize toll-like receptor ( TLR ) inhibitors for diseases such as lupus, psoriasis, and rheumatoid arthritis. We received an initial payment of \$10 million and agreed to conduct research and early clinical development in up to four programs and are eligible to receive future potential development and commercialization milestones totaling approximately \$200 million per program. GSK can exercise its exclusive option to license each program upon achievement of proof-of-concept or earlier upon certain circumstances. After exercising its option, GSK would carry out further development and commercialization of these products. We are eligible to receive tiered, up to double-digit royalties on sales and have retained an option to co-develop and co-promote one product. Revenue from the initial payment is deferred and is being recognized over the expected period of performance which is estimated to be seven years. For the three and nine months ended September 30, 2009, we recognized revenue of \$0.4 million and \$1.1 million, respectively, related to the initial payment.

***AstraZeneca***

In September 2006, we entered into a three-year research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease. The collaboration is using our proprietary second-generation TLR9 agonist immunostimulatory sequences ( ISS ). Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration. We received an upfront payment of \$10 million, and are eligible to receive research funding, preclinical milestone payments, and potential future development milestones of up to \$126 million. Upon commercialization, we are also eligible to receive royalties based on product sales.

In September 2008, we received a \$4.5 million milestone payment from AstraZeneca for the nomination of the first candidate drug, AZD1419. We are currently working on a second candidate drug, and in February 2009, we extended our research collaboration with AstraZeneca through July 2010 to provide funding for a third candidate drug. Revenue from milestones received during the development plan is deferred and recognized ratably over estimated performance period of the collaboration agreement. For the three and nine months ended September 30, 2009, we recognized revenue related to the milestone for the nomination of AZD1419 of \$0.4 million and \$1.4 million, respectively. Collaboration revenue resulting from the performance of research services amounted to \$0.8 million and \$2.6 million for the three and nine months ended

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

September 30, 2009, respectively. As of September 30, 2009, we had recorded deferred revenue of \$11.7 million associated with the milestone for the nomination of a candidate drug, upfront fee and amounts billed in advance for research services per the contract terms.

### *National Institutes of Health and Other Funding*

In September 2008, we were awarded a five-year \$17 million contract to develop our ISS technology using TLR9 agonists as vaccine adjuvants. The contract was awarded by the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) to develop novel vaccine adjuvant candidates that signal through receptors of the innate immune system. The contract supports adjuvant development for anthrax as well as other disease models. NIAID is funding 100% of the total \$17 million cost of Dynavax's program under Contract No. HHSN272200800038C. For the three and nine months ended September 30, 2009, we recognized revenue of approximately \$0.4 million and \$1.2 million, respectively.

In July 2008, we were awarded a two-year \$1.8 million grant from the NIH to develop a therapy for systemic lupus erythematosus, an autoimmune disease. Revenue associated with this grant is recognized as the related expenses are incurred. For the three and nine months ended September 30, 2009, we recognized revenue of approximately \$0.3 million and \$0.8 million, respectively.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the second quarter of 2009. In August 2007, we were awarded a two-year \$3.3 million grant to continue development of a novel universal influenza vaccine for controlling seasonal and emerging pandemic flu strains. Revenue associated with these grants is recognized as the related expenses are incurred. For the nine months ended September 30, 2009 and 2008, we recognized revenue of approximately \$0.7 million and \$1.4 million, respectively.

**Merck & Co., Inc.**

In October 2007, we entered into a global license and development collaboration agreement and a related manufacturing agreement with Merck to jointly develop HEPLISAV, a novel investigational hepatitis B vaccine. Under the terms of the agreement, Merck received worldwide exclusive rights to HEPLISAV, and agreed to fund future vaccine development and be responsible for commercialization. We received a non-refundable upfront payment of \$31.5 million. Revenue from the initial payment was deferred and recognized ratably over the estimated performance period of the collaboration agreement.

On December 18, 2008, Merck provided notice of its termination of the collaboration, at which time all development, manufacturing and commercialization rights to HEPLISAV reverted to Dynavax. As a result of Merck's termination, we accelerated the applicable performance period over which we ratably recognize revenue from the upfront fee through the effective date of the termination in June 2009. For the nine months ended September 30, 2009 and 2008, we recognized revenue of \$28.5 million and \$1.9 million, respectively, related to the upfront fee. Collaboration revenue resulting from the performance of research and development services is recognized as related research and development costs are incurred. Cost reimbursement revenue under this collaboration agreement totaled \$0.3 million and \$15.4 million for the nine months ended September 30, 2009 and 2008, respectively. Merck is obligated to make payments to Dynavax for the 180-day wind down period following Merck's written notice of termination. Merck has disagreed with the amounts for which it may be liable under the agreement and we are currently in negotiations to determine the amount of the wind down payment. Based on negotiations to date, we expect that this dispute may be submitted to arbitration under the agreement.

**9. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to Dynavax by the weighted-average number of common shares outstanding during the period and dilutive potential common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be dilutive potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and stock options to purchase 11.0 million shares of common stock as of September 30, 2009 and 2008, were excluded from the calculation of diluted net loss per share for both the three and nine months ended September 30, 2009 and 2008 because the effect would have been anti-dilutive.

The following is a reconciliation of the numerator and denominator used in the basic and diluted net loss per share computations (in thousands):

|  | <b>Three Months Ended</b> |             | <b>Nine Months Ended</b> |             |
|--|---------------------------|-------------|--------------------------|-------------|
|  | <b>September 30,</b>      |             | <b>September 30,</b>     |             |
|  | <b>2009</b>               | <b>2008</b> | <b>2009</b>              | <b>2008</b> |
| <b>Numerator:</b>  |                           |             |                          |             |
| Net loss attributable to Dynavax   | \$ (9,506)                | \$ (5,420)  | \$ (295)                 | \$ (23,938) |
| <b>Denominator:</b>  |                           |             |                          |             |
| Weighted-average common shares outstanding used for basic and diluted net loss per share | 40,153                    | 39,831      | 39,990                   | 39,807      |





**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****10. Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income or loss. Other comprehensive income or loss includes certain changes in stockholders' equity not included in net income (loss). Comprehensive income (loss) is as follows (in thousands):

|   | Nine Months Ended<br>September 30, |             |
|---|------------------------------------|-------------|
|   | 2009                               | 2008        |
| Net loss attributable to Dynavax  | \$ (295)                           | \$ (23,928) |
| Decrease in unrealized gain on marketable securities available-for-sale | (49)                               | (123)       |
| Increase (decrease) in cumulative translation adjustment                | 367                                | (533)       |
| Comprehensive income (loss) attributable to Dynavax                     | \$ 23                              | \$ (24,584) |

**11. Stockholders' Equity**

As of September 30, 2009, we have two share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan. The 2004 Stock Incentive Plan authorizes the issuance of various forms of stock-based awards including stock options, restricted stock, restricted stock units, and other equity awards to employees, consultants and members of the board of directors. The 1997 Equity Incentive Plan, or 1997 Plan, expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous service). The Company did not grant options during the three months ended September 30, 2009. The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

|                                       | Employee Stock Options                 |         |                                    |         | Employee Stock<br>Purchase Plan    |         |
|---------------------------------------|--|---------|------------------------------------|---------|------------------------------------|---------|
|                                       | Three Months Ended<br>September<br>30, |         | Nine Months Ended<br>September 30, |         | Nine Months Ended<br>September 30, |         |
|                                       | 2009                                   | 2008    | 2009                               | 2008    | 2009                               | 2008    |
| Weighted-average fair value per share | \$                                     | \$ 0.91 | \$ 0.53                            | \$ 2.60 | \$ 0.87                            | \$ 0.93 |
| Risk-free interest rate               |  | 2.7%    | 1.7%                               | 2.8%    | 0.7%                               | 2.4%    |
| Expected life (in years)              |  | 4.0     | 4.0                                | 4.4     | 1.2                                | 1.3     |
| Volatility                            |  | 0.8     | 1.6                                | 0.7     | 1.6                                | 0.8     |
| Expected dividends                    |  |         |                                    |         |                                    |         |

Expected volatility is based on historical volatility of our stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding,

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

and non-executive level employees were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

We recognized the following amounts of stock-based compensation expense (in thousands):

|  | <b>Three Months Ended<br/>September 30,</b> |                 | <b>Nine Months Ended<br/>September 30,</b> |                 |
|--|---|-----------------|--|-----------------|
|  | <b>2009</b>                                 | <b>2008</b>     | <b>2009</b>                                | <b>2008</b>     |
| Employee and director stock-based compensation expense | \$ 902                                      | \$ 1,051        | \$ 2,091                                   | \$ 2,469        |
| Other stock-based compensation expense                 | 14  | 1               | 11   | 19              |
| <b>Total</b>   | <b>\$ 916</b>                               | <b>\$ 1,052</b> | <b>\$ 2,102</b>                            | <b>\$ 2,488</b> |

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 15%. As of September 30, 2009, the total unrecognized compensation cost related to non-vested options granted amounted to \$4.1 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.5 years.

**Table of Contents****Dynavax Technologies Corporation****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

Activity under the stock option plans was as follows:

|                               | Options Available<br>for Grant | Number of Options<br>Outstanding | Weighted-Average<br>Exercise Price<br>Per Share |
|-------------------------------|--------------------------------|----------------------------------|---|
| Balance at December 31, 2008  | 660,653                        | 5,172,976                        | \$ 4.70   |
| Options authorized            | 400,000                        |                                  |   |
| Options granted               | (1,188,350)                    | 1,188,350                        | \$ 0.67   |
| Options exercised             |                                |                                  |   |
| 1997 Plan shares exercised    |                                | (2,666)                          | \$ 1.50   |
| Options cancelled:            |                                |                                  |   |
| Options forfeited (unvested)  | 443,822                        | (443,822)                        | \$ 3.11   |
| Options expired (vested)      | 436,472                        | (436,472)                        | \$ 6.62   |
| 1997 Plan options expired     | (999)                          |                                  |   |
| Balance at September 30, 2009 | 751,598                        | 5,478,366                        | \$ 3.80   |

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of September 30, 2009:

|   | Number of Shares | Weighted-<br>Average<br>Exercise<br>Price Per<br>Share | Weighted-<br>Average<br>Remaining<br>Contractual<br>Term<br>(in years) | Aggregate Intrinsic<br>Value |
|---|------------------|--|--|------------------------------|
| Outstanding options (vested and expected to vest) | 4,937,726        | \$ 3.95  | 6.9  | \$ 1,408,211                 |
| Options exercisable                               | 2,815,964        | \$ 4.76  | 5.8  | \$ 61,710                    |

**Employee Stock Purchase Plan**

As of September 30, 2009, 496,000 shares were reserved and approved for issuance under the Employee Stock Purchase Plan (the "Purchase Plan"), subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees have acquired 330,107 shares of our common stock under the Purchase Plan. At September 30, 2009, 165,893 shares of our common stock remained available for future purchases.

---

## **Table of Contents**

### **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to those set forth under Risk Factors and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.*

*The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this quarterly report and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K.*

#### **Overview**

Dynavax Technologies Corporation ( Dynavax or the Company ), a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. Our lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine.

Our pipeline is comprised of: HEPLISAV, a Phase 3 hepatitis B vaccine; clinical-stage programs for hepatitis C and hepatitis B therapies; and preclinical programs including those partnered with AstraZeneca and GlaxoSmithKline ( GSK ) and our Universal Flu vaccine.

#### **Recent Developments**

##### ***HEPLISAV***

In September 2009, the U.S. Food and Drug Administration ( FDA ) removed the clinical hold for the HEPLISAV Investigational New Drug application in individuals with chronic kidney disease. In that same month, following the FDA's decision, we initiated a Phase 3 trial for HEPLISAV in individuals with chronic kidney disease and began vaccinating subjects. We expect to initiate a second Phase 3 lot-to-lot consistency trial in early 2010. We anticipate that these two registration trials will be completed within the next 24 months and currently believe that these studies, taken together, could support registration filing of HEPLISAV with the FDA.

HEPLISAV is designed to provide increased, rapid protection with fewer doses than current licensed vaccines. Over 2,500 individuals have been vaccinated with HEPLISAV, which has completed a pivotal phase 3 study and early-stage trials in chronic kidney disease patients, all of which have demonstrated the vaccine's immunogenicity.

We are developing HEPLISAV for populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease, adults over 40 years of age, and others. We have worldwide commercial rights to HEPLISAV, which combines hepatitis B surface antigen ( HBsAg ) with a proprietary Toll-like Receptor 9 agonist to enhance the immune response.

#### **Critical Accounting Policies and the Use of Estimates**

The Company believes that there have been no significant changes in its critical accounting policies during the nine months ended September 30, 2009 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2008, except as discussed below.

In December 2007, the FASB established accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The FASB also established disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. The new accounting and reporting standards regarding noncontrolling interests became effective on January 1, 2009. The Company adopted the new accounting and reporting standards regarding noncontrolling interests and our adoption did not impact our financial statements, except for the presentation and disclosure requirements affecting all periods presented as follows:

The noncontrolling interest in SDI was reclassified to equity.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Consolidated net income or loss was adjusted to include the net income or loss attributed to the noncontrolling interest in SDI.

Consolidated comprehensive income or loss was adjusted to include the comprehensive income or loss attributed to the noncontrolling interest in SDI.

**Table of Contents**

The Company must disclose for each reporting period the amounts of consolidated income or loss attributed to the Company and to the noncontrolling interest in SDI. In addition, for each reporting period the Company must present a reconciliation at the beginning and end of the period of the carrying amount of total equity and equity attributable to the Company and to the noncontrolling interest in SDI.

**Results of Operations****Revenues**

Revenues consist of amounts earned from collaborations, government and private agency grants, and services and license fees. Collaboration revenue includes amounts recognized under our collaboration agreements. Grant revenue includes amounts earned under government and private agency grants. Services and license fees include research and development and contract manufacturing services, license fees and royalty payments.

The following is a summary of our revenues (in thousands, except for percentages):

| Revenues:                    | Three Months Ended |                    | Increase (Decrease) |       | Nine Months Ended  |                    | Increase (Decrease) |       |
|------------------------------|--------------------|--------------------|---------------------|-------|--------------------|--------------------|---------------------|-------|
|                              | September 30, 2009 | September 30, 2008 | \$                  | %     | September 30, 2009 | September 30, 2008 | \$                  | %     |
| Collaboration revenue        | \$ 1,791           | \$ 7,960           | \$ (6,169)          | (78)% | \$ 34,079          | \$ 21,435          | \$ 12,644           | 59%   |
| Grant revenue                | 887                | 581                | 306                 | 53%   | 2,921              | 2,027              | 894                 | 44%   |
| Services and license revenue | 223                | 316                | (93)                | (29)% | 1,129              | 1,687              | (558)               | (33)% |
| Total revenues               | \$ 2,901           | \$ 8,857           | \$ (5,956)          | (67)% | \$ 38,129          | \$ 25,149          | \$ 12,980           | 52%   |

Collaboration revenue in 2009 included recognition of \$28.5 million of deferred revenue associated with the upfront payment from Merck, which was accelerated through June 2009 following Merck's termination of the collaboration for HEPLISAV. The decline in total revenue for the quarter ended September 30, 2009 compared to the same period in 2008 was due to the reduction in collaboration revenue from Merck. Total revenues for the nine months ended September 30, 2009 increased over the same period in 2008 primarily due to the accelerated recognition of deferred revenue upon termination of the Merck collaboration. Grant revenue for the three and nine months ended September 30, 2009, increased over the same periods in 2008 due primarily to revenues earned from the National Institute of Health (NIH) contract we were awarded in September 2008. Services and license revenue of \$0.2 million and \$1.1 million for the three and nine months ended September 30, 2009, respectively, were derived primarily from research and development services provided to customers of Rhein Biotech GmbH (Rhein or Dynavax Europe).

**Research and Development Expense**

Research and development expense consists of compensation and related personnel costs which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates, and cost of sales relating to service and license revenue.

The following is a summary of our research and development expense (in thousands, except for percentages):

| Research and development expense:        | Three Months Ended |                    | Increase (Decrease) |       | Nine Months Ended  |                    | Increase (Decrease) |       |
|--|--------------------|--------------------|---------------------|-------|--------------------|--------------------|---------------------|-------|
|  | September 30, 2009 | September 30, 2008 | \$                  | %     | September 30, 2009 | September 30, 2008 | \$                  | %     |
| Compensation and related personnel costs | \$ 3,688           | \$ 4,519           | \$ (831)            | (18)% | \$ 11,779          | \$ 14,546          | \$ (2,767)          | (19)% |
| Outside services                         | 3,758              | 3,715              | 43                  | 1%    | 11,406             | 17,823             | (6,417)             | (36)% |
| Facility costs                           | 1,748              | 1,745              | 3                   |       | 5,213              | 5,106              | 107                 | 2%    |
| Non-cash stock-based compensation        | 437                | 477                | (40)                | (8)%  | 804                | 1,047              | (243)               | (23)% |
| Total research and development expense   | \$ 9,631           | \$ 10,456          | \$ (825)            | (8)%  | \$ 29,202          | \$ 38,522          | \$ (9,320)          | (24)% |

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Research and development expense for the three and nine months ended September 30, 2009 decreased as compared to the same periods in 2008. For the nine months ended September, 30, 2009, the decrease in outside services over the same period in 2008 is 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. For the three and nine months ended September, 30, 2009, the decrease in compensation and related personnel costs over the same periods in 2008 is primarily due to the decline in employee headcount to support the organization. We expect our research and development expense for the year ended 2009 will be less than the expense incurred in 2008.



**Table of Contents****General and Administrative Expense**

General and administrative expense consists primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance; legal costs that include corporate and patent expenses; allocated facility costs and non-cash stock-based compensation.

The following is a summary of our general and administrative expense (in thousands, except percentages):

|   | Three Months Ended |                    | Increase (Decrease) |             | Nine Months Ended  |                    | Increase (Decrease) |             |
|---|--------------------|--------------------|---------------------|-------------|--------------------|--------------------|---------------------|-------------|
|   | September 30, 2009 | September 30, 2008 | \$                  | %           | September 30, 2009 | September 30, 2008 | \$                  | %           |
| <b>General and administrative expense:</b>      |                    |                    |                     |             |                    |                    |                     |             |
| Compensation and related personnel costs        | \$ 1,386           | \$ 1,684           | \$ (298)            | (18)%       | \$ 4,725           | \$ 5,528           | \$ (803)            | (15)%       |
| Outside services                                | 1,003              | 994                | 9                   | 1%          | 2,977              | 3,182              | (205)               | (6)%        |
| Legal costs                                     | 639                | 414                | 225                 | 54%         | 2,011              | 1,036              | 975                 | 94%         |
| Facility costs                                  | 223                | 256                | (33)                | (13)%       | 690                | 739                | (49)                | (7)%        |
| Non-cash stock-based compensation               | 485                | 565                | (80)                | (14)%       | 1,290              | 1,419              | (129)               | (9)%        |
| <b>Total general and administrative expense</b> | <b>\$ 3,736</b>    | <b>\$ 3,913</b>    | <b>\$ (177)</b>     | <b>(5)%</b> | <b>\$ 11,693</b>   | <b>\$ 11,904</b>   | <b>\$ (211)</b>     | <b>(2)%</b> |

General and administrative expense for the three and nine months ended September 30, 2009 decreased as compared to the same periods in 2008. The decrease in compensation and related personnel costs and outside services is due to an overall decline in the number of administrative employees, consulting fees and other professional fees incurred. These reductions were offset by increases in legal costs related to patent activities.

**Amortization of Intangible Assets**

Intangible assets consist of the manufacturing process and customer relationships resulting from our April 2006 acquisition of Rhein and are being amortized over 5 years from the date of acquisition. Amortization of intangible assets was \$0.7 million for both the nine months ended September 30, 2009 and 2008.

**Interest Income, Loan Forgiveness, Interest Expense and Other Income (Expense)**

Interest income is reported net of amortization of premiums and discounts on marketable securities and realized gains and losses on investments. Interest income was \$0.2 million and \$1.5 million for the nine months ended September 30, 2009 and 2008, respectively. Interest income decreased by \$1.3 million, or 88%, as compared to the same period in 2008 due to lower investment balances and a decline in returns on our investment portfolio resulting from current market conditions.

Loan forgiveness represents a \$5.0 million portion of the loan from Deerfield Management and its affiliates ( Deerfield ) that was forgiven upon termination of the loan agreement in August 2008.

Interest expense includes amortization of deferred transaction costs and commitment fees related to the Deerfield financing agreement and miscellaneous banking fees. Interest expense was \$0.1 million and \$9.1 million for the nine months ended September 30, 2009 and 2008, respectively. Interest expense decreased by \$9.0 million, or 99%, compared to the same period in 2008 due to interest expense incurred from the commitment fees and warrants issued under the Deerfield financing agreement, which was terminated in August 2008.

Other income (expense) includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. We reported \$40 thousand and \$4 thousand of other expense for the nine months ended September 30, 2009 and 2008, respectively. The variance year over year resulted from the effect of Euro to U.S. Dollar exchange rates.

**Losses Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.**

Pursuant to the agreements that we entered into with SDI in April 2006, we have attributed net income or loss to Dynavax and the noncontrolling interest in SDI in our consolidated statements of operations. For the nine months ended September 30, 2009 and 2008, the losses

attributed to the noncontrolling interest were \$3.2 million and \$4.8 million, respectively.

## **Table of Contents**

### **Recent Accounting Pronouncements**

In June 2009, the FASB changed the consolidation guidance applicable to a variable interest entity ( VIE ). The FASB also amended the guidance governing the determination of whether an enterprise is the primary beneficiary of a VIE, and is therefore required to consolidate a VIE, by requiring a qualitative analysis rather than a quantitative analysis. The qualitative analysis will include, among other things, consideration of who has the power to direct the activities of the entity that most significantly impact the entity's economic performance and who has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE. This standard also requires continuous reassessments of whether an enterprise is the primary beneficiary of a VIE. Previously, the FASB required reconsideration of whether an enterprise was the primary beneficiary of a VIE only when specific events had occurred. Qualifying Special Purpose Entities, which were previously exempt from the application of this standard, will be subject to the provisions of this standard when it becomes effective. The FASB also requires enhanced disclosures about an enterprise's involvement with a VIE. The new consolidation guidance regarding a VIE will be effective for the first annual reporting periods that begin after November 15, 2009 and will be adopted by the Company in the first quarter of fiscal 2010. We do not expect the adoption of the new guidance regarding the consolidation of a VIE to have a material effect on our consolidated results of operations and financial condition.

### **Liquidity and Capital Resources**

As of September 30, 2009, we had \$46.4 million in cash, cash equivalents and marketable securities and investments held by SDI. Our funds are currently invested in a variety of securities, including institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

Cash used in operating activities was \$24.3 million during the nine months ended September 30, 2009 compared to \$21.0 million for the same period in 2008. The increase in cash usage compared to the prior year was due primarily to the decline in payments received from the collaboration with Merck, which was terminated in December 2008.

Cash provided by investing activities was \$18.2 million during the nine months ended September 30, 2009 compared to \$28.5 million for the same period in 2008. The decrease was attributed to the decline in net proceeds from sales and maturities of marketable securities.

Cash provided by financing activities was \$2.4 million during the nine months ended September 30, 2009 compared to \$1.4 million for the same period in 2008. The increase was primarily attributed to the proceeds from the sales of our common stock under an equity distribution agreement entered into with Wedbush Morgan Securities, Inc. ( Wedbush ) on August 17, 2009. Pursuant to the agreement we may offer and sell shares of our common stock having an aggregate offering price of up to \$15 million from time to time through Wedbush as our sales agent or to Wedbush as a principal. During the quarter ended September 30, 2009, we sold 1,281,100 shares of common stock under the agreement with Wedbush as our sale agent for aggregate net proceeds of \$2.3 million after deducting commissions paid to Wedbush and offering expenses. As of September 30, 2009, we could offer and sell from time to time through Wedbush up to an additional \$12.2 million in aggregate offering price of our common stock under this agreement.

We currently anticipate that our cash and marketable securities, collaboration agreements, and investments held by SDI will enable us to maintain our operations for at least the next twelve months. We are reviewing financing opportunities to fund future clinical development for HEPLISAV, which will require additional capital resources. We may raise additional funds through public or private equity offerings, collaborative, strategic alliances and licensing arrangements or other means.

Additional financing may not be available on acceptable terms, if at all and therefore may adversely affect our ability to operate as a going concern. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, fail to meet the diligence obligations under existing licenses or enter into collaborative agreements at an earlier stage of development on less favorable terms than we would otherwise choose.

### ***Contractual Obligations***

The following summarizes our significant contractual obligations as of September 30, 2009 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

| <b>Contractual Obligations:</b>   | <b>Total</b>     | <b>Less than<br/>1 Year</b> | <b>1-3 Years</b> | <b>4-5 Years</b> | <b>More than<br/>5 years</b> |
|---|------------------|-----------------------------|------------------|------------------|------------------------------|
| Future minimum payments under our operating lease, excluding payments from the sublease agreement | \$ 18,615        | \$ 652                      | \$ 8,052         | \$ 4,825         | \$ 5,086                     |
| Long-term liability from the program option exercised under the SDI collaboration                 | 15,000           |                             | 15,000           |                  |                              |
| <b>Total</b>  | <b>\$ 33,615</b> | <b>\$ 652</b>               | <b>\$ 23,052</b> | <b>\$ 4,825</b>  | <b>\$ 5,086</b>              |

We lease our facilities in Berkeley, California (the Berkeley Lease ) and Düsseldorf, Germany (the Düsseldorf Lease ) under operating leases that expire in September 2014 and March 2023, respectively. The Berkeley Lease can be terminated at no cost to us in February 2011 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$58 thousand in 2009 and \$40 thousand in 2010. The sublease rental income is offset against rent expense.

---

**Table of Contents**

In April 2007, we exercised an option to repurchase our hepatitis B program from SDI. The exercise of the program option triggered a payment obligation of \$15 million which will be due upon the expiration of the SDI collaboration in 2011, if the purchase option for all programs is not exercised. The price for the program option is payable in cash only and will be fully creditable against the exercise price for any exercise of the purchase option.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of September 30, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of September 30, 2009 and December 31, 2008. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We established a letter of credit with Deutsche Bank as security for our Düsseldorf Lease in the amount of \$0.3 million. The letter of credit remained outstanding as of September 30, 2009 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheet as of September 30, 2009.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of September 30, 2009, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$8.3 million through 2013. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. As of September 30, 2009, such fees and milestone payments to the Regents could approximate \$0.3 million in 2009.

***Off-balance Sheet Arrangements***

We do not have any off-balance sheet arrangements as defined by rules enacted by the Securities and Exchange Commission ( SEC ) and FASB, and accordingly, no such arrangements are likely to have a current or future effect on our financial position. As described above, SDI is considered a variable interest entity and included in our financial statements. Our financing arrangement with SDI does not qualify as an off-balance sheet arrangement as defined by applicable SEC regulations.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we currently maintain our portfolio of cash equivalents and investments in a variety of securities, including money market funds, government agency securities and corporate obligations, some of which are government-secured. We do not invest in auction rate securities or securities collateralized by home mortgages, mortgage bank debt, or home equity loans. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

*Foreign Currency Risk.* We have certain investments outside the U.S. for the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of September 30, 2009 was negative \$36 thousand primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

**Table of Contents**

**ITEM 4. CONTROLS AND PROCEDURES**

**(a) Evaluation of disclosure controls and procedures**

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer ( CEO ) and Vice President ( VP ), Finance, our principal financial officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and VP, Finance concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of period covered by this report are effective.

**(b) Changes in internal controls**

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations. We do not believe any of the current claims or allegations are material to our current business or operations.

**ITEM 1A. RISK FACTORS**

*Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future products, timing of development activities, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.*

**We have incurred substantial losses since inception and do not have any commercial products that generate significant revenue.**

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$249.0 million as of September 30, 2009. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate revenue. Although the U.S. Food and Drug Administration ( FDA ) has removed the clinical hold on our HEPLISAV Investigational New Drug ( IND ) application for individuals with chronic kidney disease, there can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; whether our future development efforts will be sufficient to support product approval; or whether the market for HEPLISAV will be substantial enough for us to reach profitability.

Clinical trials for certain of our other product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

demonstrating in clinical trials that our product candidates are safe and effective, in particular, in the current and planned trials for our product candidates;

obtaining regulatory approvals for our product candidates; and

entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company, or raise additional capital on less favorable terms.

**We will require substantial additional capital and our failure to obtain additional capital when needed could force us to delay, reduce or eliminate our product development programs or future commercialization efforts, or reduce or discontinue operations.**

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. In the foreseeable future, we will require substantial additional capital resources in order to continue our operations, and any such funding in the current financing environment may not allow us to continue operations as currently planned. Our future capital requirements are difficult to forecast and will depend on many factors, including:



the costs, timing and outcomes of regulatory reviews or other regulatory actions;

the scope, progress, duration, results and cost of clinical trials, as well as non-clinical studies and manufacturing-related services for our product candidates;

the timing, receipt and amount of milestone and other payments from existing and potential future collaborators and the extent to which our research and development activities result in the achievement of milestone events under our collaboration agreements;

**Table of Contents**

the costs to satisfy our obligations under existing and potential future alliances and collaborations;

the extent of our development and manufacturing costs and costs to establish sales and marketing functions for our product candidates that are not subject to our collaborations;

the timing, receipt and amount of sales or royalties, if any, from our potential products;

our ability to establish strategic alliances, collaborations and licensing or other arrangements on terms favorable to us;

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

the extent and scope of our general and administrative expenses.

Our plans provide for us to continue, either alone or with a collaborator, to advance our product candidates through the development process. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of the development of any of our product candidates. We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. However, our operating plan may change as a result of many factors, including those described above, and we may need additional funds sooner than planned to meet operational needs and capital requirements for product development and commercialization. We may seek additional capital through a combination of public and private equity offerings and collaborative, strategic alliance and licensing arrangements. If we raise additional capital through the sale of our common stock, existing stockholders may experience dilution of their current level of ownership of our common stock and the terms of the financing may adversely affect the holdings or rights of our stockholders. Our ability to raise funds in the foreseeable future may be adversely impacted by recent deterioration in the U.S. and global financial markets, and additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may:

terminate, delay or downsize clinical trials or manufacturing or other development activities for one or more of our product candidates;

delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates; or

curtail significant drug development programs that are designed to identify new product candidates.

**The success of our product candidates depends on achieving successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.**

None of our product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced product candidates. Approval processes in the U.S. and in other countries are uncertain, take many years and require the expenditure of substantial resources.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations. Even if approved, the labeling of the product may significantly limit the commercial opportunity for

such product.

**Our clinical trials may be extended, suspended, delayed or terminated at any time. Even short delays in the commencement and progress of our trials may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.**

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects or inadequate supply of the product candidate. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the target population is available for testing, which could result in a delay of a year or more.

## Table of Contents

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA and corresponding foreign regulatory agencies. Any extension, suspension, modification, termination or unanticipated delays of our clinical trials could:

adversely affect our ability to timely and successfully commercialize or market these product candidates;

result in significant additional costs;

potentially diminish any competitive advantages for those products;

potentially limit the markets for those products;

adversely affect our ability to enter into collaborations, receive milestone payments or royalties from potential collaborators;

cause us to abandon the development of the affected product candidate; or

limit our ability to obtain additional financing on acceptable terms, if at all.

**If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.**

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, we or our contract manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

**Our most advanced product candidate and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.**

Our most advanced product candidate in clinical trials is based on our 1018 ISS compound, and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. For example, from March 2008 until September 2009, the two IND applications for HEPLISAV were placed on clinical hold by the FDA following a serious adverse event that occurred in one of our clinical trials. In September 2009, the FDA removed the clinical hold on the IND application for individuals with chronic kidney disease. In addition, most of

our clinical product candidates contain ISS, and a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

**We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, delays or significantly higher costs in manufacturing our product candidates.**

We rely on a number of third parties and our facility in Düsseldorf for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the production of certain antigens, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

## **Table of Contents**

We and these third parties are required to comply with applicable FDA current good manufacturing practice regulations and other international regulatory requirements. If one of these parties fails to maintain compliance with these regulations, the production of our product candidates could be interrupted, resulting in delays and additional costs. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates.

We have relied on a single supplier to produce our ISS for clinical trials. To date, we have manufactured only small quantities of ISS ourselves for research purposes. If we were unable to maintain or replace our existing source for ISS, we would have to establish internal ISS manufacturing capability which would result in increased capital and operating costs and delays in developing and commercializing our product candidates. We or other third parties may not be able to produce ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. If HEPLISAV cannot be successfully developed or is not commercially viable, we will have to use the Düsseldorf facility for alternative manufacturing or research activities that may not fully utilize the facility's capacity, resulting in continued operating costs that may not be offset by corresponding revenues, or we may consider other alternatives for the Düsseldorf facility, including its sale or closure which would result in certain costs of disposal or discontinuation of operations.

**We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.**

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. Any extension, delay, modification or termination of our clinical trials could delay or otherwise adversely affect our ability to commercialize our products and could have a material adverse effect on our business and operations.

**If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications or marketing claims, we may be unable to generate significant revenues, if any.**

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

the indication for which the product is approved and its approved labeling;

the presence of other competing approved therapies;

the potential advantages of the product over existing and future treatment methods;

the relative convenience and ease of administration of the product;

the strength of our sales, marketing and distribution support;

the price and cost-effectiveness of the product; and

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. For example, in connection with the removal of the clinical hold on HEPLISAV in September 2009 and related discussions with the FDA, it is expected that, further development of HEPLISAV in the U.S. initially will be limited to individuals who are less responsive to current licensed vaccines, including adults over 40 years of age and individuals with chronic kidney disease. If we are unable to successfully market any approved product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

## Table of Contents

**A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.**

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV. We also may enter into collaborative relationships to provide funding to support our research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;

our contracts for collaborative arrangements may expire or terminate and we may not have alternative funding available;

our partners may choose to pursue alternative technologies, including those of our competitors;

we may have disputes with a partner that could lead to litigation or arbitration;

we do not have day to day control over the activities of our partners and have limited control over their decisions;

our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;

we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

our partners may not devote sufficient capital or resources towards our product candidates; and

our partners may not comply with applicable government regulatory requirements.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

**Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.**

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious diseases, asthma and inflammatory and autoimmune diseases. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive



## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. If we are unable to compete successfully, we may not be able to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

**We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop and commercialize our product candidates and achieve our objectives.**

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train

## **Table of Contents**

and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

**We may develop, seek regulatory approval for and market our product candidates outside the United States, requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.**

We may introduce certain of our product candidates in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;

compliance with varying international regulatory requirements, laws and treaties;

securing international distribution, marketing and sales capabilities;

adequate protection of our intellectual property rights;

legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;

adverse tax consequences;

the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and

regional and geopolitical risks.

To date, we have not filed for marketing approval for any of our product candidates outside the U.S.. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

**We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.**

Our current research and development efforts depend upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments in order to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are not able to cure or obtain waivers for such failures or amend the term of such agreements on terms

acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates.

**If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent development or commercialization of our product candidates.**

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. We are involved in various interference and other administrative proceedings related to our intellectual

## **Table of Contents**

property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck & Co., Inc., or Merck, and GlaxoSmithKline plc, or GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside the U.S., they remain in force in the U.S. To the extent we are able to commercialize HEPLISAV in the U.S. while these patents remain in force, Merck and/or GSK or the Institut Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV or any similar product candidate in the U.S., we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. In addition, we must make timely payments or meet diligence obligations in order to maintain any such licenses in effect. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

One of our potential competitors, Pfizer Inc., or Pfizer, has issued patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office and foreign patent offices, that may be asserted against our ISS products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies in order to commercialize one or more of our formulations of ISS in other than with respect to HEPLISAV, for which we have a license. A license for other uses may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

**If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.**

Our success depends on our ability to:

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the U.S., legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the U.S., where we may only be able to obtain limited patent protection.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;

the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;

the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;

we might not be able to develop additional proprietary technologies that are patentable;

---

**Table of Contents**

the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

patents issued to other parties may limit our intellectual property protection or harm our ability to do business;

other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and

other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

**We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some or all of the programs in the future. While we exercised the repurchase option with respect to one of the programs, we may not obtain sufficient clinical data in order to determine whether we should exercise our option to repurchase the other programs prior to the expiration of the development period, and we do not currently have the financial resources available to pay the exercise price if we determine that exercising the option to repurchase the other programs is in our best interests.**

In April 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapies (the Development Programs) to Symphony Dynamo, Inc. (SDI) in consideration for a commitment from Symphony Capital Partners, LP and certain of its affiliates (Symphony) to provide \$50 million of capital to advance the Development Programs. As part of the arrangement, we received an exclusive purchase option (the Purchase Option) to acquire all of the Development Programs through the purchase of all of the equity in SDI during the five-year term at specified prices ranging from \$100.7 million as of September 30, 2009, increasing quarterly up to \$144.1 million at the end of the five-year term. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an exclusive option to purchase either the hepatitis B or hepatitis C program (the Program Option) during the first year of the arrangement. In April 2007, we exercised our Program Option for the hepatitis B program. The exercise of this Program Option triggered a payment obligation of \$15 million which will either be (a) due to Symphony upon the expiration of the SDI collaboration in 2011 if the Purchase Option is not exercised; or (b) included as part of the applicable purchase price upon exercise of the Purchase Option. The current terms provide that the intellectual property rights to the remaining cancer and hepatitis C therapy programs not purchased through the exercise of the Purchase Option will remain with SDI.

We and SDI jointly manage the Development Programs and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our Purchase Option. If we do not exercise the Purchase Option prior to its expiration, then our rights in and with respect to the Development Programs will terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement.

If we elect to exercise the Purchase Option, we will be required to make a payment of at least \$106.9 million as of December 31, 2009, increasing thereafter quarterly, which at our discretion may be paid partially in shares of our common stock. As a result, in order to exercise the Purchase Option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the Purchase Option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the Purchase Option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders.

**We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.**

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.

## **Table of Contents**

### **We face uncertainty related to coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.**

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV where existing products are approved for our target indications. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

The current administration has stated that it is committed to reforming the health care system in the U.S. and multiple proposals to effect such reform have been introduced in Congress. It is likely that any legislation that is enacted will affect the biopharmaceutical industry. However, we are unable to predict whether reform legislation will be enacted and, if enacted, what impact that legislation will have on our business or future prospects. The uncertainty as to the nature and scope of any proposed reforms limits our ability to forecast changes that may affect our business and to manage our business accordingly. This uncertainty may also make it more difficult for us to enter into collaboration agreements for our product candidates and to obtain financing for future development of our product candidates.

### **We use hazardous materials in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials could be time consuming and costly to resolve.**

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

### **Our stock price is subject to volatility, and your investment may suffer a decline in value.**

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

progress or results of any of our clinical trials or regulatory efforts, in particular any announcements regarding the progress or results of our planned trials and communications from the FDA or other regulatory agencies;

our ability to establish and maintain collaborations for the development and commercialization of our product candidates;

our ability to raise additional capital to fund our operations;

technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;



## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;

our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;

our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;

**Table of Contents**

changes in government regulations, general economic conditions or industry announcements;

issuance of new or changed securities analysts' reports or recommendations;

actual or anticipated fluctuations in our quarterly financial and operating results;

our ability to maintain continued listing on the NASDAQ markets or similar exchanges; and

volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In October 2008, we experienced a decline in our market capitalization of nearly 80% based on the FDA's communication to us regarding the continuation of a clinical hold on two U.S. IND applications for HEPLISAV. While the FDA has removed the clinical hold on the IND application for individuals with chronic kidney disease, our market capitalization remains well below levels prior to the announcement of the FDA's clinical hold. In November 2008, we transferred our listing of Dynavax shares to The NASDAQ Capital Market from The NASDAQ Global Market. We may be delisted from The NASDAQ Capital Market if our share price or market value of publicly held shares does not meet certain thresholds. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial condition.

**The anti-takeover provisions of our certificate of incorporation, bylaws, Delaware law and our share purchase rights plan may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.**

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;

providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and

establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

## Edgar Filing: DYNAVAX TECHNOLOGIES CORP - Form 10-Q

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by the Company's Board of Directors. Although the rights should not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at \$0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of the Common Shares or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

**Table of Contents**

**We will continue to implement additional financial and accounting systems, procedures or controls as our business and organization changes and to satisfy new reporting requirements.**

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls in order to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent auditors are unable to issue an unqualified attestation as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**  
None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**  
None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**  
None.

**ITEM 5. OTHER INFORMATION**  
None.

**ITEM 6. EXHIBITS**

| <b>Exhibit Number</b> | <b>Document</b>  |
|-----------------------|--|
| 10.43 <sup>(1)</sup>  | Equity Distribution Agreement, dated August 17, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.                 |
| 10.44                 | Amendment to Equity Distribution Agreement, dated September 10, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc. |
| 31.1                  | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2                  | Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1                  | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 32.2                  | Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on August 17, 2009.



**Table of Contents**

**EXHIBIT INDEX**

| <b>Exhibit Number</b> | <b>Document</b>  |
|-----------------------|--|
| 10.43 <sup>(1)</sup>  | Equity Distribution Agreement, dated August 17, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc.                 |
| 10.44                 | Amendment to Equity Distribution Agreement, dated September 10, 2009, between Dynavax Technologies Corporation and Wedbush Morgan Securities, Inc. |
| 31.1                  | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2                  | Certification of Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1                  | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 32.2                  | Certification of Vice President, Finance pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |

<sup>(1)</sup> Incorporated by reference from such document filed with the SEC as an exhibit to Dynavax's Current Report on Form 8-K, as filed with the SEC on August 17, 2009.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto due authorized, in the City of Berkeley, State of California.

DYNAVAX TECHNOLOGIES CORPORATION

Date: October 30, 2009

By: /s/ DINO DINA, M.D.  
**Dino Dina, M.D.**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: October 30, 2009

By: /s/ JENNIFER LEW  
**Jennifer Lew**  
**Vice President, Finance**  
**(Principal Accounting and Financial Officer)**